

FDA Food Safety Modernization Act

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Development

To define detail, scope and purpose.

Development

This information can be used to develop food safety and quality programs that meet the requirements of modern Regulatory, Customer and Industry Standards:

- We take the time to explain the expectations and requirements of food safety and quality compliance as these relate to your food safety and quality programs.
- You may choose to use our Premium Resources to build, enhance or upgrade your food safety and quality program.
- We encourage you to share this webpage with any food compliance associates and peers you believe may benefit from our commitment to providing our users with user friendly information and resources to achieve superior Food Compliance Culture.
- We welcome your suggestions for additions of general or specific content through the haccp.com Contact Page.

Key Definitions for the FDA FSMA

- Critical Control Point or CCP: A Critical Control Point is a point, step, or procedure at which controls can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.
- cGMP: Current Good Manufacturing Practices or cGMPs include guidance provided by the U.S. FDA regarding prescribed Food Business Operational Standards.
- FDA: The Food and Drug Administration (also known as the FDA or U.S. FDA) is a federal agency of the United States Department of Health and Human Services.
- Federal Food, Drug, and Cosmetic Act: The United States Federal Food, Drug, and Cosmetic Act (abbreviated as FFDCA, FDCA, or FD&C) is a set of laws passed by Congress in 1938 giving authority to the U.S. FDA to oversee the safety of food, drugs, and cosmetics.
- FSMA: The Food Safety Modernization Act or FSMA is a regulatory act mandated by the U.S. FDA. It focuses more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The FSMA consists of several 'rules' defined as enforceable guidance.
- FSVP: The Foreign Supplier Verification Program or FSVP is a program that importers (into the U.S.) must have in place to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection as the preventive controls or produce safety regulations and to ensure that the supplier's food is not adulterated or misbranded for food allergens.
- HARPC: Hazard Analysis and Risk-Based Preventive Controls is one of many provisions of the FSMA. HARPC requirements include a documented hazard analysis that considers hazards that may be intentionally introduced for economic gain. Food defence is addressed separately under the Intentional Adulteration rule.
- Health and Human Services: The United States Department of Health and Human Services or HHS is also known as the Health Department. It is a cabinet-level department of the U.S. Federal Government and is tasked with protecting the health of all Americans and providing essential human services.
- Preventive Controls Qualified Individual or PCQI: An individual who has successfully completed training in the development and application of risk-based preventive controls under a standardised curriculum recognised by the FDA, or who is otherwise qualified through job experience to develop and apply a food safety system.
- Primary Production Farm: A Primary Production Farm is an operation under one management in one general location devoted to the growing of crops, harvesting of crops, raising of animals (including seafood), or any combination of the above-mentioned activities.
- Qualified Auditor: A person with the technical expertise, obtained through education, training, or experience, necessary to perform the auditing function, including onsite audits of suppliers.

- **Qualified Facility:** A very small business, or a facility that meets other limited criteria, that is subject to modified requirements instead of the full hazard analysis and risk-based preventive controls requirements.
- **Receiving Facility:** A facility that manufactures or processes raw materials or other ingredients that it receives from a supplier, and that must apply the supply-chain program requirements.
- **Secondary Activities Farm:** A Secondary Activities Farm is an operation devoted to harvesting, packing, and/or holding raw agricultural commodities but not located on the Primary Production Farm.

FDA FSMA Development

When considering the development, documentation, and implementation of the FDA FSMA within food safety and quality management systems, the following information should be considered to ensure effective outcomes:

About the FDA Food Safety Modernization Act



Food facilities covered by the FSMA must have a documented food safety plan that is available for review.

According to the U.S. Centers for Disease Control and Prevention, an increasing number of Americans get sick, are hospitalised, and in some cases die from largely preventable foodborne illnesses. Likewise, high-profile outbreaks and global recalls have highlighted the need to make continuous improvements in the food safety systems of the U.S.A.

The Food Safety Modernization Act signed into law by President Barack Obama in January 2011 strengthens the authority of the FDA to better protect public health by helping ensure the safety and security of the food supply. It focuses more on preventing food safety problems instead of relying primarily on reacting to problems after they occur. The FSMA is intended to build a food safety system for the future that uses modern and comprehensive science as well as risk-based preventive controls across all sectors of the food system from farm to fork. The primary idea is that the better the system of manufacturing, processing, holding, distributing, and preparing foods, the safer the food supply will be. Under the FSMA, companies are required to develop and implement a documented food safety plan, which the FDA may review during inspection. The FDA has encompassing authority to monitor participating companies, better respond to food safety problems and mandate food recalls when required. Additionally, the FDA ensures that imported foods are as safe for consumers as those foods produced in the U.S. The effectiveness and corresponding reduction in food contamination and foodborne illness depend on how successfully preventive controls address the sources of contamination, and how well controls are implemented.

The FDA has developed several guidance documents on subjects covering hazard analysis and preventive controls, environmental monitoring, food allergen controls, validation of process controls, and also a small entity compliance guide that explains the actions a small or very small business must take to comply.

History of FDA Food Safety Modernization Act

The U.S. Congress passed updated food safety laws in 2010 to ensure the U.S. Food Supply was safe by shifting the focus of Federal Regulators from responding to contamination to preventing it. The Food Safety Modernization Act was signed into law by President Obama on 4 January 2011. The FSMA gives the FDA the authority to better protect public health by strengthening the food safety and security system of the U.S.

Hazard Analysis and Risk-based Preventive Controls or HARPC is a requirement of the FSMA that applies to most

U.S. food processing facilities required to register with the FDA. The FDA published a proposed rule entitled “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” in 2013 and finalised the rule in September 2015.

FDA Authority Under the FSMA

Under the FSMA, the FDA has a legislative mandate to require comprehensive, science-based preventive controls across the food supply chain. This mandate includes mandatory preventive controls for food facilities, mandatory produce safety standards, and authority to prevent intentional contamination.

The scope of FDA Authority includes:

- Responsibility for establishing science-based minimum standards for the safe production and harvesting of fruits and vegetables. These standards must consider naturally occurring hazards, as well as those that may be introduced either accidentally or intentionally, and must address soil amendments (materials added to the soil such as compost), hygiene, packaging, temperature controls, animals in the growing area, and water;
- Issuing regulations to protect against the intentional adulteration of food, including the establishment of science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points;
- Provision of oversight, ensuring compliance with requirements, and the ability to respond effectively when problems emerge. The FSMA provides FDA with important new tools for inspection and compliance including mandated inspection frequency, record access, and testing of accredited laboratories;
- Facilitation of a risk-based inspection frequency for food facilities. The law directs FDA to inspect an increasing number of foreign facilities on an ongoing basis;
- Specification for certain food testing to be carried out by accredited laboratories and the establishment of laboratory accreditation programs to ensure that U.S. food testing laboratories meet high-quality standards;
- Mandates for tools to respond effectively when problems emerge, including mandatory food recall authority, expanded administration detention, suspension of registration, enhanced product traceability, and additional recordkeeping for high-risk foods. The FDA has the authority to issue a mandatory recall when a company fails to voluntarily recall unsafe food after being requested to do so by the FDA;
- Power to facilitate the administrative detention of food products that are potentially in violation of the law. Administrative detention is the procedure FDA uses to keep suspect food from being moved;
- Suspension of the registration of a food facility if it determines that the food poses a reasonable probability of serious adverse health consequences or death. A facility under suspension is prohibited from distributing food;
- Establishment of systems that will enhance the FDA’s ability to track and trace both domestic and imported foods. The FDA will also establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or control a foodborne illness outbreak;
- Under the FSMA, the FDA has unprecedented authority to better ensure imported products meet U.S. standards and are safe for U.S. consumers. The FDA will ensure importer accountability. Food Importers have a specific responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe;
- Establishment of a program through which qualified third parties can certify that foreign food facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports, including special requirements for imported High-Risk Foods;
- Authority to refuse entry into the U.S. any food from a foreign facility if the FDA is denied access by the facility or the country in which the facility is located;
- The law allows the FDA to enter into interagency agreements to leverage resources for the inspection of food facilities, both domestic and foreign, as well as food imports.

