

KEY REQUIREMENTS:

Final Rule on Sanitary Transportation of Human and Animal Food

The FDA Food Safety Modernization Act (FSMA) rule on Sanitary Transportation of Human and Animal Food is now final, advancing FDA's efforts to protect foods from farm to table by keeping them safe from contamination during transportation. The earliest compliance dates for some firms begin one year after publication of the final rule in the Federal Register.

This rule is one of seven foundational rules proposed since January 2013 to create a modern, risk-based framework for food safety. The goal of this rule is to prevent practices during transportation that create food safety risks, such as failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food.

The rule builds on safeguards envisioned in the 2005 Sanitary Food Transportation Act (SFTA). Because of illness outbreaks resulting from human and animal food contaminated during transportation, and incidents and reports of unsanitary transportation practices, there have long been concerns about the need for regulations to ensure that foods are being transported in a safe manner.

The rule establishes requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food to use sanitary practices to ensure the safety of that food. The requirements do not apply to transportation by ship or air because of limitations in the law.

Specifically, the FSMA rule establishes requirements for vehicles and transportation equipment, transportation operations, records, training and waivers.

WHO IS COVERED?

- With some exceptions (listed below), the final rule applies to shippers, receivers, loaders and carriers who transport food in the United States by motor or rail vehicle, whether or not the food is offered for or enters interstate commerce. It also applies to:
 - persons, e.g., shippers, in other countries who ship food to the United States directly by motor or rail vehicle (from Canada or Mexico), or by ship or air, and arrange for the transfer of the

intact container onto a motor or rail vehicle for transportation within the U.S., if that food will be consumed or distributed in the United States.

- The rule does not apply to exporters who ship food through the United States (for example, from Canada to Mexico) by motor or rail vehicle if the food does not enter U.S. distribution.
- Companies involved in the transportation of food intended for export are covered by the rule until the shipment reaches a port or U.S. border.

KEY REQUIREMENTS

Specifically, the rule would establish requirements for:

- **Vehicles and transportation equipment:**

The design and maintenance of vehicles and transportation equipment to ensure that it does not cause the food that 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:** The measures 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 of carrier personnel in sanitary transportation practices and documentation of the training. This training is required when the carrier and shipper agree that the carrier is responsible for sanitary conditions during transport.

- **Records:** Maintenance of records of written procedures, agreements and training (required of carriers). 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

The Sanitary Food Transportation Act allows the agency to waive the requirements of this FSMA rule 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.

The FDA announced in the proposed rule that it intended to publish waivers for two groups of people/businesses (see below). The agency intends to publish these waivers in the Federal Register prior to the date firms are required to comply with this rule.

The FDA also received comments asking for a waiver for transportation operations for molluscan shellfish for entities that hold valid state permits under the National Shellfish Sanitation Program. The agency continues to review comments on this request, and will issue a determination in the near future.

The agency intends to publish waivers for:

- Shippers, carriers and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments (NCIMS) Grade “A” Milk Safety program. This waiver only applies when Grade A milk and milk products—those produced under certain sanitary conditions—are being transported. FDA acknowledges that controls for such transportation operations already exist under the NCIMS program, with State enforcement and FDA oversight.
- Food establishments holding valid permits issued by a relevant regulatory authority, such as a state or tribal agency, when engaged as receivers, shippers and carriers in operations in which food is relinquished to customers after being transported from the establishment. Examples of such establishments include restaurants, supermarkets, and home grocery delivery operations. FDA acknowledges that controls for such transportation operations already exist under the Retail Food Program, with state, territorial, tribal and local enforcement and FDA oversight.

COMPLIANCE DATES

Recognizing that businesses, especially small businesses may need more time to comply with the requirements, the compliance dates are adjusted accordingly.

- **Small Businesses**—businesses other than motor carriers who are not also shippers and/or receivers employing fewer than 500 persons and motor carriers having less than \$27.5 million in annual receipts would have to comply two years after the publication of the final rule.
- **Other Businesses**—a business that is not small and is not otherwise excluded from coverage would have to comply one year after the publication of the final rule.

ASSISTANCE TO INDUSTRY

- The FDA FSMA Food Safety Technical Assistance Network is already operational to provide a central source of information to support industry understanding and implementation of FSMA. Questions submitted online or by mail will be answered by information specialists or subject matter experts.
- The FDA plans to develop an online course that would meet the training requirements for this rule. The agency anticipates this course will be available before the first compliance dates go into effect.
- The agency will also issue guidance to assist industry in complying with the final rule.

