FSMA Compliance Guidance for the Cold Chain Industry

GLOBAL COLD CHAIN ALLIANCE®

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GLOBAL COLD CHAIN ALLIANCE

214 18th Street South Arlington, VA 22202 USA

www.gcca.org

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Compliance Guide Overview

The Food Safety Modernization Act (FSMA), signed into law in January 2011, represented the first major changes to the Food and Drug Administration's (FDA) food safety authorities in over 70 years. The legislation was driven by the occurrence of several high-profile food recalls that resulted in significant numbers of illnesses and some fatalities. According to the Centers for Disease Control and Prevention about 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from food borne diseases.

FSMA is designed to enable FDA to better protect public health by strengthening the food safety system by focusing on prevention; inspections, compliance and response; import safety; and enhanced partnerships. The law emphasizes preventing food safety problems rather than relying primarily on reacting to problems after they occur; provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards; enables FDA to better respond to and contain problems when they do occur; gives FDA important new tools to hold imported foods to the same standards as domestic foods; and directs FDA to build an integrated national food safety system in partnership with state and local authorities.

Since 2013, the FDA has issued 10 rules to implement preventive safety measures across the food supply chain.

FSMA at a Glance

Rule	Relevant to Cold Storage
Preventative Controls Human Food	Yes
Preventative Controls Animal Food	Yes
Produce Safety Rule	Yes
Sanitary Transportation Rule	Yes
Food Traceability Rule (FSMA 204)	Yes
Foreign Supplier Verification Program (FSVP)	Yes, for Import Operations
Intentional Adulteration Rule	Yes, but limited
Accredited Third Party Certification	Yes, for Import Operations
Voluntary Qualified Importer Program (VQIP)	Yes, for Import Operations
Laboratory Accreditation for Analyses of Foods (LAAF)	No

This guide focuses on the FSMA regulations most likely to affect cold storage, refrigerated warehousing, transportation, and temperature-controlled logistics operations. This publication highlights the FSMA regulations and compliance considerations most applicable to cold chain operators and is meant to be a living document as FDA continues its efforts to implement FSMA. However, it is not intended to provide a comprehensive analysis of every FSMA rule or program. Companies should assess their operations and consult applicable FDA regulations to determine all requirements relevant to their business activities including state and local reporting requirements that apply in the jurisdictions in which each facility is located.

GCCA cannot and does not assume any liability or responsibility for any member's failure to comply with any applicable law, rule or regulation. Members are encouraged to read and comment on any matters covered in this document and to suggest other laws, rules and requirements that should be addressed in future editions.

Registration of Food Facilities

Background

Section 102 of FSMA requires food facilities to submit registrations to FDA containing additional information than what is required in the Federal Food, Drug and Cosmetic Act (FD&CA). Food facilities, which are defined in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), must register with FDA and renew registration biennially, beginning on October 1 and ending on December 31 of each even-numbered year. In addition, if FDA determines that food manufactured, processed, packed, received, or held by a registered food facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may suspend the registration of a facility that created, caused, or was otherwise responsible for such reasonable probability; or knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

Public refrigerated warehouses and cold storage facilities that hold food products are generally required to maintain FDA food facility registration unless a specific exemption applies. Food facility registration serves as FDA's primary mechanism for identifying facilities that manufacture, process, pack, or hold food. Registration enables FDA communication during recalls, outbreak investigations, inspections, and other food safety events. Failure to renew registration during the required biennial registration period may result in an invalid registration and potential disruption of food distribution activities.

Registration Requirements

- Initial registration completed before conducting covered operations
- Biennial renewal of food facility registrations during each even-numbered year
- Unique Facility Identifier (UFI), such as a DUNS number
- Registration updates within 60 days of any changes
- Registration cancelation if the facility closes or changes ownership
- Contact information requirements including e-mail address
- Inspection assurance requirement

FDA Enforcement Authority

- Suspension of registration when FDA determines food from the facility presents a reasonable probability of causing serious adverse health consequences or death to humans or animals.
- Refusal or detention of imported food from foreign facilities with suspended registrations.

Registration Process

FDA strongly encourages electronic submission of registration. Once received, FDA confirms registration electronically and assigns a registration number. Waivers are required for paper-based registration. The following materials are needed for registration:

- Type of facility
- Facility name, address, phone number and emergency contact phone number
- Parent company name, address and phone number (if applicable)
- Name, address and phone number of the owner, operator or agent in charge
- Email address for the contact person of the facility
- All trade names the facility uses
- Applicable food product categories, as listed on the registration form
- Name, address, phone number and emergency contact phone number of a foreign facility's U.S. agent
- Assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act
- Certification that the information submitted is true and accurate and that the person submitting it is authorized to do so

FDA confirms the registration electronically and assigns a registration number.