Key Requirements of the FDA Food Safety Modernization Act

There are four key requirements for the implementation of the FDA Food Safety Modernization Act:

- Risk-Based Preventive Controls;
- Primary Production and Secondary Activities Farming;
- Supply Chain;

- Current Good Manufacturing Practices.

FSMA Rule 1: Risk-Based Preventive Controls

The first FSMA requirement is for all covered facilities to establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. This includes requirements for a documented food safety plan including hazard analysis, preventive controls, and oversight and management of preventive controls.

In hazard identification, all known or reasonably foreseeable physical, biological, and chemical (including radiological) hazards must be considered. These hazards could be naturally occurring, unintentionally introduced, or intentionally introduced for economic gain (if food safety is affected).

Preventive measures must then be established so that the hazards identified will be minimised or prevented by these controls. Preventive controls include process, food allergen, and sanitation controls, as well as supply-chain controls and a recall plan. The rule provides flexibility in the steps needed to ensure that preventive controls are effective, as well as addresses problems that may arise by monitoring, corrections and corrective actions, and verification.

Monitoring procedures are designed to assure that preventive controls are effective and are consistently performed. It is conducted as appropriate for preventive control.

Corrections are immediate actions taken to timely identify and correct minor, isolated problems that occur during the production run. Corrections are short-term control. On the other hand, corrective actions include actions to identify a problem with preventive control implementation, reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent it from entering the market. These actions are long-term controls. They must be properly documented with records maintained.

Verification activities are required to ensure that preventive controls are consistently implemented and are working correctly. They include validating with scientific evidence that a preventive control is capable of effectively controlling an identified hazard (For example, acidity below pH 4.6 or temperature below 5°C (41°F)); calibration (or accuracy checks) of process monitoring and verification instruments such as thermometers, and reviewing records to verify that monitoring and corrective actions (as needed) are being done.

Product testing and environmental monitoring are possible verification activities but are only required as appropriate to the food, facility, nature of the preventive control, and role of that control in the facility's food safety system. Environmental pathogen testing would be required if contamination of a ready-to-eat food with an environmental pathogen (for example, *Listeria*) is a hazard requiring a preventive control.

Food facilities are required to implement a documented preventive controls plan. These plans should cover:

- Evaluating hazards that could affect food safety;
- Specifying what preventive steps (or controls) will be put in place to significantly minimise or prevent the hazards;
- Specifying how monitoring of these controls will be done by the facility to ensure they are working;
- Maintaining routine records of monitoring; and
- Specifying the actions to be undertaken by the facility to correct any problems that arise.

FSMA Rule 2: Primary Production and Secondary Activities Farming



Farms are treated differently from food facilities under the FSMA, and produce farms may be covered by the Produce Safety Rule.

The second FSMA requirement is the clarification of the definition of a “Farm” to cover two types of farm operations:

- Primary Production Farming; and
- Secondary Activities Farming.

Business operations defined as farms are not subject to the preventive controls rule.

A Primary Production Farm is an operation under one management in one general location devoted to the growing of crops, harvesting of crops, raising of animals (including seafood), or any combination of the above-mentioned activities. The Primary Production Farm is a kind that can pack or store raw agricultural commodities such as fresh produce. It may also conduct certain manufacturing/processing activities, such as dehydrating grapes to produce raisins and packaging/labelling of raisins.

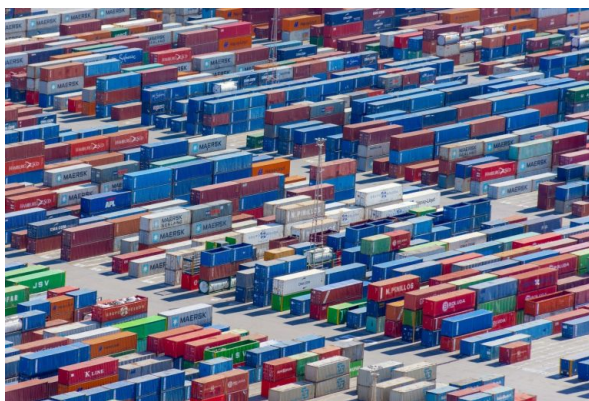
The definition of “farm” in the new rule was expanded to include farms packing or storing raw agricultural commodities such as fresh produce that are grown on a farm under different ownership. Companies that solely harvest crops from farms are also included within the “farm” definition in the final rule.

A Secondary Activities Farm is an operation devoted to harvesting, packing, and/or holding raw agricultural commodities but not located on the Primary Production Farm. It must be majority-owned by the Primary Production Farm supplying the majority of the raw agricultural products harvested, packed, and/or stored by the Secondary Activities Farm.

This definition for a Secondary Activities Farm was provided in the rule, in part, so that farmers involved in certain formerly off-farm packing now fit under the definition of “farm” as the packing is still part of the farming operation. This also covers operations in which nuts are hulled and dehydrated by an operation not located at the orchard before going to a processing plant. If the farmer that owns the orchards and supplies the majority of the nuts is a majority owner of the hulling/dehydrating facility, then the operation falls under Secondary Activities Farm.

Primary Production and Secondary Activities Farms conducting activities on produce covered by the Produce Safety Rule will be required to comply with that rule.

FSMA Rule 3: Supply Chain



Importers must verify that their foreign suppliers meet FSMA requirements.

The third FSMA requirement covers the supply chain. Under the rule, the supply chain program is more flexible, with separate compliance dates established. As mandated by the rule, a manufacturing/processing facility should have a risk-based supply chain program for those raw materials and other ingredients for which it has identified a hazard requiring a supply-chain applied control. These facilities that control a hazard using preventive controls or that follow requirements applicable when relying on a customer to control hazards, do not need to have a supply-chain program for that hazard.

Covered food facilities are responsible for ensuring that only approved products from approved suppliers are received. Products may also be received temporarily from unapproved suppliers, provided the products are subject to verification activities before being accepted for use. Approved suppliers are those approved by the facility after a consideration of factors that include a hazard analysis of the food, the entity that will be controlling that hazard, and supplier performance.

Preventive control will not be required from a facility when an identified hazard will be controlled by a subsequent entity such as a customer or other processor. The facility will have to disclose that the food is “not processed to control” (identified hazard) and obtain documented assurance from its customer regarding certain actions the customer agrees to take.

A broker or distributor, which is another entity in the supply chain, can conduct supplier verification activities but the receiving facility will need to review and assess the broker/distributor’s documentation of the verification of control of the hazard.

The supply chain program provisions have separate compliance dates set so that the food facility will not be required to comply with the supply-chain program provisions before its supplier is required to comply with the preventive controls for human food rule or the produce safety rule.

FSMA Rule 4: Current Good Manufacturing Practices

The fourth key FSMA requirement is the updating and clarification of the Current Good Manufacturing Practices (cGMPs). The final rule does not include nonbinding provisions which are more appropriate for guidance. Education and training, previously nonbinding provisions, are now binding in the new rule. All employees who manufacture, process, pack, or hold food should be qualified to perform their assigned duties. Management is required to ensure compliance. Employees with direct involvement in the production of foods must have the necessary combination of education, training, and/or experience essential to manufacture, process, pack, or hold clean and safe food. These individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene. Note that there are similar requirements related to preventive controls. Additionally, Current Good Manufacturing Practices addressing allergen cross-contact are now well defined.

