FOOD REGULATION IN THE U.S. – THE BASICS

This paper is a general summary of food regulations administered by the U.S. Food and Drug Administration (FDA). There may be other laws or regulations, such as state laws, that affect food products. This paper does not constitute legal advice for any particular situation and does not create an attorney/client relationship between Barnes & Thornburg LLP or any of its attorneys and any firm or person. For advice on any particular situation, please contact your regular counsel or one of the attorneys listed in the right margin.

U.S. Food Regulation – Food Businesses Subject to FDA Regulation

The FDA regulates all foods and food ingredients introduced or offered for sale in interstate commerce, excluding meat, poultry, and certain processed egg products regulated by the U.S. Department of Agriculture (USDA). The Federal Food, Drug and Cosmetic Act (FFDCA), provisions of the Public Health Service Act (PHSA), and Title 21 of the Code of Federal Regulations (CFR) provide the FDA with important statutory and regulatory authority to enforce food legislation. Product categories that traditionally fall under the FDA's regulatory jurisdiction include but are not limited to:

- Dietary supplements
- Bottled water
- Food additives
- Infant formula
- Other food products

I. Food Facility Registration – 21 CFR Part 1

Foreign or domestic facilities that manufacture, process, pack, or hold food that is intended for human or animal consumption in the U.S. must register with FDA before beginning these activities. A facility is defined as any establishment, structure, or structures under single ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the U.S. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership; however, a private residence is not a facility. All facilities must be registered whether or not the food from the facility enters interstate commerce. The registration requirement applies to any facility that conducts these activities, unless a facility is specifically exempted.

Title 21 of the CFR has established general food categories to group specific related foods together for the purpose of establishing tolerances or limitations for the use of direct human food ingredients. This information must be included in the food facility registration form. **A list of the categories is included in the accompanying Appendix.**

The Food Safety Modernization Act (FSMA) also requires that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the U.S. submit additional registration information to the FDA, including assurance that FDA will be permitted to inspect the facility

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at times and in the manner permitted by the FFDCA and that food facilities required to register with the FDA renew such registrations every other year. The FSMA also provides the FDA with authority to suspend the registration of a food facility in certain circumstances. Specifically, if the 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, the FDA may suspend the registered facility that is responsible for such reasonable probability, or that knew or had reason to know of such reasonable probability yet still packed, received, or held such food.

An owner or operator of a facility may complete the facility registration electronically, by fax, or by mail using Form 3537. Electronic registration is available seven days a week. The FDA strongly encourages electronic registration for the benefit of both the FDA and the registrant.

II. Importing Food Products into the U.S.

Under the FDCA, importers of food products intended for introduction into U.S. interstate commerce are responsible for ensuring that the products are safe, sanitary, and labeled according to U.S. requirements (further discussed below). FDA considers all imported food to be interstate commerce. Importers can import foods into the U.S. without prior sanction by FDA, as long as the facilities that produce, store, or otherwise handle the products are registered with FDA, and prior notice of incoming shipments is provided to FDA.

Importers must provide FDA with prior notification of food, including animal feed, that is imported or offered for import into the United States. Advance notice of import shipments allows FDA, with the support of the U.S. Customs and Border Protection (CBP), to plan inspections more effectively. All goods offered for entry into the U.S., including items for personal use, must be declared to CBP. CBP in turn refers to FDA all products regulated by FDA. CBP's regulations and requirements are at its website.

Imported food products are subject to FDA inspection when offered for import at U.S. ports of entry. FDA may detain shipments of products offered for import if the shipments are found not to be in compliance with U.S. requirements. During the entry review process, the imported products must be held and may not be distributed into U.S. commerce until FDA has determined their admissibility. FDA-regulated products are refused entry if they appear to be or have been found to be:

- adulterated, meaning the product is contaminated, is not safe, unapproved, or does not otherwise meet applicable standards
- misbranded, meaning the labels contain false or misleading information, or the product is not registered and listed, if required
- forbidden or restricted for sale

Refused products must be destroyed or exported from the United States within 90 days.

Most importers choose to hire licensed representatives when offering the goods for entry. These representatives are known as customs brokers or entry filers. The entry filers can assist the importer by submitting necessary entry information and appropriate payments to CBP on behalf of the importer. CBP's website has a clickable U.S. map that provides a list of specific ports, and under each port, you will find a list of brokers.

III. Labeling – 21 CFR Part 101

Food manufacturers are required to develop labels, including nutritional information labels, which meet the legal food labeling requirements. Labeling requirements are set forth in 21 C.F.R 101 and in the FFDCA, the Fair Packaging and Labeling Act, and the Nutrition Labeling and Education Act. Under FDA's laws and regulations, FDA does not preapprove labels for food products. Questions concerning the labeling of food products may be directed to:

Food Labeling and Standards Staff (HFS-820)
Office of Nutrition, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835
(240) 402-2371

Highlights of the general labeling guidelines and the statutory provisions that govern labeling protocols are provided below.

