KELLER AND HECKMAN LLP
Serving Business through Law and Science®

1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001
tel. 202.434.4100
fax 202.434.4646

MEMORANDUM

via Email

TO: Clients and Other Interested Parties **December 1, 2015**

RE: Overview of FDA's Final Rule to Implement FSMA's Foreign Supplier Verification Program

---

On November 27, 2015, the Food and Drug Administration (FDA) issued its final rule on the Foreign Supplier Verification Program (FSVP).[1] The FSVP rule implements Section 805 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which was created by Section 301 of the FDA Food Safety Modernization Act (FSMA). FDA issued a proposed rule to implement the FSVP provisions on July 29, 2013, followed by a supplement to the proposal on September 29, 2014.[2] Although the final rule clarifies and refines many concepts and provisions, the final regulations generally are consistent with the proposal and the supplement.

The FSVP rule establishes five central requirements for importers of food. Specifically, it requires importers of food to: (1) conduct an analysis of the hazards that are reasonably likely to cause illness or injury with the imported food; (2) evaluate and approve foreign suppliers based on that hazard analysis, as well as other factors; (3) conduct supplier verification activities; (4) take corrective actions, when appropriate, to control a hazard; and (5) maintain records of FSVP activities. Several types of food and some importers are exempt from the requirements of the FSVP rule or are subject to modified requirements. Although the final rule is effective on January 26, 2016, companies generally have 18 months from the date of publication to comply, i.e., May 29, 2017.[3] Pursuant to Section 301(zz) of the FD&C Act, it is a prohibited act to import food if the importer does not have in place a compliant FSVP.

---

[1] *See* Final Rule for Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 80 Fed. Reg. 74226 (Nov. 27, 2015), available at: http://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28158.pdf.

[2] Proposed Rule: 78 Fed. Reg. 45730 (July 29, 2013); Supplement: 79 Fed. Reg. 58574 (Sept. 29, 2014).

[3] Food imported from a supplier that is subject to the Hazard Analysis and Risk Based Preventive Controls (HARPC) regulations or the Produce Safety regulations must be in compliance with the FSVP

(continued …)

I. Key Differences between the Proposed Rule and the Final Rule

FDA has focused its efforts in developing the final rule on promoting consistency between the FSVP and the Hazard Analysis and Risk Based Preventive Controls (HARPC) regulations[4] and Produce Safety regulations.[5] In addition, the Agency has revised several provisions to clarify the requirements for covered entities under the rule. Although it is not an exhaustive description of the differences between the proposal and the final rule, we note some of the more significant changes and clarifications below:

- **"Importer" Definition Revised to Ensure the Entity with a Financial Interest in the Food is Responsible for FSVP Compliance**: The definitions of "importer" and "U.S. owner or consignee" have been revised to promote consistency with the definition provided for importer under FSMA. The adopted definitions are designed to ensure that the entity with a financial interest in the food, and with knowledge about the supply chain, is responsible for compliance with the FSVP requirements.

- **Importers Compliant with HARPC Requirements Are Deemed Compliant with Most FSVP Requirements**: FDA has clarified that certain importers that are also manufacturers or processors are deemed compliant with most FSVP requirements if: (1) they are in compliance with the supply-chain program requirements under the HARPC framework; (2) they implement preventive controls for the hazards in the food in accordance with HARPC requirements; or (3) they are not required to implement preventive controls under the HARPC framework due to circumstances such as the production of foods that could not be consumed without application of a preventive control, or when a customer will be significantly minimizing or preventing identified hazards and they comply with requirements for disclosures and written assurances.

(…continued)
regulations 6 months after the foreign supplier of the food is required to comply with the HARPC or Produce Safety requirements, as applicable.

[4] *See* Final Rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 55908 (Sept. 17, 2015), available at: http://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21920.pdf; Final Rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 80 Fed. Reg. 56170 (Sept. 17, 2015), available at: http://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21921.pdf.

[5] *See* Final Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74354 (Nov. 27, 2015), available at: http://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf.