Rules for Implementation of the FSMA

The FDA Food Safety Modernization Act has several published foundational rules for its implementation, including:

- Current Good Manufacturing Practice and Hazard Analysis and Risk-based Preventive Controls for Human Food;
- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption;

- Current Good Manufacturing Practice and Hazard Analysis and Risk-based Preventive Controls for Food for Animals;
- Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals;
- Accreditation of Third-Party Auditors / Certification Bodies to Conduct Food Safety Audits and Issue Certifications;
- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration;
- Sanitary Transportation of Human and Animal Food;
- Requirements for Additional Traceability Records for Certain Foods (the Food Traceability Rule); and
- Laboratory Accreditation for Analyses of Foods (LAAF).

Preventive Controls for Human Food Rule (cGMP and HARPC)

Under the FSMA, the FDA requires the U.S. food industry to implement hazard analysis and risk-based preventive control measures to reduce the likelihood of food contamination. All food facilities covered by the preventive controls requirements must conduct Hazard Analysis and Risk-based Preventive Controls (HARPC). The hazard analysis must consider hazards that may be intentionally introduced for economic gain, including food fraud. Food defence requirements, including vulnerability assessments and mitigation strategies, are addressed separately under the Intentional Adulteration rule.

The FDA regulation for Current Good Manufacturing Practice (cGMP) in Manufacturing, Packing, or Holding Human Food has been updated as part of the FSMA. The long-standing cGMP requirements were modernised and requirements for the domestic and foreign facilities subject to their regulation for Registration of Food Facilities to establish and implement hazard analysis and risk-based preventive controls for human food were added. Modernising the requirements of the FDA's long-standing current cGMP regulations regarding the manufacturing, processing, packing, or holding of human food involved updating, revising, and clarifying some existing regulations.

The cGMP rule is part of FDA FSMA which aims to better protect public health by adopting a modern, science-based, preventive, and risk-based approach to food safety regulation. The rule creates certain new requirements for the production of human food by registered food facilities and revises previous requirements. New requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for human food have been created. These requirements apply to establishments required to register with FDA as a food "facility". The rule requires the registered food facilities to maintain a food safety plan, perform a hazard analysis, and institute preventive controls to mitigate the hazards. Facilities must also monitor controls established, conduct verification activities to ensure controls are effective, implement appropriate corrective actions, and maintain records documenting actions done.

This final rule is a result of significant stakeholder engagement starting from the proposal of the rule. Inputs from the food industry and other stakeholders resulted in supplemental notices to ensure that the risk-based, preventive requirements are practical and protective of public health. Exemptions may apply for the following:

- Companies under the exclusive authority of the U.S. Department of Agriculture (Meat, Poultry, Pork, Eggs, etc.);
- Farms, Cooperatives, Growers, Harvesters, and other companies handling raw fresh fruits and vegetables;
- Facilities subject to and comply with FDA's seafood and juice HACCP regulations;
- More limited control to low acid and acidified canned food processors but only as regulatory controls govern and control aspects of microbial contamination; and
- Qualified facilities, including very small businesses that average less than US\$1 million per year (adjusted for inflation) in sales of human food plus the market value of human food held without sale, which are subject to modified requirements instead of the full hazard analysis and risk-based preventive controls requirements.

HARPC Methodology and Steps

All FSMA relevant facilities are required to establish and implement a food safety system that includes hazard analysis and risk-based preventive controls including specific requirements for:

- Documented Food Safety Plan;
- Hazard Analysis;

- Preventive Controls;
- Monitoring;
- Corrective Action;
- FSMA Verification Requirements;
- Supply Chain Program;
- Recall Plan; and
- Requirements Applying to Records that must be Established and Maintained.

Commonalities between HARPC and HACCP

The FDA FSMA's HARPC is a U.S. regulatory requirement as opposed to HACCP, which is a globally recognised standard, adopted by the Codex Alimentarius Commission in its General Principles of Food Hygiene (CXC 1-1969).

Both HARPC and HACCP Systems are systematic and science-based. Both identify specific hazards and measures for their control. Both focus on prevention rather than relying mainly on end-product testing, and both are capable of accommodating change (for example, changes in processing procedures, advances in equipment, designs, and other technological developments). Both systems can be applied throughout the food chain from farm to fork.

Although there are similarities between the requirements of the FSMA and the requirements of HACCP, not every provision is the same. A facility subject to FSMA must conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether hazards are requiring preventive controls. The facility should employ a preventive controls qualified individual (PCQI) or a team of qualified individuals to identify the food safety hazards and establish preventive controls to minimise the risk of these hazards.

Identifying and establishing critical control points (CCPs) and critical limits as required by HACCP is no longer essential in HARPC, as the system requires all covered facilities to identify and implement science or risk-based preventive controls. The controls to be established should be backed up with scientific data and studies.

Facilities covered by the preventive controls requirements are not required to establish a HACCP plan, although seafood, juice, and low acid canned food processors are subject to their own HACCP-based regulations. HARPC, on the other hand, is mandated under the Food Safety Modernization Act.

Documented Food Safety Plan

The qualified facility is required to prepare (or have prepared) and implement a documented food safety plan. The food safety plan must be prepared, or its preparation is overseen, by one or more preventive controls qualified individuals.

The documented food safety plan must include the documented hazard analysis, documented preventive controls, documented supply-chain program, documented recall plan, documented procedures for monitoring the implementation of the preventive controls, documented corrective action procedures, and documented verification procedures.

The food safety plan is a record that is subject to the requirements for Records for Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food.

Hazard Analysis

The facility must conduct a hazard analysis to identify and evaluate (based on experience, illness data, scientific reports, and other information) known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether any hazards are requiring a preventive control. The hazard analysis must be documented regardless of its outcome.

During hazard identification, there must be consideration of:

- Known or reasonably foreseeable hazards that include biological hazards (including microbiological hazards such as parasites, environmental pathogens, and other pathogens), chemical hazards (including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food colour, or colour additives, and food allergens), and physical hazards (e.g., stones, glass, and metal fragments);

and

- Known or reasonably foreseeable hazards that may be present in the food due to Naturally Occurring hazards, Unintentionally Introduced Hazards, or Hazards Intentionally Introduced for Purpose of Economic Gain.

The hazard analysis must include an evaluation of the hazards identified to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. The hazard evaluation must include evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment or include a control measure (such as a formulation lethal to the pathogen) that would significantly minimise the pathogen.

The hazard evaluation must also consider the effect on the safety of the finished food for the intended consumer of:

- The formulation of the food;
- The condition, function, and design of the facility and equipment;
- Raw materials and other ingredients;
- Transportation practices;
- Manufacturing / Processing procedures;
- Packaging activities and labelling activities;
- Storage and distribution;
- Intended or reasonably foreseeable use;
- Sanitation, including employee hygiene; and
- Any other relevant factors such as the temporal (for example, weather-related factors) nature of some hazards (for example, levels of some natural toxins).

Preventive Controls

The facility must identify and implement preventive controls to provide confidence that any potential hazards will be significantly minimised or prevented from occurring. Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements for preventive controls, such as hygiene training and other current good manufacturing practices. Any food manufactured, processed, packed, or held by the facility must comply with the requirements of the Federal Food, Drug, and Cosmetic Act.

Preventive controls must be documented and must include (as relevant) process controls, food allergen controls, sanitation controls, supply-chain controls, recall plans, and other controls. Preventive controls are not required to be applied at critical control points, although process controls may be applied at critical control points where appropriate.

Process controls may include procedures, practices, and processes to ensure the control of parameters during operations such as thermal processing, acidification, irradiation, and refrigeration. Process controls must also include parameters associated with the control of the identified hazard and the maximum or minimum value (or combination of values) to which any biological, chemical or physical parameter must be controlled to significantly minimise or prevent a hazard. Preventive Controls must also cover the supply chain.