U.S. Agent (GCCA Members Only)

Most non-US food facilities shipping product to the U.S. must have an Agent based in the U.S. The Agent's primary responsibility is to serve as a communications link between FDA and the foreign food facility. At the request of several non-U.S. members, GCCA offers to provide this service to our members at no cost. GCCA will serve as the U.S. Agent and be listed under Section 7 on the DHHS/FDA – Food Facility Registration Form.

If you wish to designate GCCA as your US Agent, please contact GCCA so we can be prepared for outreach from FDA. Information required for Section 7 can be found online at [Link].

Additional Information

- FDA Registration of Food Facilities Website
- Online Registration of Food Facilities | FDA
- Food Facility Registration User Guide: Step-by-Step Instructions for Registration | FDA

- Food Facility Registration User Guide: Registration of Food Facilities – Step-by-Step Instructions
- Food Facility Registration User Guide: Update Facility Registration

Inspection of Domestic Facilities

Background

Section 201 of FSMA requires FDA to allocate food inspection resources according to the risk profile of the facility and other important criteria. It calls for all high-risk domestic food facilities to be inspected within five years of the bill's signing and then at least once every three years after that. Non-high risk food facilities are to be inspected within seven years of the bill's signing and then at least once every five years thereafter. The legislation gives FDA general direction on risk characteristics, but the agency will have some discretion as it refines the risk categories.

Factors Used to Determine High-Risk Facilities

- The known safety risks of the food manufactured, processed, packed, or held at the facility
- The compliance history of a facility, including with regard to food recalls, outbreaks of food borne illness, and violations of food safety standards
- The rigor and effectiveness of the facility's hazard analysis and risk-based preventive controls
- Whether the food manufactured, processed, packed or held at the facility meets the criteria for priority under section 801(h)(1) of the FD&C Act, which relates to the prioritization to detect intentional adulteration in food offered for import into the U.S.
- Whether the food or the facility that manufactured, processed, packed, or held such food has received a certification as described in section 801(q) (concerning imported food) or 806 (voluntary qualified importer program) of the FD&C Act, as appropriate
- Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources

Potential Inspection Focus Areas

The following are the potential areas that FDA may review during an inspection:

- Food safety plans (if applicable)
- Sanitation programs and records
- Temperature monitoring records
- Pest control programs
- Environmental monitoring programs
- Allergen control programs
- Employee training records
- Traceability records
- Recall procedures
- Preventive maintenance records

- Equipment and instrument calibration records
- Supplier verification records
- Sanitary transport program
- Food defense procedures

Cold Storage Specific Inspection Areas

When visiting a cold storage facility, FDA inspector may also evaluate:

- Product temperature controls
- Trailer and dock sanitation
- Cross-contamination prevention
- Product segregation practices
- Pest management programs
- Environmental monitoring activities (when applicable)
- Product traceability and inventory controls
- Supplier verification programs
- Employee training programs and records
- Recall readiness procedures

Transportation Specific Inspection Areas

FDA inspections or investigations involving transportation operations may include review of:

- Trailer sanitation records
- Temperature calibration and monitoring records
- Equipment maintenance records
- Employee training
- Written sanitary transportation procedures
- Corrective action documentation
- Traceability records

Additional Information

- FDA Prioritization of Domestic Human Food Facility Inspections
- Inspections to Protect the Food Supply

Inspection of Foreign Food Facilities

Background

FSMA Section 306 authorizes FDA to enter into agreements and arrangements with foreign governments to facilitate the inspection of foreign facilities. The statute prohibits entry of food from a foreign facility or country that fails to permit inspection by the United States. Section 306 also authorizes the Department of Commerce, in coordination with the Department of Health and Human Services (HHS), to assess foreign facilities that import seafood into the United States and provide technical assistance.

FDA's foreign supplier oversight program includes not only direct inspections of foreign facilities but also verification of importer responsibilities under the Foreign Supplier Verification Program (FSVP). Importers are expected to evaluate and approve foreign suppliers and ensure imported foods meet applicable U.S. food safety requirements.

Goals of Inspections

- Identify potential food safety problems before products arrive in the United States
- Determine the compliance status of facilities to FDA's requirements and food safety standards
- Help the agency make admissibility decisions when food products are offered for importation into the United States
- Help ensure that food products under FDA's jurisdiction meet U.S. requirements under the Federal FD&C Act

How Facilities are Chosen for Inspection

FDA's selection of foreign food facilities for inspection is based on an overall, cross-cutting risk profile. Primary risk-factors include:

- The food safety risk associated with the commodity (the type of food)
- The manufacturing process
- The compliance history of the facility, such as refusal rates for products that were denied entry into the United States

Additional Information

- Foreign Food Facility Inspection Program
- Foreign Food Facility Inspection Program Questions & Answers

Inspection of Records

Background

Section 101 of FSMA notes that if there is a reasonable probability that a food, or a related article of food, will cause serious adverse health consequences or death to humans or animals, the FDA will be authorized to access relevant records for that food and any related article of food that may be similarly contaminated. This amends Section 414 of the FD&C Act.