A. Where Should Label Statements Be Placed?

There are two ways to label packages and containers: (1) place all required label statements on the front label panel, the principal display panel (PDP), or (2) place certain specified label statements on the PDP and other labeling on the information panel, the label panel immediately to the right of the PDP, when seen by the consumer facing the product. 21 CFR 101.1, 21 CFR 101.2, 21 CFR 101.3, 21 CFR 101.4, 21 CFR 101.5, 21 CFR 101.9, and 21 CFR 101.105.

B. What Are the PDP and the Alternate PDP?

The PDP is that portion of the package label that is most likely to be seen by the consumer at the time of purchase. Many containers are designed with two or more different surfaces that are suitable for display as the PDP. These are alternate PDPs. 21 CFR 101.1.

C. What Label Statements Must Appear on the PDP?

The statement of identity, or name of the food, and the net quantity statement, or amount of product, must be placed on the PDP and on the alternate PDP. The required type size and prominence are discussed later in this paper. 21 CFR 101.3(a) and 21 CFR 101.105(a).

D. Which Label Panel is the Information Panel?

The information panel is the label panel immediately to the right of the PDP, as displayed to the consumer. If this panel is not usable, due to package design and construction, (e.g., folded flaps), then the information panel is the next label panel immediately to the right. 21 CFR 101.2(a).

E. What is Information Panel Labeling?

The phrase "information panel labeling" refers to the label statements that are generally required to be placed together, without any intervening material, on the information panel, if such labeling does not appear on the PDP. These label statements include the name and address of the manufacturer, packer or distributor, the ingredient list, nutrition labeling and any required allergy labeling. 21 CFR 101.2(b) and (d), Section 403(w) of the FFDCA.

F. What Type Size, Prominence and Conspicuousness is Required?

For information panel labeling, use a print or type size that is prominent, conspicuous and easy to read. Use letters that are at least one-sixteenth (1/16) inch in height based on the lower case letter "o." The letters must not be more than three times as high as they are wide, and the lettering must contrast sufficiently with the background so as to be easy to read. Do not crowd required labeling with artwork or non-required labeling.

Smaller type sizes may be used for information panel labeling on very small food packages as discussed in 21 CFR 101.2(c) & (f). Different type sizes are specified for the Nutrition Facts label.

The net quantity statement (net quantity of contents) is placed as a distinct item in the bottom 30 percent of the principal display panel, in lines generally parallel with the base of the container. 21 CFR 101.105(e); 21 CFR 101.105(f).

G. What is the Prohibition Against Intervening Material?

Information that is not required by FDA is considered intervening material and is not permitted to be placed between the required labeling on the information panel. 21 CFR 101.2(e).

H. What Name and Address Must Be Listed on the Label?

Food labels must list:
1. Name and address of the manufacturer, packer or distributor. Unless the name given is the actual manufacturer, it must be accompanied by a qualifying phrase which states the firm's relation to the product (e.g., "manufactured for "or "distributed by")
2. Street address, if the firm name and address are not listed in a current city directory or telephone book
3. City or town
4. State (or country, if outside the United States)
5. ZIP code (or mailing code used in countries other than the United States)

21 CFR 101.5.

I. The Nutrition Labeling and Education Act

The Nutrition Labeling and Education Act (NLEA), which amended the FFDCA, requires most foods to bear nutrition labeling and requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements. The mandatory type specifications are listed in 21 CFR 101.9(d). Any legible type style may be used, however the heading "Nutrition Facts" must be at the largest type size in the nutrition label and should extend the width of the Nutrition Facts box. 21 CFR 101.9(a) and 21 CFR 101.9(a)(1).

Below are the listed categories providing exemptions or special provisions for nutrition labeling. Generally, a food package loses those exemptions if a nutrition claim is made or nutrition information is provided:
Final regulations have been established, but are frequently changed. It is the responsibility for the food industry to remain current

Summary of Exemption	Regulation #
*Manufactured by small businesses	21 CFR 101.9(j)(1) and 101.9(j)(18)
*Food served in restaurants, etc. or delivered to homes ready for immediate consumption	21 CFR 101.9(j)(2)
*Delicatessen-type food, bakery products and confections that are sold directly to consumers from the location where prepared	21 CFR 101.9(j)(3)
*Foods that provide no significant nutrition such as instant coffee (plain, unsweetened) and most spices	21 CFR 101.9(j)(4)
Infant formula, and infant and junior foods for children up to 4 years of age (modified label provisions for these categories)	21 CFR 101.9(j)(5) and 101.9(j)(7)
Dietary supplements (must comply with 21 CFR 101.36)	21 CFR 101.9(j)(6)
Medical foods	21 CFR 101.9(j)(8)
Bulk foods shipped for further processing or packaging before retail sale	21 CFR 101.9(j)(9)
Fresh produce and seafood (a voluntary nutrition labeling program covers these foods through the use of the appropriate means such as shelf labels, signs, and posters)	21 CFR 101.9(j)(10) and 101.45
Packaged single-ingredient fish or game meat may be labeled on basis of 3-ounce cooked portion (as prepared). Custom-processed fish and game are exempt from nutrition labeling.	21 CFR 101.9(j)(11)