- **Information Needed to Meet Certain FSVP Requirements May be Obtained from Entities Across the Supply Chain**: Due to the fact that importers of food may be separated from the foreign supplier by several steps in the supply chain, FDA has revised provisions in the FSVP rule to permit importers to obtain some information needed to establish compliance with the FSVP rule from entities other than the foreign supplier, such as distributors or consolidators of food, provided that the importer documents its review and assessment of this information.

- **Importers of Food Contact Substances (FCS) Must Comply with the FSVP**: FDA has declined to exempt importers of FCS from the requirements of the rule, despite having received industry comments noting that such substances pose a low risk to the safety of food and that their inclusion in the FSVP rule would create a resource-intensive burden for food companies, food-contact material manufacturers, and FDA.

- **Importers of "Dual Use" Substances May Need to Comply with the FSVP**: Importers of substances which have potential food and non-food uses must comply with the FSVP if the substance is reasonably likely to be directed to a food use.

- **Importers Only Need to Verify a Single Foreign Supplier for an Imported Food**: In recognizing some of the practical supply-chain challenges associated with conducting verification activities for multiple entities in the supply chain for the same imported food, FDA has clarified that the foreign supplier is the entity that manufactures or produces the food, raises the animal, or grows the food. Actors in the supply chain that conduct activities that are of a *de minimis* nature, such as packers or holders of food, are not considered foreign suppliers.

- **Definition of Foreign Supplier Revised to Reference "Growers" Rather than "Harvesters" of Food**: In instances where food is grown and harvested, the FSVP rule clarifies that the "grower" of food, rather than the "harvester," is the foreign supplier. This clarification ensures that if imported food is harvested by an entity other than the grower (i.e., the farmer), the grower continues to be the foreign supplier, even if the harvester takes ownership of the food during harvesting. The importer must still obtain assurances that hazards associated with harvesting of the food are appropriately controlled.

- **Record Access and Retention**: FDA has added flexibility to the records access and retention provisions of the FSVP rule by clarifying that records do not need to be maintained in English and can be stored in an offsite location.

- **Eliminating Duplicative Requirements in the Rule**: Where possible, FDA has attempted to eliminate duplicative requirements in the regulations promulgated to implement the FSVP.

II. Summary of Requirements in the Final Rule

As noted above, the FSVP rule generally requires importers of food to: (1) conduct an analysis of the hazards that are reasonably likely to cause illness or injury with the imported food; (2) evaluate and approve foreign suppliers based on that hazard analysis, as well as other factors; (3) conduct supplier verification activities; (4) take corrective actions, when appropriate, to control a hazard; and (5) maintain records of FSVP activities. We discuss these requirements in greater detail below.

A. Covered Entities and Scope of the Final Rule

The FSVP rule applies to all food imported into the U.S. and to importers of food. The importer of the food is responsible for complying with the FSVP regulations. An importer is the U.S. owner or consignee of an article of food that is being offered for import into the United States.[6] The U.S. owner or consignee is the person in the U.S. who, at the time of entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food. In instances where there is no U.S. owner or consignee at the time of entry, the importer is the U.S. agent or representative of the foreign owner or consignee. A U.S. owner or consignee of the imported food, or the U.S. agent or representative of a foreign entity, must be identified at the time of importation. This definition is designed to ensure that the entity with a financial interest in the food, and with knowledge about the supply chain, is responsible for compliance with the FSVP requirements.

The foreign supplier is the establishment that manufactures or processes the food, raises the animal, or grows the food that is exported to the U.S. without further manufacturing or processing by another establishment. Foreign entities that engage in activity that is *de minimis* in nature, such as holding food or labeling food, are not considered foreign suppliers. Thus, importers generally do not need to implement an FSVP for these entities.

B. Exemptions and Modified Requirements

Some importers and types of food are exempt from the FSVP requirements. FDA has also created modified FSVP requirements for certain importers and types of food. The table presented below briefly summarizes these exemptions and modified requirements.