Required Records Under FSMA

FSMA expands FDA's former records access beyond records related to the specific suspect article of food for which FDA reasonably believes is adulterated and presents a threat of serious adverse health consequences or death to humans or animals to now include records relating to any article of food that is reasonably likely to be affected in a similar manner.

FSMA authorizes FDA to access records related to articles of food for which FDA believes that there is a reasonable probability that the use of or exposure to the article of food, and any other article of food is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. Decisions from FDA are made on a case by case basis.

Examples of Records

Specific examples of records that FDA may review include:

- Receiving records
- Shipping records
- Lot and batch information
- Temperature monitoring records
- Traceability records
- Supplier verification records
- Recall documentation
- Food safety monitoring records
- Verification records
- Corrective action records
- Sanitation records
- Environmental monitoring for ready-to-eat foods
- Inventory records

Facilities should maintain records supporting:

- Product receipt and shipment
- Lot identification
- Location tracking within the facility
- Temperature management
- Recall readiness
- Inventory control
- Customer and supplier communications related to food safety events

Failure to maintain or provide required records during an FDA investigation may result in regulatory action and can significantly hinder traceback, recall, and food safety response activities.

Additional Information

- Guidance for Industry on FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, and Cosmetic Act

Hazard Analysis and Risk-Based Controls

Background

Section 103 of FSMA requires importers to conduct 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 you import to determine where there are any hazards requiring a control. Operators of a facility are required to understand the hazards that are reasonably likely to occur in operation and to put in place preventive controls to minimize or prevent the hazards or reduce them to an acceptable level. Although this rule is similar to HACCP, it differs in that preventive controls may be required at points other than at critical control points and critical limits may not be required for all preventive controls.

Requirements

Facilities subject to the full rule must:

- Conduct a written hazard analysis to identify known or reasonably foreseeable hazards, based on experience, illness data, scientific reports, and other information
- Identify and implement preventive controls for hazards that require one
- Monitor the controls
- Take corrective actions when controls fail
- Verify that the controls work and are consistently implemented
- Keep records of each of these activities
- Reanalyze the hazard analysis at least once every three years, and sooner when operations or circumstances change

The food safety plan must be prepared, or its preparation overseen, by a Preventive Controls Qualified Individual (PCQI).

Decision Matrix

Operation	Potential Requirement
Dry storage of unexposed packaged food	Exempt
Refrigerated storage of packaged food requiring temperature control	Modified requirements
Frozen storage of packaged food	Often modified requirements
Repacking activities	Full preventative controls may apply
Labeling or relabeling	Facility-specific evaluation required
Processing activities	Full preventive controls likely apply
Co-packing operations	Full preventive controls likely apply

Facilities performing activities beyond storage of packaged food that does not require temperature control should evaluate whether those activities change their regulatory obligations under the Preventive Controls Rule. For example, many GCCA members perform labeling, repackaging, cross-docking, assembly, inspection, tempering, and blast freezing. These activities can affect regulatory status and lead to the requirement for a full Hazard Analysis and Risk-Based Preventive Controls (HARPC) plan.

Food Safety Plan

Facilities are required to prepare and implement a written food safety plan, which includes:

- Hazard analysis
- Preventive controls
- Monitoring
- Corrective actions
- Verification
- Recordkeeping
- Traceability
- Recall Plan (applicable to facilities subject to full Preventive Control requirements) and strongly recommended for all foods

Exemptions

Some facilities are exempted from the preventive controls requirements. For example, dry warehouses solely engaged in the storage of "unexposed", packaged products are exempt from the preventive controls requirements although a sanitation program is required. FDA has indicated that "unexposed" pertains to food that is packaged in such a way as to prevent human contact. Another exemption is for facilities that have an FDA HACCP plan for juice or seafood that were required under earlier FDA regulations.

Modified Requirements

While a full exemption is only likely for those facilities that have an FDA HACCP plan, some refrigerated warehouses are subject to a set of modified requirements if the facilities are solely engaged in storing unexposed packaged food requiring temperature control. These modified requirements recognize that qualifying facilities pose a lower food safety risk, and that the primary risk is temperature abuse. GCCA supported a petition filed with FDA outlining the reduced risks of warehouses and suggesting that it is not necessary for warehouses to be subject to additional regulations under the preventive controls rule.

