Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

From: Joseph A. Levitt
Elizabeth Barr Fawell
Maile Gradison Hermida

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Re: **FDA Issues FSMA Final Rule on Foreign Supplier Verification Programs**

The Food and Drug Administration (FDA) recently issued its final rule addressing Foreign Supplier Verification Programs (FSVPs) under the FDA Food Safety Modernization Act (FSMA). 1/ The regulation parallels the supplier verification provisions of the preventive controls regulations, requiring "importers" to develop and implement supplier verification programs for food imported to the United States. The rule takes effect for most importers in 18 months (May 2017).

FSVP represents a paradigm shift, as it is the first time that FDA has regulated food importers. The requirements under the new regulation are very detailed and record-intensive, likely necessitating careful attention by all food importers—including retailers, brokers, and food companies importing finished goods. The regulation will have less impact on facilities that are subject to preventive controls, as they are deemed in compliance with FSVP because the supply-chain oversight requirements in both rules are essentially the same. This memorandum provides an overview of the key provisions of the FSVP final rule.

Highlights of Key Provisions

A. Scope

All "importers" of "food" into the U.S. are required to develop, maintain, and follow an FSVP. The FSVP must provide adequate assurances that their "foreign supplier" is producing food in compliance with processes and procedures that provide at least the same level of public health protection as those required under the preventive controls or produce safety regulations, if applicable, and with the prohibitions on adulteration and misbranding due to the presence of undeclared allergens. Below, key issues relating to the scope of the regulation are discussed.

"Importer" Definition

FSVP obligations apply for the "importer" of food. This is defined as the "U.S. owner or consignee of an article of food that is being offered for import into the United States." Further, the "U.S. owner or consignee" is defined as "the person in the United States who, at the time of U.S. entry either owns the food, has purchased the food, or has agreed in writing to purchase the food." If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed

1/ The final rule will be published in the Federal Register on November 27, 2015.

statement of consent to serve as the importer. The U.S. agent designated for purposes of FSVP can be a different U.S. agent than designated for purposes of facility registration.

"Food" Definition

The FSVP applies to all "food" imported into the U.S., unless it is specifically exempted. "Food" has the same broad definition as in the Federal Food, Drug, and Cosmetic Act (FFDCA) 2/, except that pesticides are exempted. This means that food contact substances (e.g., food packaging) are not exempt from supplier verification, despite industry comments urging an exemption. Likewise, the regulation applies to food-grade chemicals reasonably expected to be directed to a food use, raw agricultural commodities exempt from the produce safety rule, and live animals intended for consumption. Exemptions are discussed later in this memorandum.

"Foreign Supplier" Definition

Importers are required to verify their "foreign supplier," which is defined as "the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing that consists solely of the addition of labeling or any similar activity of a de minimis nature." Thus, in some instances the supplier requiring verification may not be the immediate previous source of the food.

Importers Subject to Preventive Controls

Importers are deemed in compliance with FSVP if they are a receiving facility under the preventive controls regulation and:

1) Implement preventive controls for the hazards in the food;
2) Implement a supply chain program under preventive controls; or
3) Are not required to implement a preventive control because: (i) the food could not be consumed without applying a control, or (ii) they rely on someone later in the supply chain to control the hazard and have appropriate documentation.

However, such importers still are required to identify the FSVP importer at entry, as discussed below.

Intra-Company Shipments

The regulation does not exempt or offer any modified requirements for intra-company shipments. This means that if, for example, a company imports finished product from its own manufacturing facility located outside of the United States, the company must have an FSVP for this food. However, a company may take account of the fact that imports are intra-company when determining appropriate verification activities (e.g., determining that an annual audit is not necessary).

B. General Requirements

The FSVP regulation requires food importers to (1) identify and evaluate the hazards in the foods they import, (2) evaluate their supplier's performance and the risk presented by the food, (3) conduct supplier verification activities, (4) engage in corrective actions, as needed, (5) reevaluate hazards and reassess the program periodically, and (6) document everything. This is consistent with the supply-chain program requirements in the preventive controls regulations.

2/ "The term 'food' means (1) articles used for food or drink or man or other animals, (2) chewing gum, and (3) articles used for components of any such article." FFDCA § 201(f).

Hazard Analysis

Importers must determine the hazards reasonably likely to cause illness or injury with each food they import. The hazard analysis requirements are nearly identical to those in the preventive controls regulations, requiring (1) identification of known or reasonably foreseeable hazards in each food; and (2) evaluation of the identified hazards to assess the probability that the hazard will occur in the absence of controls and the severity of the illness or injury if the hazard were to occur. Importers can conduct their own hazard analysis, or review and assess a hazard analysis conducted by another entity.