Food allergen controls may include procedures, practices, and processes to control food allergens. Food allergen controls must include procedures, practices, and processes employed for ensuring the protection of food from allergen cross-contact during storage, handling, and use.

Food labelling for Food Allergens must be compliant with the Federal Food, Drug, and Cosmetic Act.

Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimise or prevent hazards such as environmental pathogens and food allergens. Sanitation controls must include procedures, practices, and processes for the cleanliness of food contact surfaces, including food-contact surfaces of utensils and equipment. Control measures must also include the prevention of allergen cross-contact / cross-contamination from objects, from personnel to food, from food packaging materials and other food-contact surfaces, and from raw product to processed product.

The manufacturer/processor is not required to implement a preventive control when identifying a hazard requiring a preventive control (identified hazard) if the facility determines and documents that the type of food could not be consumed without the application of an appropriate control (for example, raw agricultural commodities like cocoa

beans, coffee beans, and grains). Likewise, implementation of a preventive control is not required if the manufacturer/processor relies on the customer who is subject to the requirements for hazard analysis and risk-based preventive controls to ensure that the identified hazard will be significantly minimised or prevented. In this case, the facility must disclose in documents accompanying the food, that the food is “not processed to control [identified hazard]” and obtain an annual documented assurance from their customer that the customer has established and is following procedures (identified in the documented assurance) that will significantly minimise or prevent the identified hazard.

Preventive controls are not required if the manufacturer/processor relies on the customer who is not subject to the requirements for hazard analysis and risk-based preventive controls to provide assurance it is manufacturing, processing, or preparing the food as per applicable food safety requirements. Additionally, the facility must disclose in documents accompanying the food, as per the practice of the trade, that the food is “not processed to control [identified hazards]” and annually obtain documented assurance from their customer that the customer is manufacturing, processing, or preparing the food as per applicable food safety requirements.

Preventive controls are not required if the facility relies on the customer to assure that the food will be processed to control the identified hazard by an entity in the distribution chain after the customer. Additionally, the facility obtains annual documented disclosures accompanying the food, that the food is “not processed to control [identified hazard]” and only sell to another entity that agrees in writing that it will follow procedures that will significantly minimise or prevent the identified hazard; or manufacture, process or prepare the food as per applicable food safety requirements; or obtain a similar documented assurance from the entity’s customer.

If the facility has established, documented, and implemented a system that ensures control of the hazards at a subsequent distribution step in the distributed food and the facility documents the implementation of the system, preventive controls are also not required. Documentation of any such circumstance must be available, including:

- The determination that the type of food could not be consumed without the application of appropriate control,
- The annual documented assurance from the facility’s customer as per the circumstances noted above, and
- The system ensures control, at a subsequent distribution step, of the hazards in the food being distributed.

The facility must provide assurances that it is manufacturing, processing, or preparing the food per applicable food safety requirements. Additionally, the customer provides assurances that the food will be processed to control the identified hazard by an entity in the distribution chain after the end customer. The facility that provides a documented assurance must act consistently with the assurance and document its actions taken to satisfy the documented assurance.

Monitoring

The facility must establish and implement documented procedures for monitoring the preventive control including the frequency with which they are to be performed. The preventive controls must be monitored with adequate frequency to assure that they are consistently performed.

The facility must document the monitoring of preventive controls that are subject to verification and records review. Records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimise or prevent the growth of (or toxin production by) pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control. Exception records may be adequate in circumstances other than monitoring refrigeration temperature.

Corrective Action

The facility must establish and implement documented corrective action procedures that must be taken if preventive controls are not properly implemented. This includes procedures to address (as appropriate):

- The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected through product testing; and
- The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted.

The corrective action procedures must describe steps taken to ensure that appropriate action is taken to identify and correct a problem that has occurred with the implementation of preventive control and that appropriate action is

taken, when necessary, to reduce the likelihood that the problem will recur. All affected food is evaluated for safety and all affected food is prevented from entering into commerce if the facility cannot ensure that the affected food is not adulterated or misbranded under relevant sections of the U.S. Food Acts.

The facility is subject to the requirements of this section if:

- The preventive control is not properly implemented and a corrective action procedure has not been established;
- The preventive control, a combination of preventive controls, or the food safety plan is found to be ineffective; or
- A review of records finds that the records are not complete, the activities conducted did not occur as per the food safety plan, or appropriate decisions were not made about corrective actions.

The facility must take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce. When appropriate, the food safety plan should be reanalyzed to determine whether modification of the plan is required.

Corrections need not be applied if the facility takes action on time to identify and correct conditions and practices that are not consistent with the food allergen controls or the sanitation controls. Corrections also need not be applied if the facility takes action on time to identify and correct a minor and isolated problem that does not directly impact product safety.

All corrective actions taken must be documented in records. These records are subject to verification and records review.

FSMA Verification Requirements

FSMA Verification requirements include the following elements:

- Validation of Preventive Controls;
- Verification of Implementation and Effectiveness;
- System Review;
- Qualified Individuals and Qualified Auditors;
- Onsite FSMA Audit.

Validation of Preventive Controls

The facility must validate that the preventive controls identified and implemented are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system.

Preventive controls must also be validated. It must be performed (or overseen) by preventive control qualified individuals:

- Before implementation of the food safety plan; or
- When necessary to demonstrate the control measures can be implemented as designed within 90 calendar days after production of the applicable food first begins; or
- Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a documented justification for a timeframe that exceeds 90 calendar days after production of the applicable food first begins.

Validation must be conducted whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards. Validation must also be conducted whenever a review of the food safety plan reveals the need to do so.

Validation processes must include obtaining and evaluating scientific and technical evidence to determine whether properly implemented preventive controls will effectively control the hazards. When such evidence is not available or is inadequate, validation studies will be conducted with records maintained.

The facility does not need to validate the food allergen controls, sanitation controls, recall plan, supply-chain program, and other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a documented justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.

Verification of Implementation and Effectiveness

As appropriate to the nature of the preventive control and its role in the facility's food safety system, verification activities must include validation, verification that monitoring is being conducted, verification that appropriate decisions about corrective actions are being made, verification of implementation and effectiveness, and system review. Outcomes of all verification activities must be recorded.

The facility must verify that the preventive controls are consistently implemented and are effectively and significantly minimising or preventing the hazards, including the following (as relevant to their business operation):

- Calibration of process monitoring instruments and verification instruments (or checking them for accuracy);
- Product testing, for a pathogen (or appropriate indicator organism) or other hazards;
- Environmental monitoring, by collecting and testing environmental samples, for an environmental pathogen or an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control. Procedures for environmental monitoring must:
 - Be scientifically valid;
 - Identify the microorganisms of concern;
 - Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;
 - Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;
 - Identify the test(s) conducted, including the analytical method(s) used;
 - Identify the laboratory conducting the testing; and
 - Include relevant corrective action procedures.
- Review of records within the specified timeframes by (or under the oversight of) preventive control qualified individuals, to ensure that the records are complete, the activities reflected in the records occurred as per the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions;
- Records of monitoring and corrective action records must be reviewed within 7 working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a documented justification for a timeframe that exceeds 7 working days;
- Records of calibration, testing (for example, product testing, environmental monitoring), supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created;
- Other activities appropriate for verification of implementation and effectiveness.

As appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, the facility must establish and implement documented procedures covering the following activities:

- The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy);
- Procedures for product testing that are scientifically valid, identify the target microorganisms and other analytical parameters; specify the procedures for identifying samples (including their relationship to specific lots of product); include the procedures for sampling (including the number of samples and the sampling frequency); identify the tests conducted including the analytical methods used, identify the laboratory conducting the testing, and include the corrective action procedures.