FDA modified requirements include:

- Establishing and implementing temperature controls
- Monitoring the temperature controls
- Taking appropriate corrective actions when there is a problem with temperature controls
- Verifying that temperature controls are consistently implemented
- Establishing and maintaining the following records:
    - Records documenting the monitoring of temperature controls
    - Records of corrective actions
    - Records documenting verification activities

Benefits of qualifying for modified requirements include:

- Facilities would not need to develop their own food safety plan.
- Facilities would not have to conduct an individual hazard analysis or reanalysis.
- Written procedures would not be required for monitoring temperature controls.
- Written procedures would not be required for corrective actions.
- Verification and reanalysis of temperature controls would not be required.

Additional Information

- Fact Sheet: FSMA Final Rule for Preventive Controls for Human Food
- Small Entity Compliance Guide: What You Need to Know About Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- 21 CFR 117.7: Facilities solely engaged in the storage of unexposed packaged food

Collection of Fees

Background

FSMA Section 107 does not require a registration fee to be paid by registered facilities. FSMA does authorize FDA to assess fees for compliance failures (recalls and re-inspections) and for participation in a voluntary qualified importer program.

FDA has authority to assess and collect fees for food recall activities associated with a recall order when a domestic food facility or importer does not comply with such order. There are also fees that can be collected for administrative costs of the voluntary qualified importer program, for costs associated with issuing food export certifications, and for costs to establish and administer the third-party accreditation program. For each fiscal year a fee schedule will be established for domestic and foreign facility re-inspections, failure to comply with recall orders, and certain importer re-inspections.

Current Rates for Facility Re-inspections, Recalls, and Importer Re-inspections

The schedule of fees are updated annually and posted on the FDA's website. Payments for assessed fees must be made within 90 days of the invoice date.

Additional Information

- Fees Under FSMA

Produce Safety Rule

Background

FSMA Section 105 contains the Produce Safety Rule, which establishes science-based minimum standards for the growing, harvesting, packing, and holding of covered produce intended for human consumption. Most cold storage operators and transportation providers are not directly subject to Produce Safety farm requirements. However, many GCCA members handle produce commodities originating from farms that must meet these requirements (covered farms) and should understand the rule's role within the broader food safety framework.

Key Areas Covered by the Rule

- Agricultural water
- Worker health and hygiene
- Equipment sanitation
- Biological soil amendments
- Harvesting and handling practices
- Sprout production requirements

Cold Chain Considerations

- Maintaining product integrity after harvest
- Temperature or humidity control, if required
- Supporting traceability efforts
- Following sanitary transportation practices
- Understanding shipper compliance expectations

Additional Information

- Frequently Asked Questions
- What to Expect from Larger Farms to Comply with Produce Safety Rule

Sanitary Transportation of Human and Animal Food

Background

FSMA Section 111 requires FDA to promulgate regulations on the sanitary transportation of food. On April 6, 2016, FDA published the final rule entitled Sanitary Transportation of Human and Animal Food. The goal of the rule is to prevent practices that create food safety risks, such as failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food during transportation. It addresses the sanitary transportation of both human and animal food traveling via motor or rail vehicle by establishing criteria for the safe transportation of food. Specifically, the rule defines the roles of shippers, loaders, carriers and receivers and establishes requirements for: vehicles and transportation equipment, transportation operations, information exchange, training, records, and waivers.

Highlights of the Final Rule

- Vehicles and transportation equipment: Vehicles and transportation equipment must be designed and maintained to ensure that it does not cause the food it transports to become unsafe. For example, they must be suitable and adequately cleanable for their intended use and capable of maintaining temperatures necessary for the safe transport of food.
- Transportation operations: Measures must be taken during transportation to ensure food safety, such as adequate temperature controls, preventing contamination of ready to eat food from touching raw food, protection of food from contamination by non-food items in the same load or previous load, and protection of food from cross-contact, i.e., the unintentional incorporation of a food allergen.
- Training: Training must be provided to carrier personnel in sanitary transportation practices and documentation maintained of the training. This training is required when the carrier and shipper agree that the carrier is responsible for sanitary conditions during transport.
- Records: Records of written procedures, agreements and training (required of carriers) must be maintained. The required retention time for these records depends upon the type of record and when the covered activity occurred, but does not exceed 12 months.
- Waivers: FDA will waive any of these requirements if it determines that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and that it is in the public interest.

Roles & Responsibilities

<u>Shippers</u>

- Define sanitary requirements.
- Specify required temperatures.

- Communicate handling requirements.
- Provide transportation instructions.

Loaders

- Verify vehicle condition.
- Check product temperatures.
- Protect against contamination.
- Ensure proper product segregation.

Carriers

- Maintain sanitary equipment.
- Maintain temperature controls.
- Train personnel.
- Maintain required records.