Summary of Exemption	Regulation #
Certain egg cartons (nutrition information inside lid or on insert in carton)	21 CFR 101.9(j)(14)
Packages labeled "This unit not labeled for retail sale" within multiunit package, and outer wrapper bears all required label statements	21 CFR 101.9(j)(15)
Self-service bulk foods--nutrition labeling by placard, or on original container displayed clearly in view	21 CFR 101.9(a)(2) and 101.9(j)(16)
Donated food that is given free (not sold) to the consumer.	You are not required to put Nutrition Facts labels on donated food unless the donated food is later placed on sale (the law applies only to food that is "offered for sale") -- 21 CFR 101.9(a)
Game meats may provide required nutrition information or labeling in accordance with 21 CFR 101.9(a)(2).	21 CFR 101.9(j)(12)

with the legal requirements for food labeling. All new regulations are published in the Federal Register prior to their effective date and compiled annually in Title 21 of the CFR.

IV. Record Keeping – 21 CFR Part 1, Subpart J

Food manufacturers, processors, packers, transporters, distributors, receivers, holders, and importers are required to establish, maintain, and make available to the FDA upon request certain records to allow the agency to identify the immediate previous sources and the immediate subsequent recipients of the food products in its chain of distribution. Each facility must maintain records that identify the names and addresses of the source facilities from which it receives its ingredients and the names and addresses of the recipient facilities.

As a non-transporting facility, the following additional information is required to be established and maintained:

- If available, the fax number and email address of the non-transporter immediate previous source, whether domestic or foreign;
- An adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);
- The date you received the food;
- For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);
- The quantity and how the food is packaged (e.g., 6 count bunches, 25 pound (lb) carton, 12 ounce (oz) bottle, 100 gallon (gal) tank); and
- The name of the firm, address, telephone number, and, if available, the fax number and email address of the transporter immediate previous source (the transporter who transported the food to you).
- If available, the fax number and email address of the non-transporter immediate subsequent recipient, whether domestic or foreign;
- An adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);
- The date you released the food;
- The name of the firm, address, telephone number, and, if available, the fax number and email address of the transporter immediate subsequent recipient (the transporter who transported the food from you); and
- Information reasonably available to identify the specific source of each ingredient used to make every lot of finished product.

As a transporting facility, the company has an option of establishing and maintaining the records listed below, the records currently required by the Department of Transportation's (DOT) Federal Motor Carrier Safety Administration, the records currently required by the DOT's Surface Transportation Board of rail and water interstate transporters, the records currently required by the Warsaw Convention of international air transporters on air waybills, or entering into an agreement with the non-transporter immediate before or after it in the distribution channel to establish and/or maintain the required information.

- Names of the transporter's immediate previous source and transporter's immediate subsequent recipient;
- Origin and destination points;
- Date shipment received and date released;
- Number of packages;
- Description of freight;
- Route of movement during the time you transported the food; and
- Transfer point(s) through which shipment moved

V. Current Good Manufacturing Practice Requirements – 21 CFR Part 110

Current Good Manufacturing Practice (cGMP) regulations require that food offered for sale or introduced into interstate commerce be produced under safe and sanitary conditions. Certain food categories have additional requirements because of the inherent hazards, particular attributes, or specific manufacturing processes. Records must be kept documenting compliance with all these requirements.

The cGMP regulations require that the grounds, buildings, equipment, and operations under the control of the operator of the facility be kept in a condition that will protect against the contamination of food. The methods of maintaining proper sanitations levels include but are not limited to:

- Properly storing and maintaining equipment
- Removing litter and waste
- Cutting weeds that may constitute an attractant, breeding place, or harbor for pests
- Maintaining roads, yards, and parking lots
- Adequately draining areas that may contaminate food by seepage
- Providing sufficient space for the maintenance of sanitary operations
- Separating of operations in which contaminations is likely to occur by one of the following means: location, time, partition, air flow, or enclosed systems
- Permitting the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means
- Keeping floors, walls, and ceilings clean
- Providing adequate lighting in hand-washing areas, dressing and locker rooms, and bathrooms
- Providing adequate ventilation and screening

When cleaning the facility, the sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and be safe and adequate under the conditions of use. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Toxic materials may be used or stored in the facility for the purposes of maintaining clean and sanitary conditions, laboratory testing procedures, plant and equipment maintenance, and plant operations; however, generally these products are prohibited from being used where food is processed or exposed.

As industry participants may be aware, the U.S. is currently in a transition phase from its existing cGMP regulations to a series of new rules governing food safety as required by the Food Safety Modernization Act (FSMA), adopted in 2011. One of the seven major new rules issued pursuant to FSMA addresses cGMPs or preventive controls for human foods, as the rule is titled. Under this rule, covered facilities must establish and implement a written food safety plan that includes:

- **Hazard analysis:** The first step is to identify known or reasonably foreseeable biological, chemical, and physical hazards. The plan must consider hazards if they occur naturally, could be unintentionally introduced, or could be intentionally introduced for economic gain (if they affect the safety of the food).
- **Preventive controls** are required to minimize or prevent identified hazards. 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** is required as appropriate to the preventive control to provide assurance that preventive controls are consistently performed.
- **Corrective actions and corrections:** Corrective actions include identifying a problem with preventive control implementation, reducing the likelihood the problem will recur, evaluating affected food for safety, and preventing it from entering commerce. Corrective actions must be documented with records. Corrections are steps taken to timely identify and correct a minor, isolated problem that occurs during food production.
- **Verification** is required to ensure that preventive controls are consistently implemented and effective. It includes validating with scientific evidence that a preventive control is capable of controlling an identified hazard, calibrating instruments for process monitoring and verification, and reviewing records to verify that monitoring and corrective actions (if necessary) are being conducted.