If the importer determines that there are no hazards requiring a control, they are not required to conduct an evaluation of their suppliers or engage in supplier verification activities. As discussed below in the section on modified requirements, importers of fruits or vegetables that are "covered produce" under the produce safety rule cannot conclude that there are no hazards requiring a control.

Evaluation of Supplier Performance and Food Risk

Importers must evaluate the risk posed by each imported food, using the results of the hazard analysis, and evaluate the foreign supplier's performance. There are a number of specified factors that must be considered when conducting this evaluation, including FDA compliance actions (e.g., Import Alerts; Warning Letters) and the supplier's food safety history. Importers also can review and assess another entity's evaluation or reevaluation of a foreign supplier's performance and the risk posed by a food. Importers must approve their foreign suppliers on the basis of this evaluation.

FDA explains in the preamble that importers may use a risk matrix or risk tier system to help them approve foreign suppliers and determine appropriate verification activities for particular foods and suppliers, but this alone is not adequate. FDA explains: "[I]mporters must document, for each food and its foreign supplier, the evaluation of the food and the supplier and the determination of the appropriate type and frequency of supplier verification activities based on that evaluation."

Importers must promptly reevaluate the supplier performance and food risk factors when they become aware of new information associated with these factors. Importers also must determine whether it is appropriate to continue to import the food from the supplier and whether the verification activities need to be changed. A reevaluation is required at least every 3 years.

Verification Activities

Based on the risk evaluation, importers must determine which verification activity (or activities) to apply and the frequency for such activities. The following are appropriate supplier verification activities:

- Onsite audits
    - Audits must consider any FDA food safety regulations applicable to the food and include a review of the supplier's food safety plan (if any) and its implementation for the hazard being controlled. Audits can be conducted by an audit agent of a certification body accredited through the FDA process without being subject to the requirements in that regulation, so long as the audit is conducted solely to meet FSVP requirements. In limited situations, inspection results also can be substituted for an audit.
- Sampling and testing
- Review of the foreign supplier's relevant food safety records
- "Other appropriate supplier verification activities"

If the supplier controls a hazard for which there is a reasonably probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA) 3/, there is a presumption that the supplier will be subject to an annual onsite audit. However, the importer can override this presumption with an adequate written determination that less frequent audits or other supplier verification activities are appropriate.

In the preamble, FDA addresses the question of whether existing third-party audits will be adequate to meet FSVP requirements. The agency responds:

> [I]t is premature to reach any definitive conclusions as to whether importers can rely on the results of audits conducted under any existing auditing schemes to verify compliance with the safety requirements of this rule. Over time, we expect that scheme owners and benchmarking organizations will develop tools to assess their schemes against FDA requirements to demonstrate the levels of health protection their schemes provide. Until such time, if an importer choses to use a GFSI, GAP, or other similar audit, the importer might need to supplement that audit to meet the requirements of [the FSVP regulation] or otherwise determine that the audit meets the requirements of this section.

Importers also can rely on a determination and/or performance of appropriate supplier verification activities made by a third-party (except for the foreign supplier itself), so long as the importer reviews and assesses whether the determination is appropriate and/or reviews and assesses the results of these activities. Importers are not required to retain documentation of supplier verification activities conducted by other entities, provided they can obtain the documentation and make it available to FDA.

Use of Approved Suppliers

Importers must follow written procedures to ensure that they only import foods from approved foreign suppliers. Use of these procedures must be documented. Food can be sourced on a temporary basis (e.g., weather-related crisis; supplier equipment breakdown) from unapproved foreign suppliers, so long as importers conduct adequate verification activities before importing the food. An entity other than a foreign supplier can establish such procedures, so long as the importer reviews and assesses that entity's documentation.

Hazards Requiring Control Downstream

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. If an imported food cannot be consumed without the hazards being controlled (e.g., raw agricultural commodities such as cocoa beans and coffee beans), or if the hazards are controlled by an entity downstream from the importer, the importer is not required to conduct an evaluation of supplier performance and food risk, or to engage in supplier verification activities.

In the latter situation, the regulation requires (1) documents accompanying the food to disclose that the food is "not processed to control [identified hazard]"; and (2) importers to obtain annual written assurance from their customer that the hazards will be appropriately controlled or that they will obtain such written assurance from their customer. This documentation requirement parallels provisions of the preventive controls regulations and requires particular attention by importers as they prepare for compliance.

3/ This is the Class I recall standard. Class I recalls typically include issues involving pathogens or undeclared allergens.