KEY CHANGES FROM THE PROPOSED RULE

The proposed rule opened for public comment on February 5, 2014. The FDA made changes throughout the rule in response to public comments, as it has for the other FSMA rules that have become final in the last seven months. The agency’s goal is protecting public health while making each rule as feasible for companies as possible.

FDA AT A GLANCE

- In keeping with the overarching food safety goal of FSMA, this rule now solely focuses on practices that create safety risks, rather than on those that affect its quality but don't necessarily make it dangerous to consume.
 - There are provisions in the Federal Food, Drug, and Cosmetic (FD&C) Act that cover spoilage and other forms of adulteration, including during transportation.
- The definition of "transportation operations" has been changed to exclude:
 - Transport of foods completely enclosed by a container (except for food that requires temperature control). The original proposal specified that the enclosed foods must be shelf-stable (safely stored at room temperature in a sealed container).
 - All transportation activities performed by a farm. Under the proposed rule, only the transportation of foods that are raw agricultural commodities would have been excluded.
 - The diversity of farms and their transportation operations make it difficult to develop regulations that would be broadly suitable. Instead, the FDA is considering providing guidance on good farm transportation practices.
 - Farms are still subject, however, to FD&C Act's provisions that prohibit the holding of food under insanitary conditions.
 - Transport of human food byproducts for use as animal food without further processing, i.e., those sold directly to farmers to be fed to livestock. These do not include byproducts that are transported to facilities to be manufactured into feed or pet food.
 - Transport of food contact substances, which include coatings, plastics, paper, adhesives, as well as colorants, antimicrobials, and antioxidants found in packaging.
 - Transport of live food animals, except for molluscan shellfish (such as oysters, clams, mussels and scallops). The original proposal excluded all live food animals, including molluscan shellfish.
- Another change is particularly important to rail carriers. Commenters raised concerns that rail operators often do not own, prepare or operate equipment, e.g, refrigeration units, in the railcars they transport, and do not have the ability to ensure that certain requirements such as temperature control and sanitary conditions, are met. The shipper or loader, and not the rail carrier, has generally assumed responsibilities, such as inspecting a railcar, to ensure that it is suitable. Shippers will continue to hold primary responsibility for sanitary conditions of transport under this rule unless the carrier has entered into a written agreement with the shipper to assume this responsibility.
 - By contrast, motor carriers generally own their vehicles and are directly involved with sanitation during transportation operations.
- "Loaders" have been added as a covered party. A loader is a person who physically loads food onto a motor or rail vehicle.
 - Before loading a food not completely enclosed by a container, the loader must determine that the transportation equipment is in appropriate sanitary condition.
 - Before loading a food requiring temperature control, the loader must determine that each mechanically refrigerated cold storage compartment is adequately prepared for refrigerated transportation, including precooling, if necessary.
- The final rule clarifies that the intended use of the vehicle or equipment (e.g., transporting animal feed versus human food) and the production stage of the food being transported (e.g., raw materials versus finished products) are relevant in determining the applicable sanitary transportation requirements.
- Requirements for the use of a temperature indicating or recording device during transport have been replaced with a more flexible approach. The shipper and carrier can agree to a temperature monitoring mechanism for foods that require temperature control for safety.
 - The original proposal specified that a compartment must be equipped with a thermometer, temperature measuring device, or temperature recording device.

FDA AT A GLANCE

- The agency agreed with commenters that there are a number of effective ways for ensuring temperature control that parties subject to this rule should be able to use.
- The agency also agreed with commenters that carriers need to demonstrate they maintained requested temperature conditions only upon request, rather than as a requirement for every shipment, as previously proposed.
- Primary responsibility for determining appropriate transportation operations now rests with the shipper, who may rely on contractual agreements to assign some of these responsibilities to other parties.
 - Shippers must develop and implement written procedures to ensure that equipment and vehicles are in appropriate sanitary condition.
 - Shippers of food transported in bulk must develop and implement written procedures to ensure that a previous cargo does not make food unsafe.
 - And shippers of food that require temperature control for safety must also develop and implement written procedures to ensure that food is transported under adequate temperature control.
- If a covered person or company at any point in the transportation chain becomes aware of a possible failure of temperature control or any other condition that may render a food unsafe, that food must not be sold or distributed until a determination of safety is made.
- 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

MORE INFORMATION

Visit <http://www.regulations.gov/>

FDA's Food Safety Modernization Act page at www.fda.gov/FSMA

EXEMPT FROM THE RULE

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

KEY REQUIREMENTS:

Final Rule on Preventive Controls for Human Food

The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food rule is now final, and compliance dates for some businesses begin in September 2016.