The rule requires a manufacturing/processing facility to have a risk-based supply chain program for those raw materials and other ingredients identified to have 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 controls 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.

When an identified hazard will be controlled by a subsequent entity, such as a customer or other processor, a facility will not be required to implement a preventive control. 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. 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.

The final rule updates and clarifies some cGMPs. Management must 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.

Compliance dates for businesses are staggered over several years after publication of the final rule, which occurred on September 17, 2015:

- **Very small business** (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, which had a compliance date of Jan. 1, 2016.
- **Business subject to the Pasteurized Milk Ordinance (PMO)** (compliance dates extended to allow time for changes to the PMO safety standards that incorporate the requirements of this preventive controls rule): Three years after publication.
- **Small business** (a business with fewer than 500 full-time equivalent employees): Two years after publication.
- **All other businesses:** One year after publication.

VI. Produce Safety

Another of the major new rules adopted pursuant to FSMA governs produce safety. The rule focuses on five major routes of contamination and also discusses sprouts. The five major routes of contamination and related provisions include:

- **Worker Training and Health and Hygiene**
- Establish qualification and training requirements for all personnel who handle (contact) covered produce or food contact surfaces and their supervisors (§§ 112.21, 112.22, and 112.23);
- Require documentation of required training and corrective actions (§ 112.30); and,
- Establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance (§§ 112.31, 112.32, and 112.33).

- **Agricultural Water**
- Require that all agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41). Agricultural water is defined in part as water that is intended to, or is likely to, contact the harvestable portion of covered produce or food-contact surfaces (§ 112.3(c));
- Establish requirements for inspection, maintenance, and certain other actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding of covered produce (§§ 112.42 and 112.48);
- If a farm chooses to treat agricultural water to meet relevant requirements for its intended use, establish requirements related to methods of treatment and monitoring such treatment (§ 112.43);
- Establish specific requirements for the microbial quality of agricultural water that is used for certain specified purposes, including provisions requiring periodic analytical testing of such water (with exemptions provided for use of public water supplies, under certain specified conditions, and treated water), and requiring certain actions to be taken when such water is not safe or of adequate sanitary quality for its intended use and/or does not meet the microbial quality requirements (§§ 112.44, 112.45, 112.46, and 112.47); and provide for the use of alternative requirements for certain provisions under certain conditions (§§ 112.12 and 112.49); and
- Require certain records, including documentation of inspection findings, water testing results, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, scientific data or information relied on to support microbial die-off or removal rates or any permitted alternatives to requirements, time intervals or log reductions applied, and corrective actions (§ 112.50).

- **Biological Soil Amendments**
- Establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated, and for their handling, conveying, and storing (§§ 112.51 and 112.52);
- Prohibit the use of human waste for growing covered produce except in compliance with U.S. Environmental Protection Agency (EPA) regulations for such uses or equivalent regulatory requirements (§ 112.53);
- Establish requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, biological, physical and/or chemical processes that satisfy certain specific microbial standards (§§ 112.54 and 112.55), including examples of such processes;
- Establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (§ 112.56); and
- Require certain records, including documentation from suppliers of treated biological soil amendments of animal origin, documentation that process controls were achieved, and corrective actions (§ 112.60).

- **Domesticated and Wild Animals**
- If there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce, require measures to assess as needed relevant areas during growing and, if significant evidence of potential contamination is found, take measures reasonably necessary to assist later during harvest when the farm must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard (§§ 112.83 and 112.112).

• Equipment, Tools, and Buildings

- Establish requirements related to equipment and tools that contact covered produce and instruments and controls (including equipment used in transport), buildings, domesticated animals in and around fully-enclosed buildings, pest control, hand-washing and toilet facilities, sewage, trash, plumbing, and animal excreta (§§ 112.121-134); and
- Require certain records related to the date and method of cleaning or sanitizing equipment used in growing operations or sprouts, and in covered harvesting, packing, or holding activities, and corrective actions (§ 112.140).

• Sprouts

- Establish scope of applicability of sprout provisions (§ 112.141);
- Establish measures that must be taken related to seeds or beans for sprouting (§ 112.142);
- Establish measures that must be taken for the growing, harvesting, packing, and holding of sprouts (§ 112.143);
- Require testing the growing environment for Listeria species (Listeria spp.) or Listeria monocytogenes (L. monocytogenes) and testing each production batch of spent sprout irrigation water or sprouts for Escherichia coli (E. coli) O157:H7, Salmonella species (Salmonella spp.) and, under certain conditions, other pathogen(s), and taking appropriate follow-up actions (§§ 112.144-112.148); and
- Require certain records, including documentation of treatment of seeds or beans for sprouting, a written environmental monitoring plan and sampling plan, test results, certain test methods used, and corrective actions (§ 112.150).