Receivers

- Assess product condition upon arrival.
- Review temperature records, when required.
- Document exceptions and corrective actions.

Common Transportation Records

- Training records
- Trailer inspection records
- Cleaning and sanitation documentation
- Temperature monitoring records
- Corrective action records
- Preventative maintenance records
- Written agreements with shippers
- Seal documentation

Exemptions

The proposed rule includes a list of activities that would be exempt from the requirements of the regulation. Please note that exemption from the Sanitary Transportation Rule does not eliminate compliance obligations under other FDA regulations, customer requirements, contractual obligations, or company food safety programs

- Shippers, receivers, or carriers engaged in food transportation operations that have less than $500,000 in average annual revenue

- Transportation activities performed by a farm
- Transportation of food that is transshipped through the United States to another country
- Transportation of food that is imported for future export and that is neither consumed or distributed in the United States
- Transportation of compressed food gases (e.g. carbon dioxide, nitrogen or oxygen authorized for use in food and beverage products), and food contact substances
- Transportation of human food byproducts transported for use as animal food without further processing
- Transportation of food that is completely enclosed by a container except a food that requires temperature control for safety
- Transportation of live food animals, except molluscan shellfish

Additional Information

- GCCA Transportation Best Practices
- FDA Fact Sheet on Final Rule
- Full Text of Final Rule

Traceability

Background

Section 204 of FSMA establishes the Requirements for Additional Traceability Records for Certain Foods (also called Food Traceability Final Rule). Published on November 15, 2022, the rule establishes traceability recordkeeping requirements for those who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL). At its core, the rule requires businesses to maintain records containing Key Data Elements (KDEs) for specific supply chain activities known as Critical Tracking Events (CTEs) and to make that data available to the FDA in a sortable spreadsheet within 24 hours upon request, retaining records for a minimum of 24 months. CTEs include harvesting, cooling, initial packing, receiving, shipping, and transformation. Facilities are also required to have a traceability plan. **The compliance deadline is July 20, 2028.**

Food Traceability List

The Food Traceability List (FTL) identifies the foods for which the additional traceability records are required. The additional recordkeeping requirements apply to the foods specifically listed on the FTL, and to foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (e.g., fresh) in which it appears on the list. The list includes:

- Certain types of cheese
- Shell eggs
- Nut butters
- Fresh cucumbers
- Fresh herbs
- Fresh and fresh-cut leafy greens
- Fresh melons
- Fresh peppers
- Fresh sprouts
- Fresh tomatoes
- Fresh tropical tree fruits
- Fresh-cut fruits
- Fresh-cut vegetables
- Finfish, including smoked finfish
- Crustaceans
- Molluscan shellfish, bivalves
- Ready-to-eat deli salads

The list is subject to change. The FDA maintains the Food Traceability List on their website. The link is provided under Additional Information.

Critical Tracking Events & Key Data Elements

The following are CTEs and KDEs most relevant to GCCA members.

- Shipping KDES
    - Traceability lot code for the food
    - Quantity and unit of measure of the food
    - Product description for the food
    - Location description for the immediate subsequent recipient (other than a transporter) of the food
    - Location description for the location from which you shipped the food
    - Date you shipped the food
    - Location description for the traceability lot code source or the traceability lot code source reference
    - Reference document type and reference document number (maintain only)
- Receiving KDEs
    - Traceability lot code for the food
    - Quantity and unit of measure of the food
    - Product description for the food
    - Location description for the immediate previous source (other than a transporter) for the food
    - Location description for where the food was received
    - Date you received the food
    - Location description for the traceability lot code source or the traceability lot code source reference
    - Reference document type and reference document number

Traceability Lot Code

The traceability lot code (TLC) is an integral component of the rule's requirements. It links to the other KDEs required, including the TLC Source, which provides the physical location where the traceability lot code for an FTL food was assigned.

A traceability lot code means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source (defined below).

Unless the relevant entity is exempt from the rule, the traceability lot code is assigned when the food is initially packed (for raw agricultural commodities not obtained from a fishing vessel),

received by the first land-based receiver (for food obtained from a fishing vessel), or transformed. Once a TLC is assigned, it must stay the same as the food moves through the supply chain; it can only be changed if the food is transformed.

Electronic Sortable Spreadsheet

The manner in which information is tracked and maintained is left to the industry and companies to determine. However, requested information must be provided to FDA in a sortable spreadsheet. There is a template provided by FDA listed in Additional Information.