This final rule is the product of an unprecedented level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local and tribal regulatory counterparts, academia and other stakeholders. This outreach began before the rule was proposed in January 2013.

In response to input received during the comment period and during hundreds of engagements that included public meetings, webinars, listening sessions, and visits to farms and food facilities across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective for industry, while still advancing the FDA's food safety goals.

The final rule has elements of both the original and supplemental proposals, in addition to new requirements that are the outgrowth of public input received during the comment period for both proposals. For example, flexibility has been built into key requirements, including control of the supply chain, and the definition of farms—which are exempt from these regulations—has significantly changed to reflect modern farming practices.

Below are the key requirements and compliance dates.

1. COVERED FACILITIES MUST ESTABLISH AND IMPLEMENT A FOOD SAFETY SYSTEM THAT INCLUDES AN ANALYSIS OF HAZARDS AND RISK-BASED PREVENTIVE CONTROLS. THE RULE SETS REQUIREMENTS FOR A WRITTEN FOOD SAFETY PLAN THAT INCLUDES:

■ **Hazard analysis:** The first step is hazard identification, which must consider known or reasonably foreseeable biological, chemical, and physical hazards. These hazards could be present

because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).

■ **Preventive controls:** These measures are required to ensure that hazards requiring a preventive control will be minimized or prevented. They include process, food allergen, and sanitation controls, as well as supply-chain controls and a recall plan.

■ **Oversight and management of preventive controls.** The final rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise.

- **Monitoring:** These procedures are designed to provide assurance that preventive controls are consistently performed.

Monitoring is conducted as appropriate to the preventive control. For example, monitoring of a heat process to kill pathogens would include actual temperature values and be more frequent than monitoring preventive maintenance activities used to minimize metal hazards, which could be a simple record of the date on which the activity took place.

- **Corrective actions and corrections:** Corrections are steps taken to timely identify and correct a minor, isolated problem that occurs during food production. Corrective actions include actions to identify a problem with preventive control implementation, to reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent it from entering commerce. Corrective actions must be documented with records.

- **Verification:** These activities are required to ensure that preventive controls are consistently implemented and effective. They include validating with scientific evidence that a preventive control is capable of effectively controlling an identified hazard; calibration (or accuracy checks) of process monitoring and verification instruments such as thermometers, and reviewing records to verify that monitoring and corrective actions (if necessary) are being conducted.

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 the role of that control in the facility's food safety system. Environmental monitoring generally would be required if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control.

2. THE DEFINITION OF A 'FARM' IS CLARIFIED TO COVER TWO TYPES OF FARM OPERATIONS. OPERATIONS DEFINED AS FARMS ARE NOT SUBJECT TO THE PREVENTIVE CONTROLS RULE.

■ **Primary Production Farm:** This is an operation under one management in one general, but not necessarily contiguous, location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. This kind of farm can pack or hold raw agricultural commodities such as fresh produce and may conduct certain manufacturing/processing activities, such as dehydrating grapes to produce raisins and packaging and labeling raisins.

The supplemental rule proposed, and the final rule includes, a change to expand the definition of "farm" to include packing or holding raw agricultural commodities (such as fresh produce) that are grown on a farm under a different ownership. The final rule also includes within the "farm" definition companies that solely harvest crops from farms.

■ **Secondary Activities Farm:** This is an operation not located on the Primary Production Farm that is devoted to harvesting, packing and/or holding raw agricultural commodities. It must be majority owned by the Primary Production Farm that supplies the majority of the raw agricultural commodities harvested, packed, or held by the Secondary Activities Farm.

This definition for a Secondary Activities Farm was provided, 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. In addition to off-farm produce packing operations, another example of a Secondary Activities Farm could be an operation 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, that operation is a 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.

3. SUPPLY-CHAIN PROGRAM IS MORE FLEXIBLE, WITH SEPARATE COMPLIANCE DATES ESTABLISHED.

■ The rule mandates that a manufacturing/processing facility have a risk-based supply chain program for those raw material and other ingredients for which it has identified a hazard requiring a supply-chain applied control. Manufacturing/processing facilities that control a hazard using preventive controls, or who 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 these foods are received only from approved suppliers, or on a temporary basis from unapproved suppliers whose materials 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.)