Importer/Food Type	21 C.F.R. Reference	Applicability of FSVP Requirements
Food subject to seafood, juice, and	§ 1.501(b)(1)-(2)	Exempt, except that for LACF

[6] The definitions and most of the other provisions created by the FSVP regulations are codified in a new "Subpart L" in Part 1 of Title 21 of the Code of Federal Regulations. *See* 21 C.F.R. §§ 1.500 *et seq.*

low-acid canned food (LACF) hazard analysis and critical control points (HACCP) requirements		facilities, the exemption only applies with respect to microbiological hazards
Food imported for research/evaluation and food imported for personal use	§ 1.501(c), (d)	Exempt
Alcoholic beverages imported from a foreign supplier that is a facility provided that: (1) if it were a domestic facility, it would be required to obtain a permit from, register with, or obtain approval from the Secretary of the Treasury as a condition of doing business in the U.S. and (2) it is required to register as a facility under section 415 of the FD&C Act because it is engaged in the manufacturing/processing of one or more alcoholic beverages[7]	§ 1.501(e)	Exempt
Food that is transshipped or imported for processing and export	§ 1.501(f)	Exempt
Food that is returned to the U.S. without further processing in a foreign country	§ 1.501(g)	Exempt
Certain meat, poultry, and egg products that are subject to the jurisdiction of the U.S. Department of Agriculture (USDA) at the time of importation[8]	§ 1.501(h)	Exempt
Importers that are receiving facilities (as defined in the HARPC regulations) and that comply with applicable	§ 1.502(c)	Exempt, except from the requirements in § 1.509 relating to importer identification at the

[7] Under some circumstances, these exemptions also apply to certain types of non-alcoholic food produced in these foreign facilities that is imported in the U.S. In addition, raw materials imported into the U.S. for use in the production of alcoholic beverages are exempt from the FSVP rule, provided that the importer is also exempt from the HARPC rule pursuant to 21 U.S.C. § 117.5.

[8] Specifically, this includes: (1) meat food products that, at the time of importation, are subject to requirements under the Federal Meat Inspection Act (21 U.S.C. §§ 601 *et seq.*); (2) poultry products that, at the time of importation, are subject to requirements under the Poultry Products Inspection Act (21 U.S.C. §§ 451 *et seq.*), and (3) egg products that, at the time of importation, are subject to requirements under the Egg Products Inspection Act (21 U.S.C. §§ 1031 *et seq.*).

HARPC requirements, namely: (1) by implementing required preventive controls; (2) by being exempt from the requirement to implement preventive controls under HARPC; or (3) by establishing and implementing a risk-based supply-chain program under HARPC		time of entry
Importers of raw agricultural commodities that are fruits and vegetables subject to the Produce Safety rule[9]	§ 1.504(e)	Exempt from the requirement to determine whether there are any biological hazards that require a control
Foods for which a hazard analysis has been conducted but where there are no identifiable hazards requiring a control	§ 1.504(f)	Exempt from the requirement to conduct foreign supplier approval and verification activities pursuant to §1.505 and §1.506[10]
Imported food that cannot be consumed unless the hazard is controlled or for which the hazard is not controlled until after importation	§ 1.507	See Section II.C.5 below
Importers of dietary supplements who must establish specifications under § 111.70 (b) or (d) and who comply with § 111.73 and §111.75	§ 1.511	Generally exempt, except from the requirements in § 1.509 relating to importer identification at the time of entry and the requirements in § 1.503 related to qualified individuals and auditors who can develop an FSVP and inspect a foreign facility[11]

[9] Importers of produce that is not considered a raw agricultural commodity and produce that is rarely consumed raw and intended for commercial processing – both of which are not subject to the Produce Safety rule – must comply with all applicable provisions in the FSVP rule.

[10] This exemption does not apply to imported food that is a raw agricultural commodity that is a fruit or vegetable that is "covered produce" under 21 C.F.R. § 112.3.