Food Traceability Plan

There is no specific format required for the traceability plan, but the information in the traceability plan must reflect the current practices specific to the covered entity and must contain the following requirements:

- A description of the procedures used to maintain the records an entity is required to keep, including the format and location of these records.
- A description of the procedures used to identify foods on the Food Traceability List that the entity manufactures, processes, packs, or holds
- A description of how TLCs are assigned to foods on the Food Traceability List, if applicable
- A statement identifying a point of contact for questions regarding the traceability plan and records
- Farms must include a farm showing the areas in which FTL foods are grown or raised

The traceability plan must be updated as needed to ensure that the information provided reflects current practices and to ensure that an entity is in compliance with the requirements of the Food Traceability Rule. Previous traceability plans must be kept for 2 years after the plan is updated.

Additional Information

- GS1 US
- Partnership for Food Traceability
- Federal Registrar Final Rule
- FDA FSMA 204

Mandatory Recall Authority

Background

FSMA Section 206 gives FDA the authority to order food recalls when firms fail to voluntarily recall products that are either adulterated or contain undeclared allergens and which will cause serious adverse health consequences or death to humans or animals. The voluntary recall process remains intact.

Role of Warehouses and Transportation Providers During a Recall

In the event of a recall, cold storage operators and transportation providers may be asked to identify affected inventory; place product on hold; prevent further distribution; locate product by lot or traceability code; assist customers with product recovery; and maintain records demonstrating product disposition.

FDA investigators may ask about capabilities so facilities are encouraged to maintain procedures such as:

- Product identification
- Lot traceability
- Inventory location tracking
- Customer notification processes
- Product hold and segregation procedures
- Product disposition management
- Record retrieval

Required Information in a Recall

- Product Information
- Codes (Production Identification Numbers)
- Recalling Firm
- Manufacturer
- Identify Firm Responsible
- Reason for the Recall
- Health and Hazard Assessment
- Volume of Recalled Product
- Distribution Pattern
- Recall Strategy

Additional Information

- Regulatory Procedures Manual
- CFR. Recall Guidance on Policy, Procedures, and Industry Responsibilities

Administrative Detention of Food

Background

Section 207 of FSMA allows FDA to use administrative detention to hold food for a short period of time when FDA has reason to believe that a food is adulterated or misbranded. An officer or qualified employee of FDA may order the administrative detention of any article of food that is found during an inspection, examination, or investigation under the FD&C Act if the officer or qualified employee has reason to believe that the article of food is adulterated or misbranded.

Foods subjection to detention include:

- articles used for food or drink for man or other animals (including dietary supplements)
- chewing gum
- articles used for components of any such article

Length of Detention

Not to exceed 20 calendar days. However, additional 10 days may be required in case of greater seizure or injunction actions. The entire detention period may not exceed 30 calendar days.

Detention Notice

FDA will issue the administrative detention order to the owner, operator, or agent in charge of the location where the article of food is being detained. If the owner of the article of food is different from the owner, operator, or agent in charge of the place where the article of food is detained, then FDA will also provide a copy of the administrative detention order to the owner of the article of food, if the owner's identity can be determined readily.

Cost Responsibility

The party or parties responsible for paying the storage costs of food that FDA orders administratively detained is a matter between the private parties involved with the food. FDA is not liable for those costs

Additional Information

- FDA Guidance for Industry on Administrative Detention

Foreign Supplier Verification Program

Background

FSMA Section 301 of FSMA the Foreign Supplier Verification Program (FSVP), requires importers to conduct risk-based foreign supplier verification activities to verify that imported food is not adulterated and that it was produced in compliance with FDA's preventive controls requirements and produce safety standards. Importation of food by an importer who does not have such a program in place is prohibited. Importers in compliance with existing seafood, juice, and low-acid canned foods regulations are exempted from this requirement.

Requirements

The FSVP importer is defined as the U.S. owner or consignee of the food offered for import. If there is no U.S. owner or consignee at time of entry, the FSVP importer is the U.S. agent/representative of the foreign owner/consignee, as confirmed in a signed statement of consent.

Under the final rule, all importers must develop, maintain, and follow a written FSVP for each food they import. The FSVP must provide adequate assurances that the foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under the Federal FD&C Act.

Evaluation of Food Risk and Supplier Performance

To determine food risk and supplier performance, importers should evaluate the following:

- The hazard analysis
- The entity that will be significantly minimizing or preventing the hazards
- A foreign supplier's procedures, processes, and practices related to the safety of food
- Applicable FDA food safety regulations, and information regarding the foreign supplier's compliance
- The foreign supplier's food safety history, including the responsiveness of the foreign supplier in correcting past problems
- Other factors as necessary, including storage and transportation practices

Importers can rely on a third party to perform the evaluation of risk, so long as the importer reviews and assesses the relevant documentation.

Supplier Verification

Based upon the evaluation of risk conducted, importers must establish written procedures to ensure imports are from approved foreign suppliers and must conduct appropriate supplier verification activities. Verification activities may include:

- Annual on-site audits of the supplier's facility (may be required if reasonable probability determined)
- Sampling and testing
- A review of the supplier's relevant food safety records

An importer can rely on a third-party to determine and perform appropriate supplier verification activities, so long as the importer reviews and assesses the relevant documentation.