The produce safety rule became effective on January 26, 2016, but compliance dates again vary by size of entity. For this rule, the compliance date is measured from the effective date and for very small businesses is four years; for small businesses is three years; and for all other farms is two years. The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond each of these compliance dates.

VII. Foreign Supplier Verification Program

A third of the major FSMA rules establishes the foreign supplier verification program (FSVP). The FSVP regulation focuses on known or reasonably foreseeable food safety hazards, identified and considered through a hazard analysis and evaluation process, rather than all adulteration covered by the adulteration provisions in the Food, Drug & Cosmetic Act (FDCA).
Under the final rule, importers are responsible for the following:

- Determining the hazards reasonably likely to cause illness or injury with each food. Importers can conduct their own analysis of the potential hazards with a food or review and assess a hazard analysis conducted by another entity.

- Evaluating the risk posed by a food, using the results of the hazard analysis, and evaluating the foreign supplier's performance. This evaluation informs the approval of foreign suppliers and the determination of appropriate supplier verification activities. An importer may rely on another entity to conduct this evaluation and to determine the appropriate supplier verification activities as long as the importer reviews and assesses the evaluation, determination, or both, as applicable. An importer must approve its own foreign suppliers.

- Conducting supplier verification activities. In general, importers must establish and follow written procedures to ensure they only import foods from foreign suppliers they have approved importers may, however, import food from unapproved foreign suppliers, on a temporary basis when necessary and appropriate, if they subject the food from these suppliers to adequate verification activities before importing it.

- Importers are responsible for determining and documenting foreign supplier verification activities (as well as the frequency with which those activities must be conducted) that are appropriate to provide assurance that hazards requiring a control in food are significantly minimized or prevented. Importers must conduct supplier verification activities for each foreign supplier before importing a food into the United States and periodically thereafter. An importer may determine, document, and conduct these activities itself or may rely on other entities to perform those tasks, as long as the importer reviews and assesses the relevant documentation, including the results of supplier verification activities.

- The appropriate verification activities and their frequency will vary depending on the food, the foreign supplier, and the nature of the control. Appropriate verification activities include: onsite auditing, sampling and testing of a food, review of the foreign

supplier's relevant food safety records, and other activities that are appropriate based on the evaluation of the risk posed by the food and foreign supplier performance.

- When a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the default appropriate verification activity under the regulation is an annual onsite audit of the foreign supplier. To provide flexibility even in these circumstances, the rule allows for the performance of a different supplier verification activity and/or less frequent onsite auditing provided an adequate written determination is made that the other approach will meet the public health purpose of supplier verification.

- The final rule does not require an importer to conduct supplier verification (or evaluate the risk posed by a food and the foreign supplier's performance) when the hazard requiring a control in a food will be controlled by a subsequent entity in the distribution chain in the United States. For example, if an importer's customer will control the hazard, the importer can rely on its customer to provide written assurance that the food will be processed for food safety and must disclose that the food has not been processed to control the identified hazard. If the hazard will be controlled by a subsequent entity in the distribution chain, the final rule requires disclosure that the food has not been processed to control the identified hazard as well as a series of written assurances starting with assurances from the customer to the importer and continuing the obligation to provide written assurance of processing for food safety throughout the distribution chain. The final rule provides flexibility for an importer to establish, document, and implement an alternative system that ensures adequate control, at a later distribution step, of the hazards in a food product distributed by a manufacturing/processing facility.

- Under the final rule, an importer must take appropriate corrective actions promptly if it determines that a foreign supplier of a food it imports does not produce the food in compliance with the processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FDCA, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the FDCA. This determination could be based on a review of consumer, customer, or other complaints related to food safety, verification activities, or other information. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the problem is resolved.

- Finally, importers must identify themselves as the importer of the food for each line of food product offered for importation into the United States and must retain records of their FSVP activities.

Exceptions to the Standard FSVP Requirements

The final rule provides several exceptions to the standard FSVP requirements for certain types of importers. First, for dietary supplements and dietary supplement components, importers who establish and verify compliance with certain specifications (concerning dietary supplement components and packaging) under the dietary supplement cGMP regulations will not be required to comply with most of the standard FSVP requirements, including hazard analysis and standard supplier verification activities. The same exception 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. In contrast, importers of other dietary supplements would be required to comply with most of the standard FSVP requirements but would not have to conduct hazard analyses, and their supplier verification activities would focus on verifying that the supplier is in compliance with the dietary supplement cGMP regulation, rather than verifying that hazards requiring a control are significantly minimized or prevented, as required under the standard supplier verification activity provisions.