■ A facility will not be required to implement a preventive control 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 written assurance from its customer regarding certain actions the customer agrees to take.

■ Another entity in the supply chain, such as a broker or distributor, can conduct supplier verification activities, but the receiving facility must review and assess that entity's documentation of the verification of control of the hazard.

■ Separate compliance dates have been established for the supply-chain program provisions so that a 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.

4. CURRENT GOOD MANUFACTURING PRACTICES (CGMPs) ARE UPDATED AND CLARIFIED.

- The final rule does not include nonbinding provisions, which are more appropriate for guidance.
- Some of the previously nonbinding provisions, such as education and training, are now binding.
 - Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.
 - Such employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold clean and safe food. 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.
- The FDA's longstanding position that CGMPs address allergen cross-contact is now explicit in the regulatory text.

COMPLIANCE DATES

Compliance dates for businesses are staggered over several years after publication of the final rule.

- **Very small businesses** (averaging less than \$1 million per year (adjusted for inflation) in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale): Three years, except for records to support its status as a very small business (January 1, 2016).
- **Businesses subject to the Pasteurized Milk Ordinance** (compliance dates extended to allow time for changes to the PMO safety standards that incorporate the requirements of this preventive controls rule): Three years

- **Small businesses** (a business with fewer than 500 full-time equivalent employees): Two years

- **All other businesses:** One year

Compliance dates after publication of the final rule for the requirements of the supply chain program:

- **Receiving facility is a small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule:** Two years
- **Receiving facility is a small business and its supplier will be subject to the human preventive controls rule or the produce safety rule:** Two years or six months after the supplier is required to comply with the applicable rule, whichever is later
- **Receiving facility is not a small or very small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule:** 18 months
- **Receiving facility is not a small or very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule:** Six months after the supplier is required to comply with the applicable rule

ASSISTANCE TO INDUSTRY

The FDA is developing several guidance documents on subjects that include:

- Hazard analysis and preventive controls,
- Environmental monitoring,
- Food allergen controls,
- Validation of process controls,
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.

Plans for training and technical assistance are well under way. They include:

- Establishing a Food Safety Technical Assistance Network within the agency to provide a central source of information to support industry understanding and implementation of FSMA.
- Collaborating with the Food Safety Preventive Controls Alliance to establish training and technical assistance programs.
- Partnering with the National Institute of Food and Agriculture in the U.S. Department of Agriculture to administer a grant program to provide technical assistance to small and mid-size farms and small food processors.

MORE INFORMATION

Federal Register
www.regulations.gov

Frequently Asked Questions
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#PC_Rules

FDA Food Safety Modernization Act
www.fda.gov/fsma

FDA's FSMA Technical Assistance Network
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

KEY REQUIREMENTS:

FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration

The FDA Food Safety Modernization Act (FSMA) final rule is aimed at preventing intentional adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply. Such acts, while not likely to occur, could cause illness, death, economic disruption of the food supply absent mitigation strategies.

Rather than targeting specific foods or hazards, this rule requires mitigation (risk-reducing) strategies for processes in certain registered food facilities.

The proposed rule was issued in December 2013. The changes in the final rule are largely designed to provide either more information, where stakeholders requested it, or greater flexibility for food facilities in determining how they will assess their facilities, implement mitigation strategies, and ensure that the mitigation strategies are working as intended.

In developing the rule, FDA interacted with the intelligence community and considered vulnerability assessments conducted in collaboration with the food industry.

While acts of intentional adulteration may have many other forms, including acts of disgruntled employees or economically motivated adulteration, the goal of this rule is to prevent acts intended to cause wide-scale harm. Economic adulteration is addressed in the final preventive controls rules for human and animal foods.

WHO IS COVERED?

With some exceptions listed below, this rule applies to both domestic and foreign companies that are required to register with the FDA as food facilities under the Federal Food, Drug, and Cosmetic (FD&C) Act.

This rule is designed to primarily cover large companies whose products reach many people, exempting smaller companies. There are 3,400 covered firms that operate 9,800 food facilities.

It does not cover farms.