[11] Importers of dietary supplements whose *customer* must establish specifications under § 111.70(b) or (d) and who comply with § 111.73 and §111.75 are subject the requirements in §§ 1.503, 1.509, *and* 1.510 (relating to record retention). Importers of dietary supplements that do not need to establish

(continued …)

Very small importers and importers of food from certain small foreign suppliers	§ 1.512	See Section II.C.9 below
Food imported from a country with an officially recognized or equivalent food safety system[12]	§ 1.513[13]	Generally exempt, except from the requirements in § 1.509 relating to importer identification at the time of entry, the record retention requirements in § 1.510, and the requirements in § 1.503 related to qualified individuals and auditors who can develop an FSVP and inspect a foreign facility[14]

C. FSVP Framework

1. Qualified Individuals and Auditors (21 C.F.R. § 1.503)

All activities related to designing, implementing, and managing an FSVP must be carried out by a qualified individual. Qualified individuals must have the training, education, or experience (or some combination thereof) necessary to develop the FSVP. In addition, qualified individuals performing verification activities must not have any financial conflicts of interest that influence the results of the verification activities. Where an onsite audit of a foreign facility is conducted pursuant to an FSVP, that audit must be conducted by an auditor qualified through training, education, or experience (or some combination thereof).

(…continued)
specifications under § 111.70(b) or (d) or comply with § 111.73 and § 111.75 must comply with additional provisions of the FSVP rule, as described in § 1.511(c).

[12] FDA has indicated it will begin a systems recognition initiative to determine which foreign countries have equivalent food safety systems.

[13] This section only applies to food that is not intended for further manufacturing/processing before consumption.

[14] Of course, the foreign supplier must be within the regulatory oversight and in compliance with the foreign country's food safety system for this provision to apply. In addition, the importer must continually monitor the foreign supplier to ensure it remains in good standing with the food safety authority of the country in which the foreign supplier is located.

2. Hazard Analysis (21 C.F.R. § 1.504)

Importers must document and conduct a hazard analysis for all known or reasonably foreseeable hazards to determine whether there is a need to implement any measures to control those hazards. A hazard analysis consists of two central components: (1) hazard identification and (2) hazard evaluation. Hazard identification should consider known or reasonably foreseeable hazards, including those hazards which may occur naturally, may be unintentionally introduced, or may be intentionally introduced (e.g., economically motivated adulteration).[15] Hazard evaluation requires that a qualified individual assess the probability that a hazard will occur in the absence of appropriate controls and the health risks associated with such hazard. Enumerated factors to consider when evaluating a hazard include, among others, the formulation of the food, the conditions of the establishment that produces the food, transportation practices, packaging and labeling activities, and the intended use of the food.

As alluded to above, the final rule permits an importer to review another entity's hazard analysis of the food to be imported, provided that a qualified individual conducts the analysis and that the importer documents its review and assessment of that analysis. Notably, the final rule also provides that an importer does not need to conduct foreign supplier approval and verification activities if the importer conducts a hazard analysis and determines there are no hazards requiring a control.[16]

3. Foreign Supplier Evaluation: Making Approval Determinations and Identifying Appropriate Verification Activities (21 C.F.R. § 1.505)

Food must be imported from foreign suppliers that have been evaluated and approved.[17] In evaluating and approving foreign suppliers, as well as in determining what supplier verification activities might be appropriate, importers must consider: (1) their hazard analysis, (2) the entities that will be responsible for controlling or minimizing those hazards, including entities other than the foreign supplier, if applicable; (3) the foreign supplier's food safety performance history; (4) the foreign supplier's food safety protocols and procedures; and (5) the foreign supplier's compliance status under applicable FDA or foreign regulations. Importers can rely on another entity's evaluation of a foreign supplier for purposes of establishing compliance

---

[15] FDA notes that a hazard analysis must consider: (1) biological hazards (including microbiological hazards); (2) chemical hazards (including, among others, unapproved additives, food allergens, and pesticide and drug residues); and (3) physical hazards (e.g., stones, glass, metal, etc.).

[16] This provision does not apply to imported food that is a raw agricultural commodity that is a fruit or vegetable that is "covered produce" under 21 C.F.R. § 112.3.