Second, the rule establishes modified FSVP requirements for very small importers and importers of food from certain small foreign suppliers. The final rule aligns the definition of "very small importer" with the definitions of "very small business" under the regulations on preventive controls for human food and animal food. For the importation of human food, the definition of very small importer has an annual sales ceiling of $1 million , which is consistent with the $1 million annual sales ceiling for a very small business under the preventive controls for human food regulation. For the importation of animal food, the definition of very small importer has an annual sales ceiling of $2.5 million , which is consistent with the $2.5 million annual sales ceiling for a very small business under the preventive controls for animal food regulation.

In addition, food from three types of small foreign suppliers is not subject to standard supplier verification requirements. Those foreign suppliers are: (1) qualified facilities under either of the preventive controls regulations, (2) farms that are not "covered farms" under the produce safety regulation in part 112 (21 CFR part 112) in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, and (3) shell egg producers not subject to part 118 (21 CFR part 118) because the shell egg producer has 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 producers.

Third, the rule excludes from most of the standard FSVP requirements (including hazard analysis and verification that identified hazards are significantly minimized or prevented) certain types of food from a foreign supplier in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that:

- The food is within the scope of the relevant official recognition or equivalency determination;
- The importer determines that the foreign supplier of the food is in good compliance standing with the relevant food safety authority; and
- The food is not intended for further processing in the United States, e.g., packaged food products and raw agricultural commodities (RACs) that will not be processed further before consumption.

Although FSVP requirements apply to most imported food under FDA's regulatory jurisdiction, certain categories of imported food are not covered under the FSVP regulation. These exemptions include certain juice, fish, and fishery products (which are already subject to verification under FDA's hazard analysis and critical control point (HACCP) regulations for those products), food for research or evaluation, food for personal consumption, alcoholic beverages, food that is transshipped, food imported for processing and future export, food exported from and returned to the United States without manufacturing/processing in a foreign country, and certain meat, poultry, and egg products regulated by the USDA.

The date by which importers must comply with the FSVP regulations is the latest of the following dates: (1) 18 months after publication of the final rule on November 27, 2015); (2) 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; or (3) 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 (discussed above).

VIII. Third-Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications

Accrediting third-party certification bodies to conduct food safety audits and issue certifications is the subject of another of the major FSMA rules. FSMA specifies two uses for the food and facility certifications issued by accredited third-party certification bodies. First, facility certifications will be used by importers to establish eligibility for Voluntary Qualified Importer Program (VQIP). VQIP offers participating importers expedited review and entry of food.

Second, FDA has the authority to make a risk-based determination to require, as a condition of admissibility, that a food imported or offered for import into the United States be accompanied by a certification or other assurance that the food meets the applicable requirements of the FDCA. When FDA has determined that a food import is subject to such certification, FDA will require, as a condition of entry, a certification issued either by an accredited third-party certification body under this rule or by an agency or representative of the government of the country from which the food at issue originated.

In addition, facilities and importers may choose to use onsite audits conducted by third-party certification bodies accredited under the program set out in this rule to meet supplier verification requirements discussed above. Under the final rules for preventive controls for human and animal food and for foreign supplier verification, in circumstances where an onsite audit is the appropriate supplier verification activity, such audit must be conducted by a "qualified auditor." The definitions of "qualified auditor" in those rules make clear that an example of a potential qualified auditor includes, but is not limited to, an audit agent of a certification body that has been accredited in accordance with this rule.

The final rule sets requirements for the legal authority, competency, capacity, conflict of interest safeguards, quality assurance, and records procedures that accreditation bodies and third-party certification bodies must demonstrate to be eligible for recognition. The final rule also requires accredited third-party certification bodies to perform unannounced facility audits, to notify FDA upon

discovering a condition that could cause or contribute to a serious risk to the public health, and to submit to FDA reports of regulatory audits conducted for certification purposes. The rule includes stringent requirements to prevent conflicts of interest from influencing the decisions of recognized accreditation bodies and accredited third-party certification bodies. The rule does not, however, establish the audit criteria that accredited third-party certification bodies will use in examining eligible entities for compliance with the applicable food safety requirements of the FDCA and FDA regulations, because those criteria appear elsewhere in FDA regulations and the FDCA.

IX. Focused Mitigation Strategies to Protect Food Against Intentional Adulteration

Another FSMA rule, proposed but not finalized as of February 2016, addresses protecting food against intentional adulteration. The rule seeks to protect the food supply against acts of terrorism designed to cause widespread and significant harm to public health. The rule is expressly not designed to cover acts of disgruntled employees, consumers or competitors designed to harm a company's reputation – even though harm to public health may occur – or economically motivated adulteration (although it discusses an approach to this latter problem also).