System Review

The facility must conduct a review of the food safety plan as a whole at least once every three years. The facility must conduct a review of the food safety plan as a whole or the applicable portion of the food safety plan:

- Whenever a significant change in the activities conducted at the facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

- Whenever the facility becomes aware of new information about potential hazards associated with the food;
- Whenever appropriate after an unanticipated food safety problem; and
- Whenever the facility finds that a preventive control, a combination of preventive controls, or the food safety plan as a whole is ineffective.

As relevant to the nature of the preventive control and its role in the facility's food safety system, the facility must complete the system review and validate any additional preventive controls needed to address the hazard identified:

- Before any change in activities (including any change in preventive control) at the facility is operative; or
- When necessary to demonstrate the control measures can be implemented as designed within 90 calendar days after production of the applicable food first begins; or
- Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a documented justification for a timeframe that exceeds 90 calendar days after production of the applicable food first begins.

Revision of the documented food safety plan must be done if a significant change in the activities conducted at the facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or document the basis for the conclusion that no revisions are needed. Reviews must be conducted (or overseen) by a preventive controls qualified individual.

The facility must also conduct a review of the food safety plan when the FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

Food safety plans are not submitted to the FDA, but they must be available for review during inspection. Possible consequences of violating the FDA FSMA and HARPC requirements may include:

- Criminal charges upon the company or owner/operator/agent;
- Issue of a Public Warning Letter or an Import Alert;
- Suspension of the facility's food facility registration; and
- Detaining shipment of importations thereby barring entry from the U.S. market.

Qualified Individuals and Qualified Auditors

One or more preventive controls qualified individuals must do (or oversee) the following activities:

- The preparation of the food safety plan;
- Validation of the preventive controls;
- Documented justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable food;
- Determination that validation is not required;
- Review of records;
- Documented justification for a review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days;
- System review of the food safety plan; and
- Determination that system review can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable food.

A qualified auditor must conduct an onsite audit.

The preventive controls qualified individual must have completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardised curriculum recognised as adequate by FDA, or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardised curriculum. This individual may be but is not required to be an employee of the facility.

To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, and/or experience necessary to perform the auditing function.

All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

Onsite FSMA Audit

Only a qualified auditor must conduct an onsite audit of a supplier. If the raw material or other ingredients at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's documented plan (for example, HACCP plan or other food safety plan), if any, and its implementation, for the hazard being controlled. When applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognised as comparable or has determined to be equivalent to that of the U.S.

Provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted, the following may be substituted for an onsite audit:

- The documented results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by the FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives of State, local, tribal, or territorial agencies; or
- For a foreign supplier, the documented results of an inspection by the FDA or the food safety authority of a country whose food safety system FDA has officially recognised as comparable or has determined to be equivalent to that of the United States.

For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognised as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

If the onsite audit is solely conducted to meet requirements by an audit agent of a certification body that is accredited, the audit is not subject to the requirements in those regulations.

Supply Chain Program

The receiving facility must establish and implement a risk-based supply chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain applied control. The supply-chain program must be documented. This requirement does not apply to food that is supplied for research or evaluation use provided that such food is not intended for retail sale and is not sold or distributed to the public. Such foods need to be labelled with the statement "Food for research or evaluation use" and must be supplied in a small quantity that is consistent with research, analysis, or quality assurance purposes. The food can only be used for specified purposes. Any unused quantity of such materials needs to be properly disposed of and must be accompanied by documentation stating that the material has been used for research or evaluation purposes and cannot be sold or distributed to the public.

The supply chain program must include:

- Use of approved suppliers;
- Determination of appropriate supplier verification activities including the required frequency of such verification activities;
- Facilitation of supplier verification activities;
- Records of supplier verification activities; and
- Verification of a supply chain control applied by an entity other than the receiving facility's supplier and recording that verification or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment.

Supplier verification activities for raw materials and other ingredients include onsite audits, sampling and testing of the raw material or other ingredients, review of the supplier's relevant food safety records, and other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredients.

The supply chain program must assure that a hazard requiring a supply-chain applied control has been significantly

minimised or prevented. In approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, the following must be considered:

- The hazard analysis of the food, including the nature of the hazard controlled before receipt of the raw material or other ingredients, applicable to the raw material and other ingredients;
- The entity or entities that will be applying controls for the hazards requiring a supply-chain applied control; and
- Supplier performance.

Supplier performance includes the supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients. Supplier performance also includes applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of food and other FDA compliance actions related to food safety (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognised as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations). Additionally, supplier performance includes the supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems); and any other factors as appropriate and necessary, such as storage and transportation practices.

If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, document review, relevant consumer, customer, or other complaints or otherwise that the supplier is not controlling hazards that the receiving facility has identified as requiring a supply-chain applied control, the receiving facility must take and record prompt action to ensure that raw materials or other ingredients from the supplier do not cause the food that is manufactured or processed by the receiving facility to be adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act.

If a receiving facility is an FSVP compliant importer and has documentation of verification activities (which assures that the hazards requiring a supply-chain applied to control for the raw material or other ingredients have been significantly minimised or prevented), that receiving facility does not need to conduct supplier verification activities for related raw materials or ingredients.

When a supply chain applied control is applied by an entity other than the receiving facility's supplier (for example, When a non-supplier applies controls to certain products because growing, harvesting, and packing activities are under different management), the receiving facility must verify the supply-chain applied control, or obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation and document that review and assessment.

Using Approved Suppliers

The receiving facility must approve suppliers and document that approval before receiving raw materials and other ingredients from such suppliers. Documented procedures for receiving raw materials and other ingredients must be established and followed. These procedures for receiving raw materials and other ingredients must ensure that raw materials and other ingredients are received only from approved suppliers (or, when necessary and appropriate, temporarily from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use). Use of the documented procedures for receiving raw materials and other ingredients must be documented.

Appropriate supplier verification activities (including the frequency of conducting the activity) must be determined. Supplier verification activities must be conducted for each supplier before using the raw material or other ingredients from that supplier and periodically thereafter. When a hazard in raw material or other ingredients will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans, the appropriate supplier verification activity is an onsite audit of the supplier. The audit must be conducted before using the raw material or other ingredients from the supplier and at least annually thereafter. The audit may not be required if there is a documented determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

If a supplier is an FSMA qualified facility, the receiving facility does not need to comply with these requirements if

the receiving facility:

- Obtains documented assurance that the supplier is a qualified facility before first approving the supplier for an applicable calendar year and on an annual basis thereafter by December 31 of each calendar year for the following calendar year;
- Obtains documented assurance, at least every two years, that the supplier is producing the raw material or other ingredients in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognised as comparable or has determined to be equivalent to that of the United States). The documented assurance must include either a brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or a statement that the facility complies with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

If a supplier is a farm that grows produce, the receiving facility need not comply with requirement activities if the receiving facility obtains documented assurance, at least every 2 years, that the farm acknowledges that its food is subject to the relevant section of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognised as comparable or has determined to be equivalent to that of the United States).

If a supplier is a shell egg producer that is not subject to the requirements because it has less than 3000 laying hens, the receiving facility does not need to comply if the receiving facility obtains documented assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to the relevant section of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognised as comparable or has determined to be equivalent to that of the United States).

There must not be any financial conflicts of interests that influence the results of the verification activities and payment must not be related to the results of the activity.

Facility Receivals

The receiving facility must approve suppliers and must determine and conduct appropriate supplier verification activities. An entity other than the receiving facility may do the following provided that the receiving facility reviews and assesses the entity's applicable documentation and records:

- Establish documented procedures for receiving raw materials and other ingredients by the entity;
- Document that documented procedures for receiving raw materials and other ingredients are being followed by the entity.

The supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of the product and provide such documentation to the receiving facility, provided that the receiving facility reviews and assesses that documentation and documents that review and assessment. A receiving facility may not accept any of the following as a supplier verification activity:

- A determination by its supplier of the appropriate supplier verification activities for that supplier;
- An audit conducted by its supplier;
- A review by its supplier of that supplier's own relevant food safety records; or
- The conduct by its supplier of other appropriate supplier verification activities for that supplier.

The receiving facility may rely on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor.

Supply Chain Program Records

The records documenting the supply-chain program are subject to the records requirements previously discussed. The receiving facility must review the records and must document the documented supply-chain program, which includes:

- Documentation that a receiving facility that is an importer complies with the foreign supplier verification program,

including documentation of verification activities;

- Documentation of the approval of a supplier;
- Documented procedures for receiving raw materials and other ingredients;
- Documentation demonstrating the use of the documented procedures for receiving raw materials and other ingredients;
- Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients;
- Documentation of the conduct of an onsite audit with the document containing the name of the supplier subject to the onsite audit, documentation of audit procedures, the dates the audit was conducted, the conclusions of the audit, corrective actions taken in response to significant deficiencies identified during audit and documentation that the audit was conducted by a qualified auditor.

Also included is documentation of sampling and testing conducted as a supplier verification activity. The documentation must incorporate:

- Identification of the raw material or other ingredient tested (including lot number as appropriate) and the number of samples tested;
- Identification of the test(s) conducted, including the analytical method(s) used; the date(s) on which the test(s) were conducted, and the date of the report;
- The results of the testing; corrective actions taken in response to detection of hazards; and
- Information identifying the laboratory conducting the testing.

Documentation of the review of the supplier's relevant food safety records must also be maintained, including:

- The name of the supplier whose records were reviewed;
- The date(s) of review;
- The general nature of the records reviewed;
- The conclusions of the review; and
- Corrective actions taken in response to significant deficiencies identified during the review.

Appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredients must also be documented. Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier provide adequate assurance that the hazards are controlled when a hazard will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans. Alternative verification activities for suppliers that are a qualified facility must also be documented. This could be a documented assurance that the supplier is a qualified facility before approving the supplier and on an annual basis thereafter; and documented assurance that the supplier is producing the raw material or other ingredients in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognised as comparable or has determined to be equivalent to that of the United States).

For a supplier that is a farm that supplies raw material or other ingredients that is not covered, the following documentation of an alternative verification activity can be considered:

- Documented assurance that supplier is not a covered farm before approving the supplier and on an annual basis thereafter; and
- Documented assurance that the farm acknowledges that its food is subject to the relevant section of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognised as comparable or has determined to be equivalent to that of the United States).

For a supplier that is a shell egg producer that is not subject to the requirements, the following documentation of an alternative verification activity is considered:

- The documented assurance that the shell eggs provided by the supplier are not subject to the requirement because the supplier has less than 3000 laying hens before approving the supplier and on an annual basis thereafter; and

- The documented assurance that the shell egg producer acknowledges that its food is subject to the relevant section of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognised as comparable or has determined to be equivalent to that of the United States).

Documented results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection are substituted for an onsite audit is also included.

The supply chain program must include records of actions taken for supplier non-conformance including:

- Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier;
- When applicable, documentation of the receiving facility's review and assessment of applicable documentation from an entity other than the receiving facility that documented procedures for receiving raw materials and other ingredients are being followed;
- Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;
- Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;
- Applicable documentation from its suppliers (of results of sampling and testing conducted by the supplier; or results of an audit conducted by a third-party qualified auditor); and
- Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

Recall Plan

For food with a hazard requiring a preventive control, the facility must establish a documented recall plan for the food. The documented recall plan must include procedures that describe the steps to be taken and assign responsibility for taking those steps to:

- Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;
- To protect public health, notify the public about any hazard presented by the food when appropriate;
- Conduct effectiveness checks to verify that the recall is carried out; and
- Appropriately dispose of recalled food (e.g., through reprocessing, reworking, diverting to use that does not present a safety concern, or destroying the food).

Record Keeping



Records must be accurate, legible, and available for official review.

The facility must establish and maintain the following records documenting the implementation of the food safety plan:

- Documentation of the basis for not establishing preventive control;
- Records that document the monitoring of preventive controls;
- Records that document corrective actions;
- Records that document verification including those related to validation, verification of monitoring, verification of corrective actions, calibration of process monitoring and verification instruments, product testing, environmental testing, records review, and system review;
- Records that document the supply-chain program; and
- Records that document applicable training for the preventive controls qualified individual and the qualified auditor.

Records applicable for the documented food safety plan must be kept as original records or true copies such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records or electronic records. Records must contain the actual values and observations obtained during monitoring and verification activities. Records must be accurate, indelible, and legible.

Records must be created concurrently with the performance of the activity documented and be as detailed as necessary to provide a history of work performed. They must include information adequate to identify the plant or facility (for example, the name and when necessary, the location of the plant or facility), the date, and when appropriate, the time of the activity documented, the signature or initials of the person performing the activity, and where appropriate, the identity of the product and the lot code if any.

The owner, operator, or agent in charge of the facility must sign and date the food safety plan upon initial completion and following any modification.

All records must be retained at the plant or facility for at least two years after the date they were prepared.

Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least two years after their use is discontinued (for example, because the facility has updated the documented food safety plan or records that document validation of the documented food safety plan).

Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of the request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location. The food safety plan must remain onsite. If the facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request. All records must be promptly available to a duly authorised representative of the Secretary of Health and Human Services for official review and copying upon oral or documented request. Records obtained by FDA are subject to public disclosure within the scope of related legislation. Existing records (for example, records that are kept to comply with other Federal, State, or Local regulations or for any other reason) do not need to be duplicated if they contain all of the required information. The information does not need to be kept in one set of records. If existing records contain some of the required information, any new information required may be kept either separately or combined with the existing records.

Any documented assurance must include the effective date, printed names, and signatures of authorised officials and must include:

- Acknowledgment that the facility that provides the documented assurance assumes legal responsibility to act consistently with the assurance and document its actions taken to satisfy the documented assurance; and
- Provision that if the assurance is terminated in writing by either entity, responsibility for compliance with the applicable provisions of this part reverts to the manufacturer/processor as of the date of termination.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific FDA FSMA Development requirements in relation to their items.

Food Traceability Rule

The FSMA Food Traceability Rule sets additional traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods on the FDA Food Traceability List. The requirements are set out in Subpart S of 21 CFR Part 1. Key elements include:

- Critical Tracking Events, such as harvesting, cooling, initial packing, shipping, receiving, and transformation;
- Key Data Elements that must be recorded for each Critical Tracking Event performed;
- Traceability lot codes that are assigned at specified points and carried through the records;
- A traceability plan that describes the procedures for maintaining records, identifying listed foods, and assigning lot codes, together with a point of contact;
- Records that must be available to the FDA within 24 hours of a request, including an electronic sortable spreadsheet where required.

The original compliance date was 20 January 2026. Congress has directed the FDA not to enforce the rule before 20 July 2028, and the FDA has stated that it intends to comply with that direction. Exemptions and modified requirements apply to some businesses and foods, so check the current position on the [FDA Food Traceability Rule](#) page.

Intentional Adulteration Rule (Food Defence)

The FSMA Mitigation Strategies to Protect Food Against Intentional Adulteration rule requires covered food facilities to prepare and implement a written food defence plan. Key elements include:

- A vulnerability assessment that identifies actionable process steps for each type of food handled, evaluated for the severity and scale of the potential public health impact, the degree of physical access to the product, and the ability to successfully contaminate the product;
- Focused mitigation strategies that are applied at each actionable process step;
- Monitoring, corrective actions, and verification of the mitigation strategies;
- Training for personnel assigned to vulnerable areas, and records of monitoring, corrective actions, and verification;
- Reanalysis of the plan at least once every three years, or sooner when specified criteria are met.