Corrective Actions

Importers must take corrective actions if a foreign supplier if not following processes and procedures required under the produce safety and preventive controls regulations or if the supplier produces food that is adulterated or misbranded with respect to allergen labeling. The appropriate corrective measure will depend on the circumstances, but could include discontinuing use of the foreign supplier until the cause of noncompliance, adulteration, or misbranding has been adequately addressed.

Applicable Exemptions

The requirements do not apply to a facility if the owner, operator, or agent in charge is subject to, and in compliance with FDA's seafood, juice, or low-acid canned food products requirements.

Additional Information

- Foreign Supplier Verification Program for Food Importers
- Final Rule on Foreign Supplier Verification Programs (FSVP) Key Requirements
- Foreign Food Facility Inspection Program Questions & Answers | FDA

Voluntary Qualified Importer Program

Background

The Voluntary Qualified Importer Program (VQIP), established in Section 302, is a voluntary fee-based program that provides expedited review and import entry of human and animal foods into the United States for participating importers. Participation in the VQIP includes importation of food from facilities that have been certified in accordance with FDA's program for Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to issue certifications, as well as other measures that support a high level of confidence in the safety and security of the food they import.

While VQIP is directed at importers, GCCA members involved in imported food supply chains may benefit indirectly from participation in the program through reduced entry delays, improved supply chain predictability, and expedited release of eligible imported foods.

To participate, importers must pay a user fee that covers the FDA's administration of the program and meet eligibility criteria including:

- Maintain an adequate FSVP.
- Import foods from certified foreign suppliers.
- Demonstrate a history of compliance with FDA requirements.
- Meet applicable quality assurance and recordkeeping expectations.

Additional Information

- VQIP Portal User Guide
- FDA Page on VQIP

Accreditation of Third-Party Auditors

Background

FSMA Section 307 authorized FDA to establish a program for accreditation of third-party auditors, also known as certification bodies. Under this program, the FDA recognizes accreditation bodies which accredit third-party certification bodies (also known as auditors) to conduct food safety audits and issue certifications for foreign facilities and food under specified programs. The program is intended to assist FDA in making admissibility decisions when the agency has determined that an imported food poses a food safety risk and in facilitating rapid entry of food under the Voluntary Qualified Importer Program.

While most GCCA members will not become accredited third-party auditors, the program plays an important role in imported food safety and supply chain assurance. Certifications issued by accredited third-party certification bodies may support import admissibility decisions and participation in FDA's Voluntary Qualified Importer Program (VQIP).

Recognized Accreditation Bodies

Accreditation Bodies can be a foreign government/agency or a private third-party. They are able to assess and monitor the third-party certification bodies they accredit. They may also assess and correct any problems in their own performance, submit reports to the FDA, and maintain records for the FDA on this program.

Third Party Certification Bodies

Third-party Certification Bodies can be a foreign government or other third-party entity or individual. They are required to perform unannounced facility audits and to notify the FDA upon discovering any conditions that pose a serious risk to public health. They are required to:

- Ensure their audit agents are competent and objective
- Verify the effectiveness of corrective actions to address identified deficiencies in audited entities
- Assess and correct any problems in their own performance
- Maintain and provide the FDA access to records required to be kept under the program

Accredited third-party certification bodies can perform consultative and regulatory audits. A consultative audit is conducted in preparation for a regulatory audit and is for internal use. Only a regulatory audit can be the basis for certification

Additional Information

- FSMA Final Rule on Accredited Third-Party Certification

Prior Notice of Imported Food

Background

FSMA Section 304 includes a requirement that a person submitting a prior notice of imported food must provide FDA with information regarding "any country to which the article has been refused entry." This in addition to the information required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) which requires that FDA receive certain information about imported foods before arrival in the United States and provides that that an article of food imported or offered for import is subject to refusal of admission into the United States if adequate prior notice has not been provided to FDA.

Responsibility for Prior Notice

Prior Notice is typically submitted by:

- Importers
- Customs brokers
- U.S. agents
- Other authorized parties

Failure to submit accurate Prior Notice information may result in shipment delays, port holds, refusal of admission, storage disruptions, additional handling costs, and temperature-control challenges for refrigerated and frozen foods.