[17] On a temporary basis, food can be imported from unapproved suppliers, provided that the importer subjects the food to adequate verification activities to ensure its safety before the food is imported.

with Section 1.505.[18] In the event that an importer becomes aware of a new hazard associated with a foreign supplier's food, the importer must promptly reevaluate the risks associated with importing food sourced from that foreign supplier, whether any additional verification activities are appropriate, and whether it should continue to import food from that foreign supplier. Importers must reevaluate their foreign suppliers at least once every three years and must thoroughly document the approval and evaluation process used for foreign suppliers.

4. Foreign Supplier Verification Activities (21 C.F.R. § 1.506)

Importers must establish and follow written procedures that verify they only import food from approved suppliers and that the hazards identified in the imported food are appropriately controlled. FDA has declined to specify certain mandatory activities that must be conducted to verify the safety of imported food, primarily in recognition of the fact that food hazards and associated risks vary considerably on a case-by-case basis. Examples of potentially appropriate verification activities provided by FDA include: (1) onsite audits of foreign suppliers; (2) sampling and testing of food; and (3) review of the foreign supplier's relevant food safety records.[19] The final rule also permits an importer to review another entity's verification activities associated with the foreign supplier of the food to be imported, provided that a qualified individual conducted the verification and that the importer documents its review and assessment of that verification.[20] Records of all foreign supplier verification activities must be documented and maintained.

5. Imported Food that Cannot be Consumed Unless the Hazard is Controlled or for which the Hazard is Not Controlled Until After Importation (21 C.F.R. § 1.507)

Foreign supplier approval (§ 1.505) and verification (§ 1.506) activities are not required when the importer determines and documents that the food cannot be consumed without application of an appropriate control, or if the importer establishes, implements and documents a system that ensures the hazards in the food are controlled at a subsequent distribution step. Foreign supplier approval and verification activities are also not required in the scenarios presented in the table below:

---

[18] The evaluation that is relied upon must have been conducted by a qualified individual and must be documented appropriately by the importer.

[19] Annual mandatory onsite audits, or documentation thereof, are required where exposure to a hazard will result in serious adverse health consequences of death, unless the importer has an adequate basis to determine that less frequent onsite audits are appropriate or that alternative verification activities are appropriate to ensure the hazard is controlled.

[20] One exception to this provision is that the importer may not rely on verification activities performed by the foreign supplier itself, or an employee of the foreign supplier, unless that verification activity relates to sampling or testing of the imported food.

Scenario	Requirements to be Exempt from § 1.505 and § 1.506
The importer relies on a customer who is subject to the HARPC requirements to ensure that the hazard is controlled	The importer discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]" and The importer annually obtains from its customer written assurance that it has established and is following appropriate procedures to minimize or prevent the identified hazard
The importer relies on a customer who is not subject to the HARPC requirements to ensure that the hazard is controlled	
The importer relies on a customer to ensure that the food will be subsequently processed to control the hazard	The importer discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]" and The importer annually obtains from its customer written assurance that the customer will: (1) disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]" and (2) will only sell the food to another entity that agrees, in writing, to follow procedures to minimize or prevent the hazard or produce the food in conformity with applicable food safety requirements

6. Corrective Actions (21 C.F.R. § 1.508)

Importers are required to take corrective actions if it is determined that a foreign supplier is producing food in a manner that does not provide the same level of public health protection as food in compliance with the HARPC and Produce Safety rules, or if the imported food is otherwise adulterated or misbranded. A determination that some corrective action should be taken can be based on a number of grounds, including, but not limited to, consumer/customer complaints or information obtained during the course of supplier verification activities. If a determination is made that a corrective action is necessary, and that determination is not based on information obtained from supplier verification activities conducted pursuant to the FSVP rule, the importer must promptly re-evaluate its FSVP to determine whether it is adequate and, if appropriate, modify the FSVP. Any corrective actions, investigations, or modifications to an FSVP must be documented.