KEY PROVISIONS

While this is the first time that companies are required to create a food defense plan, the FDA has taken an approach similar to Hazard Analysis Critical Control Point (HACCP) system, an approach adopted by industry for the identification, evaluation and control of food safety hazards. The FSMA rules advance and strengthen those safeguards.

Each covered facility is required to prepare and implement a food defense plan. 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.

■ **Vulnerability assessment:** This is the identification of vulnerabilities and actionable process steps for each type of food manufactured, processed, packed or held at the food facility. For each point, step, or procedure in the facility's process, these elements must be evaluated:

- The severity and scale of the potential impact on public health. This would include such considerations as the volume of product, the number of servings, the number of exposures, how fast the food moves through the distribution system, potential agents of concern and the infectious/lethal dose of each; and the possible number of illnesses and deaths.
- The degree of physical access to the product. Things to be considered would include the presence of such physical barriers as gates, railings, doors, lids, seals and shields.
- The ability to successfully contaminate the product.

■ **Mitigation strategies:** These should be identified and implemented 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.

FDA AT A GLANCE

- The final rule removes the distinction between “broad” and “focused” mitigation strategies. The original proposal only required “focused” mitigation strategies because “broad” mitigation strategies, such as a fence around the entire facility, did not protect specific points from being attacked by an insider.
- The final rule recognizes that a mitigation strategy, applied in a directed and appropriate way to protect the actionable process step from an insider attack, would sufficiently minimize the risk of intentional adulteration.

■ Mitigation strategy management components:

Steps must be taken to ensure the proper implementation of each mitigation strategy. In each of these areas of food defense, the facilities are given more flexibility in the final rule to establish the actions most appropriate to their operation and product.

- **Monitoring:** Establishing and implementing procedures, including the frequency with which they are to be performed, for monitoring the mitigation strategies.
- **Corrective actions:** The response if mitigation strategies are not properly implemented.
- **Verification:** Verification activities would ensure that monitoring is being conducted and appropriate decisions about corrective actions are being made.

■ **Training and recordkeeping:** Facilities must ensure that personnel assigned to the vulnerable areas receive appropriate training; facilities must maintain records for food defense monitoring, corrective actions, and verification activities.

COMPLIANCE DATES

■ This rule is a first of its kind, so education and outreach is critical. Additionally, FDA recognizes that many of the food facilities covered by this rule will also be meeting the requirements of other FSMA rules. Therefore, FDA is providing a longer timeline in the final rule for facilities to comply with the intentional adulteration rule.

■ **Very Small Businesses**—a business (including any subsidiaries and affiliates) averaging less than \$10,000,000, adjusted for inflation, per year, during the three-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). These businesses would have to comply with modified requirements within five years after the publication of the final rule.

■ **Small Businesses**—a business employing fewer than 500 persons would have to comply four years after the publication of the final rule.

■ **Other Businesses**—a business that is not small or very small and does not qualify for exemptions would have to comply three years after the publication of the final rule.

EXEMPTIONS

■ 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.

ASSISTANCE TO INDUSTRY

- FDA has established an Intentional Adulteration Subcommittee with the Food Safety Preventive Controls Alliance to develop food defense training resources for industry and regulators alike.
- The agency intends to publish guidance documents to provide information relevant to the provisions of the final rule, such as conducting a vulnerability assessment, identifying and implementing mitigation strategies, and writing procedures for food defense monitoring, corrective actions and verification.
- In addition, FDA has a number of tools and resources currently available on our website (www.fda.gov/fooddefense) that were developed for our voluntary food defense program.
- The Mitigation Strategies Database is an online, searchable listing of mitigation strategies that can be applied to different steps in a food operation to reduce the risk of intentional adulteration.
- The FDA FSMA Food Safety Technical Assistance Network is already operational and provides a central source of information to support industry understanding and implementation of FSMA. Questions submitted online or by mail will be answered by information specialists or subject matter experts.

MORE INFORMATION

Visit <http://www.regulations.gov/>

FDA's Food Safety Modernization Act page at www.fda.gov/FSMA

KEY REQUIREMENTS:

Final Rule on Foreign Supplier Verification Programs



The FDA FSMA rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals is final, and the first compliance dates begin May 30, 2017.

The final rule requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards. This rule is the product of a significant level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local, tribal and international regulatory counterparts, academia and other stakeholders. The FDA first proposed this rule in July 2013.