Potential Consequences

Failure to comply with Prior Notice requirements may result in:

- Refusal of admission into the United States
- Holding of shipments at the port of entry
- Delayed release of cargo
- Additional examinations by FDA
- Product spoilage risks for temperature-sensitive products

Information Commonly Included in Prior Notice

- Product identity
- Manufacturer information
- Grower information (when applicable)
- Country of origin
- Shipper information
- Importer information

- Anticipated port of arrival
- Arrival timing
- Quantity and packaging details

Additional Information

- Final Rule on Prior Notice of Imported Food
- Guidance for Industry: Prior Notification of Imported Food Questions and Answers (Edition 4)

Employee Protections

Background

Section 402 of FSMA prohibits retaliation by manufacturers, processors, packagers, transporters, distributers, receivers, holders, or importers against their employees who have, in relation to potential or real food safety violations, provided information to officials, assisted or testified in violation proceedings, or refused to participate in any work-related activity that they believe may be a food safety violation.

Whistleblower Protections

FSMA provides whistleblower protection for employees who:

- Provide, or cause to be provided, to the employer, the federal government or the attorney general of state information relating to any violation of the Federal Food Drug & Cosmetic Act (FDCA), or any act or omission the employee reasonably believes to be an FDCA violation;
- Testify, or are about to testify, in a proceeding concerning an FDCA violation;
- Assist or participate, or are about to assist or participate, in a proceeding concerning an FDCA violation; or
- Object to, or refuse to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believes to be in violation of any provision of the FDCA, or any order, rule, regulation, standard or ban under the FDCA

Process Summary

Employee believed to be discriminated against or discharged should file a complaint no later than 180 days after which violations have occurred, to Secretary of Labor. The individual should name the alleged suspect of caused discrimination or discharge.

Additional Information

- FDA FSMA Whistleblower Protections

Mitigation Strategies to Protect Food Against Intentional Adulteration (Food Defense)

Background

FDA's rule on food defense requires domestic and foreign facilities to address vulnerable processes in their operations to prevent acts on the food supply intended to cause large-scale public harm. Food businesses are required to have a written food defense plan that addresses significant vulnerabilities in a food operation. This written plan must identify vulnerabilities and actionable process steps, mitigation strategies, and procedures for food defense monitoring, corrective actions and verification. A reanalysis is required every three years or when certain criteria are met, including mitigation strategies that are determined to be improperly implemented. The intentional adulteration provisions of FSMA are codified in sections 418, 419, and 420 of the FD&C Act.

Food Defense Plan

Each facility covered by this rule is required to prepare and implement a written food defense plan, which includes the following:

- Vulnerability Assessment. Identification of vulnerabilities and actionable process steps for each type of food manufactured, processed, packed or held at the food facility. Must evaluate the severity and scale of the potential impact on public health; the degree of physical access to the product; and the ability to successfully contaminate the product.
- Mitigation Strategies. Identification and implementation at each actionable process step to provide assurances that vulnerabilities will be minimized or prevented. The mitigation strategies must be tailored to the facility and its procedures.
- Mitigation Strategy Management Components. Steps to ensure the proper implementation of each mitigation strategy. Facilities have flexibility to establish the actions most appropriate to their operation and product for monitoring, correction actions, and verification.
- Training and Recordkeeping. Personnel assigned to the vulnerable areas receive appropriate training; facilities must maintain records for food defense monitoring, corrective actions, and verification activities.

Food Defense Considerations for Cold Storage Operations

Potential food defense controls may include:

- Facility access controls
- Visitor management

- Employee identification procedures
- Security camera systems
- Seal management
- Contractor oversight
- Product hold procedures
- Inventory accountability
- Incident reporting procedures

Facilities subject to the rule should:

- Conduct periodic vulnerability assessments.
- Review physical security measures.
- Train employees on suspicious activity recognition.
- Test incident response procedures.
- Periodically review mitigation strategy effectiveness.
- Reassess plans following operational changes.

Food safety programs focus on preventing unintentional contamination, while food defense programs focus on preventing intentional acts designed to cause harm.

Exemptions

The rule includes exemptions that may apply to GCCA members. Specifically, there is an exemption for facilities holding food (other than holding food in liquid storage tanks). There is also an exemption for packing, re-packing, labeling and re-labeling where the container directly contacting the food remains intact. Available exemptions include:

- A very small business. While exempt, the business would be required to provide to FDA, upon request, documentation to demonstrate that the business is very small.
- The holding of food, except the holding of food in liquid storage tanks
- The packing, re-packing, labeling or re-labeling of food where the container that directly contacts the food remains intact
- Activities that fall within the definition of “farm”
- Manufacturing, processing, packing, or holding of food for animals
- Alcoholic beverages under certain conditions
- On-farm manufacturing, processing, packing, or holding by a small or very small business of certain foods identified as having low-risk production practices. The exemption applies if such activities are the only activities conducted by the business subject to the rule. These foods include certain types of eggs, and certain types of game meats.

Additional Information

- FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration
- Key Requirements: FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration
- Federal Register Mitigation Strategies To Protect Food Against Intentional Adulteration