7. Importer Identification (21 C.F.R. § 1.509)

For each line entry of food product offered for importation into the U.S., the importer must provide U.S. Customs and Border Protection (CBP) with his or her name and e-mail address. Notably, importers also must electronically provide to CBP a unique facility identifier number that identifies the importer and that is recognized as acceptable by FDA. The Agency intends to release a guidance document that explains which unique facility identifiers are recognized as acceptable by FDA.[21]

8. Record Maintenance (21 C.F.R. § 1.510)

Importers must maintain signed and dated records related to their FSVP, including records related to their hazard analysis, supplier evaluation and approval program, supplier verification activities, and any corrective actions taken to address identified food safety problems. Any records relevant to an FSVP must be made available promptly to FDA upon request. Offsite storage of records is permissible, provided that such records can be retrieved within 24 hours. Records retained in foreign languages are acceptable, but an English version of the record must be delivered to FDA within a reasonable time after a request for the English version of the record is made. Records can be maintained in an electronic format, and are considered to be located at a foreign facility if they can be accessed from that facility. Written requests for records can be sent electronically or through any other medium that ensures prompt delivery. In addition, records must be maintained for at least two years after their creation date, or for at least two years after their use is discontinued, whichever is longer.

If an importer has existing records that may be relied on to establish compliance with the FSVP, the importer does not need to create a duplicate copy of those records. Records related to an FSVP may be maintained in separate files. Finally, FSVP records are subject to disclosure under the Freedom of Information Act (FOIA); the protections provided in FOIA prohibiting the disclosure of confidential business and trade secret information still apply.

9. Very Small Importers and Importers of Food from Certain Small Foreign Suppliers (21 C.F.R. § 1.512)

Very small importers[22] and importers of food from certain small foreign suppliers[23] can choose to be subject to modified compliance requirements under the FSVP rule, provided that

---

[21] FDA has indicated that it expects it will recognize Dun & Bradstreet Data Universal Numbering System (DUNS) numbers which identify importers as acceptable.

[22] A very small importer is an importer averaging less than $1,000,000 per year in human food sales during the 3 year period preceding the applicable calendar year, or $2,500,000 per year in animal food sales during the 3 year period preceding the applicable calendar year.

[23] Importers of food from certain small foreign suppliers that are subject to the modified compliance requirements under section 1.512 of the FSVP rule must be importing from a foreign supplier that meets

(continued …)

such entities meet the prerequisite criteria to be considered very small importers or importers of food from certain small foreign suppliers. These modified compliance provisions generally require very small importers and importers of food from certain small foreign suppliers to: (1) implement an FSVP that ensures the imported food is in compliance with processes and procedures that provide at least the same level of public health protection as those required under the HARPC and Produce Safety rules; (2) use a qualified individual to prepare their FSVP; and (3) identify themselves as the importer as required in 21 C.F.R. § 1.509. In addition, very small importers and importers of food from certain small foreign suppliers must obtain written assurance every 2 years that the foreign supplier is producing food under conditions that provide at least the same level of public health protection as the HARPC and Produce Safety regulations.[24] Finally, very small importers must document annually that they meet the requirements of the definition of very small importer in 21 C.F.R. § 1.500, while importers of food from certain small foreign suppliers must document annually that they meet the criteria specified in 21 C.F.R. § 1.512(a)(2) relating to small foreign suppliers.

***

We will continue to monitor and report on FDA's activities to implement the FSVP requirements and other FSMA related activities.

(…continued)
the following requirements: (1) the foreign supplier is a qualified facility as that term is defined in 21 C.F.R. § 117.3 or § 507.3; (2) the foreign supplier is a farm that grows produce but is not a covered farm under 21 C.F.R. part 112; or (3) the foreign supplier is a shell egg supplier that is not subject to the requirements of 21 C.F.R. § 118 because it has fewer than 3,000 laying hens.

[24] Some additional modified requirements under the FSVP rule applicable to very small importers and importers of food from certain small foreign suppliers are set forth in 21 C.F.R. § 1.512(b)-(c).