The rule does not apply to farms. Very small businesses that average less than US\$10 million per year (adjusted for inflation) in sales of human food plus the market value of human food held without sale are exempt, but must provide documentation to the FDA on request. Hazards introduced for economic gain, including food fraud, are addressed through the hazard analysis, as described in [Food Fraud Risk Management](#).

Regulatory and Industry References

The following references provide further information on the FDA FSMA. Always check that you are working to the current requirements:

- [FDA Food Safety Modernization Act \(FSMA\) overview](#);
- [FSMA Final Rule for Preventive Controls for Human Food](#);
- [FSMA Final Rule on Produce Safety](#);
- [FSMA Final Rule on Foreign Supplier Verification Programs \(FSVP\) for Importers of Food for Humans and](#)

Animals;

- FSMA Final Rule on Accredited Third-Party Certification;
- FSMA Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration;
- FSMA Final Rule on Sanitary Transportation of Human and Animal Food;
- FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods;
- FSMA Final Rule on Laboratory Accreditation for Analyses of Foods (LAAF);
- Codex Alimentarius Codes of Practice listing, including the General Principles of Food Hygiene (CXC 1-1969).

FDA FSMA Development Key Points

- FDA FSMA programs must be developed to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The Senior Management of your business facilitates a commitment to ensuring adequate resources for the development of your FDA FSMA program;
- Should you require additional resources for the development of FDA FSMA program elements, please discuss this with the relevant Senior Management representative;
- A properly developed FDA FSMA program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly developed FDA FSMA program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Documentation

To establish the developed detail in a viewable format to facilitate information.

Documentation

Document: A document provides guidance and/or direction for performing work, making decisions, or rendering judgments that affect the safety or quality of the products or services that customers receive.

Documented policies, procedures, work instructions, and schedules form the basis of any food safety and quality management system. The following documentation formats may be considered to ensure ongoing compliance with specified requirements for the FDA FSMA:

- FDA FSMA policy;
- FDA FSMA development procedures;
- FDA FSMA implementation procedures and work instructions;
- FDA FSMA monitoring procedures;
- FDA FSMA corrective and preventative action procedures;
- FDA FSMA verification schedule;
- FDA FSMA verification procedures;
- FDA FSMA validation schedule;
- FDA FSMA validation procedures;
- FDA FSMA training procedures.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific FDA FSMA Documentation requirements in relation to their items.

You may wish to visit the FDA FSMA Templates section of haccp.com for examples of FDA FSMA documentation, record, and resource formats commonly applied within food safety and quality systems.

FDA FSMA Documentation Key Points

- FDA FSMA programs must be documented to meet relevant Regulatory, Industry, and Customer standards and requirements;
- All documented FDA FSMA program elements must be controlled to ensure compliance;
- Key documented FDA FSMA program elements should be available to your business team at all times to ensure they can facilitate required tasks;
- A properly documented FDA FSMA program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly documented FDA FSMA program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Implementation

To facilitate the application of the documentation.

Implementation

Implementation: Implementation is the application of documented food safety and quality system elements into the actual business operation.

The implementation of the FDA FSMA within any food business requires genuine commitment from senior management, staff, and visitors to ensure the nominated goals of implementation are achievable on an ongoing basis. It is a step that requires significant planning and consideration of general and specific food business circumstances to ensure the outcomes of the FDA FSMA do not negatively impact the safety and quality of the food items dispatched from the business.

Implementation of the FDA FSMA must include a clear definition of responsibilities and authorities for all levels of participation by senior management, staff, and visitors to the site.

When implementing the FDA FSMA within the food safety and quality system, you may wish to consider the following requirements before completion:

- Communication and display of the FDA FSMA policy;
- Completion of Verification and Validation of the FDA FSMA development procedures;
- Availability of the FDA FSMA implementation procedures and work instructions;
- Availability of the FDA FSMA monitoring procedures and record templates where applicable;
- Availability of the FDA FSMA corrective and preventative action procedures and record templates where applicable;
- Availability of the FDA FSMA verification schedule;
- Availability of the FDA FSMA verification procedures;
- Availability of the FDA FSMA validation schedule;
- Availability of the FDA FSMA validation procedures;
- Completion of the FDA FSMA training procedures;
- Completion of product design and development requirements related to the FDA FSMA
- Completion of process design and development requirements related to the FDA FSMA;
- Completion of training for team members who have responsibilities and involvement within the FDA FSMA;
- Completion of competency approval for team members who have responsibilities and involvement within the FDA FSMA.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific FDA FSMA Implementation requirements in relation to their items.

FDA FSMA Implementation Key Points

- FDA FSMA programs must be implemented to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Your FDA FSMA program must be fully implemented as per relevant documented Policies, Procedures, and Work Instructions;
- The implementation of FDA FSMA requires a commitment to the provision of resources by the Senior Management of your business;
- A properly implemented FDA FSMA program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly implemented FDA FSMA program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Monitoring

To review, confirm and document evidence of the implementation against documented limits.

Monitor

Monitoring: Monitoring is the act of reviewing and confirming measurable parameters of a defined process or product status.

Monitoring requirements within food industry sectors are generally identified against limits of acceptability defined within HACCP plans, implementation procedures, and work instructions. Monitoring usually includes some element of record-keeping, which may be maintained manually or through digital systems. It is important to consider that advancements in technology have spawned many systems and processes which are self-monitored and/or self-adjusted when variances are identified. Regardless of the system used, the goal of any monitoring activity is to provide sufficient evidence that any limit of acceptability has been met.

FDA FSMA monitoring requirements include manual recording and the application of corrective actions when the results of monitoring are found to be outside acceptable limits. Corrective Actions should also generally be strongly linked to the monitoring process where applied to ensure full traceability of the applied actions.

Common monitoring activities and record formats may apply to the FDA FSMA:

- Food Safety and Quality Program Records.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific FDA FSMA Monitoring requirements in relation to their items.

You may wish to visit the FDA FSMA Templates section of haccp.com for examples of FDA FSMA documentation, record, and resource formats commonly applied within food safety and quality systems.

FDA FSMA Monitoring Key Points

- Monitoring provides real-time confirmation and evidence that your risk-based FS&Q Controls are effectively implemented;
- FDA FSMA programs must be monitored to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Monitoring of FDA FSMA must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated monitoring records for FDA FSMA must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- A properly monitored FDA FSMA program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly monitored FDA FSMA program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Corrective Action and Preventative Action

To apply “real time” interventions to documented monitoring limits.

Corrective Action

Corrective Action: Corrective action is mandatory action to be taken when a deviation to the Quality System occurs, particularly to a Critical Control Point.

Preventative Action: At any step in the process where a hazard has been identified, preventive action must be put into place to prevent recurrence.

Corrective Action and Preventative Action are implemented to ensure that any identified non-conformance issues are documented, investigated, and rectified within appropriate time frames. Corrective action is any action applied to regain control over a product, process, policy, or procedure that has been identified as being non-conforming or outside nominated limits of acceptability. Preventative action is any action applied to prevent any identified non-conformance from reoccurring.

The outcomes of corrective and preventative actions should result in regained process control after effective application. Specified corrective actions are commonly linked to the HACCP Plans and the food business certification process.