After input received during the comment period and during numerous engagements that included public meetings, webinars, and listening sessions, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions included providing importers flexibility in determining appropriate verification measures based on food and supplier risks, while acknowledging the greater risk to public health posed by the most serious hazards in foods.

The final rule has elements of both the original and supplemental proposals, with the addition of greater flexibility in meeting certain requirements to better reflect modern supply and distribution chains. For example, importers can meet key FSVP obligations by relying on analyses, evaluations, and activities performed by other entities in certain circumstances, as long as those importers review and assess the corresponding documentation.

The FDA is committed to helping ensure that importers can meet the FSVP requirements. In order to facilitate compliance, FDA will provide guidance, outreach, and training.

1. SCOPE

■ Who is covered by the rule?

- For the purposes of FSVP, an importer is the U.S. owner or consignee of a food offered for import into the United States. If there is no U.S. owner or consignee, the importer is the U.S. agency or representative of the foreign owner of consignee at the time of entry, as confirmed in a signed statement of consent. See [Am I Subject to FSVP?](#) (PDF: 69KB) for more information.
- There are exemptions discussed below.

■ **What is an FSVP?** It is a program that importers covered by the rule 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, as appropriate, and to ensure that the supplier's food is not adulterated and is not misbranded with respect to allergen labeling.

■ Importers are responsible for actions that include (and are explained further below):

- Determining known or reasonably foreseeable hazards with each food
- Evaluating the risk posed by a food, based on the hazard analysis, and the foreign supplier's performance
- Using that evaluation of the risk posed by an imported food and the supplier's performance to approve suppliers and determine appropriate supplier verification activities
- Conducting supplier verification activities
- Conducting corrective actions

■ Importers must establish and follow written procedures to ensure that they import foods only from foreign suppliers approved based on an evaluation of the risk posed by the imported food

FDA AT A GLANCE

and the supplier's performance or, when necessary on a temporary basis, from unapproved suppliers whose foods are subjected to adequate verification activities before being imported.

- Importers are required to develop, maintain, and follow an FSVP for each food brought into the United States and the foreign supplier of that food. If the importer obtains a certain food from a few different suppliers, a separate FSVP would be required for each of those suppliers. Similarly, if the importer obtains many different foods, from a single supplier, a separate FSVP would be required for each food.
- Certain importers that are also manufacturers/processors are deemed in compliance with most FSVP requirements if:
 - they are in compliance with the supply-chain program requirements under the preventive controls rules;
 - they implement preventive controls for the hazards in the food in accordance with the requirements in the preventive controls rules; or
 - they are not required to implement preventive controls under those rules in certain specified circumstances. Examples of such circumstances include when the type of food (e.g., such as coffee beans) could not be consumed without application of a preventive control, or when the customer will be significantly minimizing or preventing identified hazards) and they comply with requirements for disclosures and written assurances.
- The evaluation of the risk posed by the imported food and the supplier's performance must be reevaluated at least every three years, or when new information comes to light about a potential hazard or the foreign supplier's performance.
- Importers are not required to evaluate the food and supplier or conduct supplier verification activities if they receive adequate assurances that a subsequent entity in the distribution chain, such as the importer's customer, is processing the food for food safety in accordance with applicable requirements. FDA has extended the compliance date for obtaining these written assurances for two years. However, as required by the final rule, importers must disclose in documents accompanying the food that the food is not processed to control the identified hazard.

2. HAZARD ANALYSIS

- **What do we mean by 'hazard'?** An importer is required to identify and evaluate—based on experience, illness data, scientific reports and other information—the known or reasonably foreseeable hazards for each type of food it imports to determine if there are any hazards requiring a control. These include:
 - Biological hazards, including parasites and disease-causing bacteria
 - Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, food decomposition, unapproved food or color additives, and food allergens
 - Physical hazards, such as glass
- They may be hazards reasonably likely to cause illness or injury that occur naturally, are unintentionally introduced, or are intentionally introduced for purposes of economic gain, such as substituting a less costly ingredient.
- The analysis must assess the probability that these hazards will occur in the absence of controls and the severity of the illness or injury that could occur.
- The evaluation would have to consider factors that include the:
 - Formulation of the food
 - Condition, function and design of the establishment and equipment of a typical entity that produces the food
 - Raw materials and other ingredients
 - Transportation practices
 - Harvesting, raising, manufacturing, processing, and packing procedures
 - Packaging and labeling activities
 - Storage and distribution
 - Intended or reasonably foreseeable use
 - Sanitation, including employee hygiene
- An importer can rely on another entity to conduct the hazard analysis, so long as the importer reviews and assesses the relevant documentation.