The proposed rule would require covered facilities to complete the following defense measures:

- Prepare and implement a written food defense plan that includes actionable process steps, focused mitigation strategies, and procedures for monitoring, corrective actions, and verification.
- Identify any actionable process steps, using one of two procedures. FDA has determined that the presence of one or more of (1) bulk liquid receiving and loading, (2) liquid storage and handling, (3) secondary ingredient handling, and (4) mixing and similar activities during a process step (e.g., manufacturing, processing, packing, or holding of food) indicates a significant vulnerability and that food is at high risk of intentional adulteration caused by acts of terrorism. Facilities may identify actionable process steps using the FDA-identified key activity types or conduct their own facility-specific vulnerability assessments.
- Identify and implement focused mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated.
- Establish and implement procedures, including the frequency with which they are to be performed, for monitoring the focused mitigation strategies.
- Establish and implement corrective action procedures that must be taken if focused mitigation strategies are not properly implemented.
- Verify that monitoring is being conducted and appropriate decisions about corrective actions are being made; verify that the focused mitigation strategies are consistently implemented and are effectively and significantly minimizing or preventing the significant vulnerabilities; and conduct a reanalysis of the food defense plan.
- Ensure that personnel and supervisors assigned to perform actionable process steps receive appropriate training in food defense awareness and their respective responsibilities in implementing focused mitigation strategies.
- Establish and maintain certain records, including the written food defense plan; written identification of actionable process steps and the assessment leading to that identification; written focused mitigation strategies; written procedures for monitoring, corrective actions, and verification; and documentation related to training of personnel.

The proposed effective date is 60 days after a final rule is published. As with the other rules, however, the FDA is providing a longer timeline for facilities to comply with the final rule.

X. Reporting

Registered food facilities must report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. FDA allows conventional food manufacturers, processors, packers, transporters, distributors, receivers, holders, and importers to forward reports of serious adverse events in connection with their products to FDA by filing Form 3500.

The FDA then adds the report to the Reportable Food Registry (RFR). The RFR is the electronic portal used to report when there is a reasonable probability that an article of food will cause serious adverse health consequences. Federal, state, and local government officials may also voluntarily use the RFR portal to report information that may come to them about reportable foods. The FDA

uses the registry to track patterns and better protect the public health by performing targeted inspections of potential problem facilities. The RFR applies to all FDA-regulated categories of food and feed, except dietary supplements and infant formula.

APPENDIX

The general food categories established in Title 21 of the Code of Federal Regulations for use in the registration process include:

- Baked goods and baking mixes, including all ready-to-eat and ready-to-bake products, flours, and mixes requiring preparation before serving.
- Beverages, alcoholic, including malt beverages, wines, distilled liquors, and cocktail mix.
- Beverages and beverage bases, nonalcoholic, including only special or spiced teas, soft drinks, coffee substitutes, and fruit and vegetable flavored gelatin drinks.
- Breakfast cereals, including ready-to-eat and instant and regular hot cereals.
- Cheeses, including curd and whey cheeses, cream, natural, grating, processed, spread, dip, and miscellaneous cheeses.
- Chewing gum, including all forms.
- Coffee and tea, including regular, decaffeinated, and instant types.
- Condiments and relishes, including plain seasoning sauces and spreads, olives, pickles, and relishes, but not spices or herbs.
- Confections and frostings, including candy and flavored frostings, marshmallows, baking chocolate, and brown, lump, rock, maple, powdered, and raw sugars.
- Dairy product analogs, including nondairy milk, frozen or liquid creamers, coffee whiteners, toppings, and other nondairy products.
- Egg products, including liquid, frozen, or dried eggs, and egg dishes made therefrom, i.e., egg roll, egg foo young, egg salad, and frozen multicourse egg meals, but not fresh eggs.
- Fats and oils, including margarine, dressings for salads, butter, salad oils, shortenings and cooking oils.
- Fish products, including all prepared main dishes, salads, appetizers, frozen multicourse meals, and spreads containing fish, shellfish, and other aquatic animals, but not fresh fish.
- Fresh eggs, including cooked eggs and egg dishes made only from fresh shell eggs.
- Fresh fish, including only fresh and frozen fish, shellfish, and other aquatic animals.
- Fresh fruits and fruit juices, including only raw fruits, citrus, melons, and berries, and home-prepared "ades" and punches made therefrom.
- Fresh meats, including only fresh or home-frozen beef or veal, pork, lamb or mutton and home-prepared fresh meat-containing dishes, salads, appetizers, or sandwich spreads made therefrom.
- Fresh poultry, including only fresh or home-frozen poultry and game birds and home-prepared fresh poultry-containing dishes, salads, appetizers, or sandwich spreads made therefrom.
- Fresh vegetables, tomatoes, and potatoes, including only fresh and home-prepared vegetables.
- Frozen dairy desserts and mixes, including ice cream, ice milks, sherbets, and other frozen dairy desserts and specialties.
- Fruit and water ices, including all frozen fruit and water ices.
- Gelatins, puddings, and fillings, including flavored gelatin desserts, puddings, custards, parfaits, pie fillings, and gelatin base salads.
- Grain products and pastas, including macaroni and noodle products, rice dishes, and frozen multicourse meals, without meat or vegetables.
- Gravies and sauces, including all meat sauces and gravies, and tomato, milk, buttery, and specialty sauces.
- Hard candy and cough drops, including all hard type candies.
- Herbs, seeds, spices, seasonings, blends, extracts, and flavorings, including all natural and artificial spices, blends, and flavors.
- Jams and jellies, home-prepared, including only home-prepared jams, jellies, fruit butters, preserves, and sweet spreads.
- Jams and jellies, commercial, including only commercially processed jams, jellies, fruit butters, preserves, and sweet spreads.
- Meat products, including all meats and meat containing dishes, salads, appetizers, frozen multicourse meat meals, and sandwich ingredients prepared by commercial processing or using commercially processed meats with home preparation.
- Milk, whole and skim, including only whole, lowfat, and skim fluid milks.
- Milk products, including flavored milks and milk drinks, dry milks, toppings, snack dips, spreads, weight control milk beverages, and other milk origin products.
- Nuts and nut products, including whole or shelled tree nuts, peanuts, coconut, and nut and peanut spreads.