Corrective Actions

Importers must take corrective actions if they determine that their foreign supplier does not produce food in compliance with the FFDCA (or processes and procedures that provide the same level of public health protection). The regulations provide that this determination could be based on a review of consumer, customer, and other complaints related to food safety, but there is not requirement to review such complaints (unlike in the proposed rule, which did require such a review). If an importer determines through means other than verification activities or reevaluation that a foreign supplier does not produce food in compliance, the importer must promptly investigate to determine whether their FSVP is adequate and, when appropriate, modify their FSVP.

Identification of Importer at Entry

The importer must provide their name, email address, and "unique facility identifier recognized as acceptable by FDA" for each line entry of food offered for importation into the United States. FDA anticipates that it will issue a guidance document that recognizes Dun & Bradstreet Data Universal Numbering System (DUNS) numbers as being acceptable facility identifiers. FDA also explains in the preamble that it will allow importers to request use of different identification numbers, but it is possible that FDA's information technology systems will not be able to accommodate any numbers other than those that the agency may specifically recognize as acceptable in guidance, in which case FDA would have to manually review entry submissions that include alternate unique facility identifiers.

Reliance on Other Entities

In a significant revision to the proposed rule and supplemental proposed rule, the final rule recognizes the challenges that supplier verification can pose for importers who are not experienced with food safety or when the foreign supplier is not the immediate source of the imported food (e.g., for consolidated raw agricultural commodities). The regulation provides for importers to rely on assessments conducted or activities performed by other entities, as also referenced in the discussion above. An importer may review and assess hazard analyses, evaluations of the risk posed by a food and the foreign supplier's performance, determinations of appropriate foreign supplier verification activities, and results of such activities conducted by other entities for an imported food. The importer must document their review and assessment.

Qualifications

A "qualified individual" must develop the FSVP and perform each of the required activities. "Qualified individual" is defined as "a person who has the education, training, or experience (or combination thereof) necessary to perform an activity required under [the FSVP regulation], and can read or understand the language of any records that the person must review in performing this activity." This is consistent with the preventive controls regulation, in that the person or people responsible for the FSVP must have adequate experience to perform the activities they are engaging in—but there is no requirement to be qualified to perform all FSVP activities or to be a "preventive controls qualified individual."

Audits must be performed by a "qualified auditor," which is defined as a "qualified individual" who "has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function."

C. Recordkeeping and Records Access

Recordkeeping

The FSVP regulation requires nearly every activity to be documented. Unlike the preventive controls regulation, however, there is no single regulation that summarizes all of the records that need to be maintained. Rather, the regulation identifies documentation requirements throughout. The general recordkeeping requirements are as follows:

- All records concerning the FSVP must be signed and dated upon initial completion and any modification.
- Records must be retained for at least 2 years after they are created, obtained, or after their use is discontinued (for documents like procedures).
- Records can be stored offsite, so long as they are accessible within 24 hours. They also can be stored electronically and electronic records are exempt from 21 CFR Part 11.
- Records are not required to be maintained in English (unlike in the proposed rule), but upon FDA request importers must provide FDA with an English translation within a reasonable time.
- Records are subject to public disclosure under the Freedom of Information Act (FOIA), but are subject to the FOIA exemptions for issues such as trade secrets and confidential commercial information. FDA acknowledges that many FSVP records will be exempt from public disclosure (e.g., evaluations of foreign supplier performance; results of onsite audits).

FDA's Records Access Authority

All required records must be made available to FDA, upon request, for inspection and copying. Significantly, the regulation provides FDA with remote records access. This means that if requested in writing by FDA, importers must send records to the agency electronically (or through another prompt means) rather than making the records available for review at their place of business.

The remote records access requirement runs counter to many industry comments during the rulemaking, which urged FDA not to finalize this aspect of the proposal and questioned the agency's legal authority for doing so. FDA explains in the preamble that remote records access will enable the agency to more efficiently review importers' FSVP records, therefore allowing for more FSVP inspections to be conducted. The agency distinguishes from preventive controls inspections where a critical component of the inspection may be viewing the facility and conditions in person, and reviewing the records in context, because often an FSVP can be evaluated entirely by reviewing the records provided. FDA also rejected arguments that such a requirement is contrary to Congressional intent and beyond the scope of the statute.