3. EVALUATION OF FOOD RISK AND SUPPLIER PERFORMANCE

■ What evaluation must be done of the risk posed by an imported food and a supplier's performance?

An importer must evaluate:

- The hazard analysis
- The entity that will be significantly minimizing or preventing the hazards, such as the foreign supplier or the supplier's raw material or ingredient supplier
- 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

- The importer can rely on another entity (other than the foreign supplier) to perform the evaluation of risk, so long as the importer reviews and assesses the relevant documentation.

4. SUPPLIER VERIFICATION

- **What supplier verification activities must be conducted?** Based upon the evaluation of risk conducted, the importer must establish and follow written procedures to ensure, in most instances, that it only imports from approved foreign suppliers and must conduct appropriate supplier verification activities.

- Importers have the flexibility to tailor supplier verification activities to unique food risks and supplier characteristics. The options include:
 - Annual on-site audits of the supplier's facility. This is generally required when there is a reasonable probability that exposure to a hazard controlled by the foreign supplier will result in serious adverse health consequences or death to humans or animals (called a SAHCODHA hazard). However, the importer can choose another means of verification provided that the importer documents that the alternate choice is

appropriate and provides adequate assurances that the foreign supplier is producing the food in accordance with applicable U.S. safety standards.

- Sampling and testing
- A review of the supplier's relevant food safety records

- An importer can rely on another entity (other than the foreign supplier) to determine and perform appropriate supplier verification activities, so long as the importer reviews and assesses the relevant documentation.

5. CORRECTIVE ACTIONS

- **What if something goes wrong?** Importers must promptly take appropriate corrective actions if they determine that a foreign supplier has not used processes and procedures that provide the same level of public health protection as required under the produce safety and preventive controls regulations, as applicable, or that 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.

6. EXEMPTIONS AND MODIFIED STANDARDS

- The requirements for dietary supplements vary according to a number of factors, including whether the import is a finished product or an ingredient/component.
 - Importers who establish and verify compliance with certain specifications (concerning dietary supplement components and packaging) required under the separate, pre-existing dietary supplement Current Good Manufacturing Practices (CGMP) regulation will not be required to comply with most of the standard FSVP requirements.
 - The same would apply to importers whose customer is required to establish such specifications and verify that they are met, except that the importer would have to obtain written assurance that its customer is complying with those requirements.
 - Importers of other dietary supplements, including finished products, would be required to comply

FDA AT A GLANCE

with most of the standard FSVP requirements (except the hazard analysis requirement), but their verification activities would focus on compliance with the dietary supplement CGMP regulations.

- Modified FSVP requirements are established for very small importers and importers of food from certain small suppliers. (An example of these modified requirements is that certain importers would not have to conduct hazard analyses and would be able to verify their foreign suppliers by obtaining written assurances from their supplier.)

- The definition of very small importer is consistent with the definition of very small business in the preventive controls rules: \$1 million for human food and \$2.5 million for animal food of annual sales (averaged over three year period) combined with the U.S. market value of food that is imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).
- Importers of certain small foreign suppliers are subject to modified FSVP requirements. Those small suppliers are:
 - Facilities subject to modified requirements under the preventive controls rules because they are qualified facilities
 - Farms that are not covered farms under the produce safety rule because they average \$25,000 or less in annual produce sales or because they meet requirements for a qualified exemption
 - Shell egg producers with fewer than 3,000 laying hens
 - Each of these types of producers is either exempt from their underlying FDA food safety regulations or subject to modified requirements, mostly, and in some cases entirely, because of the size of these firms.

- There are modified requirements for certain foods from a foreign supplier in a country whose food safety system has been recognized as comparable or determined to be the equivalent of the United States' system.