- Plant protein products, including the National Academy of Sciences/National Research Council "reconstituted vegetable protein" category, and meat, poultry, and fish substitutes, analogs, and extender products made from plant proteins.
- Poultry products, including all poultry and poultry-containing dishes, salads, appetizers, frozen multicourse poultry meals, and sandwich ingredients prepared by commercial processing or using commercially processed poultry with home preparation.
- Processed fruits and fruit juices, including all commercially processed fruits, citrus, berries, and mixtures; salads, juices and juice punches, concentrates, dilutions, "ades", and drink substitutes made therefrom.
- Processed vegetables and vegetable juices, including all commercially processed vegetables, vegetable dishes, frozen multicourse vegetable meals, and vegetable juices and blends.
- Snack foods, including chips, pretzels, and other novelty snacks.
- Soft candy, including candy bars, chocolates, fudge, mints, and other chewy or nougat candies.
- Soups, home-prepared, including meat, fish, poultry, vegetable, and combination home-prepared soups.
- Soups and soup mixes, including commercially prepared meat, fish, poultry, vegetable, and combination soups and soup mixes.
- Sugar, white, granulated, including only white granulated sugar.
- Sugar substitutes, including granulated, liquid, and tablet sugar substitutes.
- Sweet sauces, toppings, and syrups, including chocolate, berry, fruit, corn syrup, and maple sweet sauces and toppings.

The general food product category, a mandatory field on the facility registration form, was amended by the Food Safety Modernization Act (FSMA) to include additional mandatory categories. A complete facility registration includes not only information necessary to notify the FDA of the general food category, as identified in 21 CFR 170.3, of food manufactured, processed, packed, or held at the facility, but also any other food categories as determined appropriate by the FDA. The additional food categories as identified by the FDA for human consumption are:

- Acidified Food (see 21 CFR 114.3(b));
- Baby (Infant and Junior) Food Products Including Infant Formula*;
- Cheese and Cheese Product Categories: Soft, Ripened Cheese; Semi-Soft Cheese; Hard Cheese; Other Cheeses and Cheese Products;
- Dietary Supplement Categories: Proteins, Amino Acids, Fats and Lipid Substances; Animal By-Products and Extracts; Herbals and Botanicals;
- Fishery/Seafood Product Categories: Fin Fish, Whole or Filet; Shellfish; Ready to Eat (RTE) Fishery Products; Processed and Other Fishery Products;
- Fruit and Fruit Products: Fresh Cut Produce; Raw Agricultural Commodities; Other Fruit and Fruit Products;
- Fruit or Vegetable Juice, Pulp or Concentrate Products;
- Low Acid Canned Food (LACF) Products (see 21 CFR 113.3(n));
- Nuts and Edible Seed Product Categories: Nut and Nut Products; Edible Seed andEdible Seed Products;
- Shell Egg and Egg Product Categories: Chicken Egg and Egg Products; Other Egg and Egg Products;
- Vegetable and Vegetable Product Categories: Fresh Cut Products; Raw Agricultural Commodities; Other Vegetable and Vegetable Products; and
- If none of the human food categories listed in the registration form apply, print the applicable food category or categories.

These additional food categories for animal consumption are:

- Grain or Grain Products (i.e., barley, grain sorghums, maize, oat, rice, rye, wheat, other grains or grain products)*;
- Oilseed or Oilseed Products (i.e., cottonseed, soybeans, other oilseeds or oilseed products)*;
- Alfalfa Products or Lespedeza Products*;Amino Acids or Related Products*;
- BAnimal-Derived Products*;
- Brewer Products*;
- Chemical Preservatives*;
- Citrus Products*;
- Distillery Products*;
- Enzymes*;
- Fats or Oils*;
- Fermentation Products*;
- Marine Products*;

- Milk Products*;
- Minerals or Mineral Products*;
- Miscellaneous or Special Purpose Products*;
- Molasses or Molasses Products*;
- Non-protein Nitrogen Products*;
- Peanut Products*;
- Recycled Animal Waste Products*;
- Screenings*;
- Vitamins or Vitamin Products*;Yeast Products*;
- Mixed Feed (e.g., poultry, livestock, equine)*;
- Pet Food*;
- Pet Treats or Pet Chews;
- Pet Nutritional Supplements (e.g., vitamins, minerals); and
- If none of the above food categories apply, print the applicable food category or categories (that does not or do not appear above).

*Food product categories for foods for human and animal consumption marked with asterisks were previously included on the food facility registration form as optional fields. Individual food products included within these categories are determined according to the detailed classification lists contained in Exhibit 33B of the report of the National Academy of Sciences/National Research Council report, "A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe" (September 1972).