D. Exemptions and Modified Requirements

Exemptions

The FSVP regulation does not apply to the following:

1. Suppliers covered by the seafood or juice HACCP regulations;

2. Raw materials or ingredients for use in a food produced under the seafood or juice HACCP regulations;

3. Food imported for research or evaluation, provided that such food:
    a. Is not intended for retail sale and is not sold or distributed to the public;
    b. Is labeled with the statement "Food for research or evaluation use";
    c. Is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is only used for this purpose, and any unused quantity is properly disposed of; and
    d. Is accompanied, when filing entry with U.S. Customs and Border Protection, by an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public 4/;

4. Food imported for personal consumption, provided that such food is not intended for retail sale and is not sold or distributed to the public;

5. Alcoholic beverages;

6. Food that is transshipped through the United States to another country and is not sold or distributed to the public in the U.S.;

7. Food that is imported for processing and future export and that is not sold or distributed to the public in the U.S.;

8. U.S. food returned (i.e., food manufactured, raised, or grown in the U.S., exported, and returned here without further processing in a foreign country); and

9. Meat, poultry, and egg products subject to USDA jurisdiction.

Modified Requirements

1. Raw Fruits and Vegetables

For imports of fruits or vegetables that are "covered produce" as defined under the produce safety regulation 5/, the hazard analysis is not required to assess biological hazards. This is because biological hazards in such fruits or vegetables always require a control under the produce safety regulation, so the foods are presumed to present such hazards. However, importers must determine whether there are any other types of hazards requiring control in such foods (e.g., chemical hazards, physical hazards). Imported fruits or vegetables that are "covered produce" always require supplier verification (e.g., produce that will not receive commercial processing that adequately reduces the presence of microorganisms of public health significance and/or lacks appropriate documentation of such treatment; produce designated as "rarely consumed raw"). Further, there is a presumption that "covered produce" will be subject to an annual audit (because the produce safety rule controls for SAHCODHA microbiological hazards), unless the importer makes an adequate written determination that this is not necessary.

4/ Note that the research and development exemption could extend to imported samples of a competitor's food.

5/ Our memorandum regarding the produce safety regulation provides additional information regarding the meaning of "covered produce."

2. Low-Acid Canned Foods (LACF)

For imports of LACF produced under 21 CFR Part 113, importers must verify and document that the food was produced in accordance with Part 113. Additionally, an FSVP is required for non-microbiological hazards in such foods.

For raw materials or other ingredients that are imported for use in manufacturing LACF under Part 113, the FSVP does not need to address microbiological hazards. However, an FSVP is required for all non-microbiological hazards in the imported foods.

3. Dietary Supplements

The requirements for dietary supplements vary according to a number of factors, including whether the import is a finished product or an ingredient/component. Although dietary supplement manufacturers and ingredients for use in dietary supplements are not exempt from FSVP, they generally are subject to less stringent requirements.

4. Comparability/Equivalence

Many of the standard FSVP requirements do not apply to food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the U.S. In particular, importers must determine and document whether the foreign supplier is in good compliance standing with the food safety authority of the country in which the foreign supplier is located. New Zealand currently is the only country determined to meet these criteria, but Canada is actively being considered for this status and other countries are likely to be considered over time.

5. Very Small Importers and Certain Small Foreign Suppliers

The FSVP regulation has modified requirements for "very small importers," defined as importers that average less than $1 million per year in sales of human food and $2.5 million per year in sales of animal food (as a 3-year average). Very small importers must document their status annually. They also must obtain written assurance at least every 2 years for each food they import that their foreign supplier is producing food in compliance with the FFDCA (or with processes and procedures that provide the same level of public health protection).

Additionally, modified requirements apply to imports from the following small foreign suppliers: (1) a qualified facility under the preventive controls regulations; (2) produce from a farm that grows produce and is not covered by the produce safety rule; or (3) shell eggs from a foreign supplier that is not subject to the shell egg rule because it has fewer than 3,000 laying hens. Importers must obtain written assurance annually that their foreign suppliers meet such criteria. At least every 2 years, they must obtain certain written assurances from their suppliers regarding compliance. Additional requirements apply if food is imported from such small foreign suppliers and the importer is not a very small importer.

E. Compliance Dates

Importers need to comply by the latest of the following dates:

- 18 months after publication of the final rule (May 2017);
- For importation of food from a supplier subject to preventive controls or the produce rule, 6 months after the foreign supplier is required to comply with the relevant regulations; or

- For an importer that also is subject to the supply-chain program provisions in the preventive controls rule, the date the importer (as a receiving facility) is required to comply with the supply-chain program provisions of the preventive controls regulation.

F. Enforcement

FSVP inspections will be records-based and generally will occur where FSVP records are kept (e.g., importers offices). The results of FSVP inspections will be incorporated into the PREDICT system to better target food imports based on risk. Failure to comply with FSVP can result in refusal of admission of imported food. FDA is developing guidance on FSVP implementation that will provide additional insight on the agency's expectations and enforcement plans.

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We will continue to closely monitor all developments related to FDA's implementation of FSMA. If you have any questions regarding the final rules and how to ensure compliance with them, please do not hesitate to contact us.