- Additionally, certain categories of imported food are not covered by FSVP. These include:

- Juice, fish, and fishery products subject to and in compliance with FDA's Hazard Analysis and Critical Control Point (HACCP) regulations for those products, and certain ingredients for use in juice and fish and fishery products subject to the HACCP regulations.
- Food for research or evaluation
- Food for personal consumption
- Alcoholic beverages and certain ingredients for use in alcoholic beverages
- Food that is imported for processing and future export
- Low-acid canned foods (LACF), such as canned vegetables, but only with respect to microbiological hazards covered by other regulations, as well as certain ingredients for use in LACF products (but only with respect to microbiological hazards).
- Certain meat, poultry and egg products regulated by the U.S. Department of Agriculture at the time of importation

7. UNIQUE FACILITY IDENTIFIER

- The final FSVP rule requires that an importer provide its name, electronic mail address, and unique facility identifier (UFI) recognized as acceptable by the FDA for each line entry of food product offered for importation into the United States.
- The FDA has recognized the Data Universal Numbering System (DUNS) number as an acceptable UFI for FSVP.
- DUNS numbers, assigned and managed by DUN & Bradstreet, are available free of charge to importers by visiting FDAadunslookup.com.
- The FDA has also issued guidance stating that for FSVP importers temporarily unable to obtain a DUNS number, FDA intends to temporarily allow filers to transmit the value "UNK" (to represent "unknown") in the UFI field. This option will be available beginning May 30, 2017 so that food offered for import can be processed through the Customs and Border Patrol (CBP) Automated Commercial Environment (ACE) system, even if the importer has not yet provided a DUNS number.

COMPLIANCE DATES

The date by which importers must comply with the FSVP regulations is the latest of the following dates:

- 18 months after publication of the final rule;
- For the importation of food from a supplier that is subject to the preventive controls or produce safety rules, six months after the foreign supplier is required to meet the relevant regulations;
- For an importer that is itself a manufacturer or processor subject to the supply-chain program provisions in the preventive controls regulations, the date by which it has to comply with those provisions. A range of compliance dates were established in the preventive controls rules for the supply-chain program provisions, which vary based on the size of the receiving facility and when the receiving facility's supplier is required to comply with the new FSMA regulations.

Read more on Compliance Dates for the FSVP Final Rule and Compliance Date Extensions and Clarifications for FSMA Final Rules at FDA.gov.

ASSISTANCE TO INDUSTRY

The FDA has developed and continues to develop several guidance documents on subjects that include:

- Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA
- Training and Technical Assistance: The FDA has established the FSMA Food Safety Technical Assistance Network, to provide a central source of information to support industry understanding and implementation of FSMA.
- FDA has collaborated with the Food Safety Preventive Controls Alliance (FSPCA) to establish training and technical assistance programs.

ADDITIONAL INFORMATION:

- FSVP Fact Sheet:
<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM502160.pdf>
- Food Safety Preventive Controls Alliance:
<http://www.iit.edu/ifsh/alliance/>
- Am I subject to FSVP?
<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472461.pdf>
- FSVP Compliance Dates
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm>

FDA RESOURCE WEBSITES

Bio Terrorism Act of 2002

Food Defense Security Preventive Measure Guidance:

<https://www.fda.gov/Food/FoodDefense/default.htm>

Tools and Educational Materials:

<https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/default.htm>

Reportable Food Registry for Industry (RFR):

<https://www.fda.gov/food/complianceenforcement/rfr/UCM200958.htm>

Food Facility Registration (FFR):

<https://www.fda.gov/food/guidanceregulation/foodfacilityregistration/default.htm>

FFR Documents and Regulatory Information:

<https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/food-defense-guidance-documents-regulatory-information>

FSMA Biannual FFR renewal:

<https://www.fda.gov/food/guidanceregulation/FoodFacilityRegistration/UCM324780.htm>

Facilities Required to Register who have not: <https://www.access.fda.gov/>

Food Safety Modernization Act (FSMA) of 2011

FSMA Final Rule for Preventive Controls for Human Food Information

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food>

FSMA Facts Final Rule on Sanitary Transportation of Human and Animal Food Fact Sheet

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM494118.pdf>

FSMA Protecting Food Against Intentional Adulteration Rule

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-mitigation-strategies-protect-food-against-intentional-adulteration>

FSMA FDA Rule on Foreign Supplier Verification Programs (FSVP)

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472890.pdf>

***Qualified Facility Attestation*

<https://www.fda.gov/food/registration-food-facilities-and-other-submissions/qualified-facility-attestation>

***Determination of status as a Qualified Facility...Guidance for Industry*

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-determination-status-qualified-facility>

FDA Changes to the Nutrition Facts Label

<https://www.fda.gov/food/food-labeling-nutrition/changes-nutrition-facts-label>

Side by Side Comparison of Original Label and New Label

<https://www.fda.gov/media/97999/download>