Below are Corrective Action and Preventative Action examples which may be associated with FDA FSMA related non-conformance:

- Review of the FDA FSMA policy;
- Review of the FDA FSMA development procedures;
- Review of the FDA FSMA implementation procedures and work instructions;
- Review of the FDA FSMA monitoring procedures;
- Review of the FDA FSMA corrective and preventative action procedures;
- Review of the FDA FSMA verification schedule;
- Review of the FDA FSMA verification procedures;
- Review of the FDA FSMA validation schedule;
- Review of the FDA FSMA validation procedures;
- Review of the FDA FSMA training procedures;
- Re-training in the FDA FSMA;
- Review of management review activities to include FDA FSMA as an agenda item;
- Initiation of 'product hold' procedures where safety or quality may be compromised;
- Initiation of a product recall or product recall procedures where investigations show that there is a substantial safety and/or quality risk to the released product;
- Contacting stakeholders including customers regarding any confirmed or potential FDA FSMA concerns involving their product.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific FDA FSMA Corrective Action requirements in relation to their items.

You may wish to visit the Corrective Action and Preventative Action section of haccp.com for examples of best practice applications for this food safety and quality system element.

FDA FSMA Corrective Action and Preventative Action Key Points

- The implementation of Corrective Action and Preventative Action provides confidence that your FS&Q Program is effectively implemented and that FS&Q criteria are being met;
- Where deviations or variations are observed, Corrective Action and Preventative Actions must be facilitated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Corrective Action and Preventative Action of FDA FSMA must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;

- Records of Corrective Action and Preventative Action for FDA FSMA must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- Proper application of Corrective Action and Preventative Action for your FDA FSMA program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- Poor application of Corrective Action and Preventative Action for your FDA FSMA program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Verification

To review and confirm documented monitoring and corrective actions against documented parameters.

Verify

Verification: The act of reviewing, inspecting, testing, checking, auditing, or otherwise establishing and documenting whether items, processes, services, or documents conform to specified requirements.

Verification is the detailed review of all food safety and quality system elements to confirm that they are effectively developed, documented, implemented, monitored, and reviewed. All food safety and quality system elements, including documented policies, procedures, training, HACCP plans, and their operational applications must be verified on an ongoing scheduled basis. The verification process commonly includes a defined schedule for which verification activities are required, how often they are conducted, who is responsible, and detailed documented procedures for each nominated verification activity.

The general goal of an established verification process is to ensure any systemic non-conformance issues are identified and rectified within an appropriate time frame. When non-conformance issues are identified through the verification process, Corrective Actions and Preventative Actions should be implemented to ensure they do not impact the effectiveness of the food safety and quality system.

The following examples of verification activities may apply to the FDA FSMA:

- Review of the FDA FSMA policy;
- Review of the FDA FSMA development procedures;
- Review of the FDA FSMA implementation procedures and work instructions;
- Review of the FDA FSMA monitoring procedures;
- Review of the FDA FSMA monitoring records;
- Review of the FDA FSMA corrective and preventative action procedures;
- Review of the FDA FSMA verification schedule;
- Review of the FDA FSMA verification procedures;
- Review of the FDA FSMA validation schedule;
- Review of the FDA FSMA validation procedures;
- Review of the FDA FSMA training procedures;
- Review of the FDA FSMA performance since the last review and historically;
- Analytical testing of product or process to ensure the effectiveness of the FDA FSMA;
- Inclusion of the FDA FSMA as an agenda item within the Management Review Process.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific FDA FSMA Verification requirements in relation to their items.

You may wish to visit the Verification Activities section of haccp.com for examples of best practice applications for this food safety and quality system element.

FDA FSMA Verification Key Points

- Your verification program provides evidence that your FS&Q Controls have worked;
- FDA FSMA programs must be verified to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The verification of FDA FSMA must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated verification records for FDA FSMA must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- A properly verified FDA FSMA program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly verified FDA FSMA program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Validation

To confirm the documented monitoring or procedural limits.

Validate

Validation: The process of gathering evidence to provide a scientific basis for the documented act of demonstrating that a procedure, process, and activity will consistently lead to the expected results. It often includes the qualification of systems and equipment.

Validation is the provision of evidence to support the limits of control or acceptability for food safety or quality parameters nominated within systemic elements. Limits of control or acceptability are commonly included within documented food safety and quality systems elements such as procedures, HACCP plans, and specifications.

Common sources of validation include regulatory and legislative standards, finished product specifications and customer requirements, industry codes of practice and guidelines, verified and validated research, historical product, and process control outcomes, and analytical testing.

The general goal of an established verification process is to ensure any systemic non-conformance issues are identified and rectified within an appropriate time frame. When non-conformance issues are identified through the verification process, Corrective Actions and Preventative Actions should be implemented to ensure they do not impact the effectiveness of the food safety and quality system.

Validation activities are commonly defined within the verification schedules and procedures of established food safety and quality management systems.

The following examples may apply to validation of the limits of control or acceptability for the FDA FSMA:

- Confirmation of nominated food safety and food quality control limits for the FDA FSMA. These limits may apply to regulatory, industry, customer, or finished product specifications;
- Confirmation of analytical testing methods being used to confirm the effectiveness of the FDA FSMA and ensure the accuracy of outcomes.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific FDA FSMA Validation requirements in relation to their items.

You may wish to visit the Validation Activities section of haccp.com for examples of best practice applications for this food safety and quality system element.

FDA FSMA Validation Key Points

- Your validation program provides evidence that your FS&Q Controls will work;
- FDA FSMA programs must be validated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The validation of FDA FSMA must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;

- Nominated validation records and supporting documentation for FDA FSMA must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- A properly validated FDA FSMA program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly validated FDA FSMA program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Training, Competency and Resources

Skills, knowledge and competency requirements to facilitate development, documentation, implementation, monitoring, corrective action, verification and validation of every Food Safety and Quality System Element.

Skills and Knowledge

Skills and Knowledge: Skills and knowledge are attributes of human interactions commonly linked to competency within any specified job-related task.

Training and competency requirements for the FDA FSMA must be ongoing, including regularly scheduled reviews to ensure the effectiveness of training and competency outcomes.

Team members who have defined responsibilities regarding the FDA FSMA should have knowledge including:

- Basic FDA FSMA requirements;
- Positive outcomes of the FDA FSMA;
- Negative outcomes of a lack of the FDA FSMA;
- Current FDA FSMA procedures, methods, and techniques;
- General operational, corporate, and social awareness regarding the FDA FSMA;
- Regulatory, industry, and customer requirements regarding the FDA FSMA.

Team members who have defined responsibilities regarding the FDA FSMA should have skills including:

- Competency regarding basic FDA FSMA;
- Effective application of current FDA FSMA procedures, methods, and techniques;
- The basic development, documentation, and implementation of HACCP and Prerequisite Programs within the food industry sector.

Team members who have defined responsibilities regarding the FDA FSMA should have access to resources including:

- FDA FSMA training;
- FDA FSMA associations and events;
- Regulatory standards, industry and customer information, and updates regarding the FDA FSMA;
- Incidents within the food industry sector regarding the FDA FSMA;
- Commitment to the FDA FSMA by senior management;
- Suitably qualified food industry professionals with verified experience in the FDA FSMA;
- Effective communication systems including email, internet, and phone through which FDA FSMA information can be sent and received within suitable timeframes.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific FDA FSMA Training, Competency, and Resources requirements in relation to their items.

You may wish to visit the Training, Competency, and Resources section of haccp.com for examples of best practice applications for this food safety and quality system element.

FDA FSMA Training, Skills, and Knowledge Key Points

- Your Training, Skills, and Knowledge program ensures all participating personnel, visitors, and contracted have the required skills and knowledge to effectively facilitate the requirements of your FS&Q Program;
- Training, Skills, and Knowledge programs for FDA FSMA must be facilitated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Training, Skills, and Knowledge programs for FDA FSMA must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Training, Skills, and Knowledge records for FDA FSMA must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- Properly applied Training, Skills, and Knowledge programs for FDA FSMA will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- Poorly applied Training, Skills, and Knowledge programs for FDA FSMA will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.



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