Food Safety Modernization Act FSVP & VQIP

Perry Johnson Registrars Food Safety, Inc.

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Perry Johnson Registrars Food Safety, Inc.

- Founded by Perry L. Johnson in 2012
- Global third party certification body headquartered in Troy, Michigan USA
- Accredited by American National Standards Institution (ANSI) for SQF, BRC, GLOBALG.A.P. certification schemes.
- Accredited by ANSI and recognized by the FDA for FSMA-FSVP/VQIP

Food Safety Modernization Act

- Shifts responsibility from responding to a foodborne illness to preventing it
- Comprised of 7 Major rules:
  - Preventive Controls for Human Food
  - Preventive Controls for Animal Food
  - Produce Rule
  - Foreign Supplier Verification Program
  - Voluntary Qualified Importer Program (VQIP)
  - Sanitary Transportation Rule
  - Accredited Third-Party Certification

Foreign Supplier Verification Program (FSVP)

- Mandates requirements for importers responsible for bringing food into the United States
- Requires assurances that foreign suppliers of the imported food products are complying with applicable FSMA rules
  - Preventive Control for Human Food
  - Preventive Control for Animal Food
  - Produce Rule
- Requires importers to perform risk based supplier verification activities

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FSVP Exemptions

- FSVP Exemptions include:
  - Meat, poultry and egg products that are subject to USDA regulation at the time of entry
  - Fish and Fishery Products in compliance with Seafood HACCP Regulations (Part 123)
  - Juice in compliance with Juice HACCP Regulations (Part 120)
  - Alcoholic beverages
  - Food imported for research or evaluation
  - Food imported for personal consumption
  - Food that is transshipped through the USA
  - Food that is imported for processing and export
  - Food that is exported and returned without further manufacturing/processing in a foreign country

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FSVP Requirements for Imported Food

- Importers must develop a Food Safety Verification Program for each food from each supplier brought into the United States.

- An FSVP is a program showing that the food is produced in a manner that provides the same level of public health protection as the preventive controls or produce safety regulations.

Importer Responsibility

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

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Supplier Verification

- Importers have the flexibility to tailor supplier verification activities to unique food risks and supplier characteristics. The options include:
  - Annual on-site audits of the supplier's facility
  - Sampling and testing
  - A review of the supplier's relevant food safety records

- PJRFSI can perform the annual on-site audit of the supplier's facilities either as an consultative or regulatory audit.

Voluntary Qualified Importer Program (VQIP)

- The Voluntary Qualified Importer Program (VQIP) is a voluntary fee-based program that provides expedited review and import entry of human and animal foods into the United States for participating importers.

- Participating importers will be able to import their products to the U.S. with greater speed and predictability, avoiding unexpected delays at the point of import entry.

VQIP Application Period

- Current application opened early on Oct 1, 2018. It will be open until May 31, 2019. Benefits will begin Oct 1, 2019 through Sept 29, 2020.
- Typically open from January 31-May 31 for the next benefit year Oct 1-Sept 29.
- Letter of intent and application sent through FDA website: https://www.access.fda.gov/

Benefits of VQIP

- *Quicker, easier entry*
- *Limited examination and sampling*
- *FDA sampling at preferred location*
- *Faster lab results*
- *Help Desk*

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VQIP Eligibility

- You have a 3-year history of importing food into the United States.
- You have a Data Universal Numbering System (DUNS) number.
- None of the foods you import, including ones you do not intend to include in your VQIP application, is subject to an import alert or Class 1 recall at the time you submit your application.
- Neither you nor the non-applicant entities associated with a VQIP food are subject to an ongoing FDA administrative or judicial action
- You develop and implement a VQIP Quality Assurance Program (QAP).
- Within the past 3 years, you have not been the subject of any U.S. Customs and Border Protection penalties, forfeitures, or sanctions that are related to the safety and security of any FDA-regulated product that you imported or offered for import.
- You must pay the user fee before October 1, the start of VQIP fiscal year, each year that you are approved to participate in the VQIP.

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VQIP Eligibility

- If you are the FSVP or HACCP importer (U.S. owner or consignee at the time of entry into the United States or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the U.S.) for a VQIP food, you are in compliance with the supplier verification and other importer responsibilities under the applicable FSVP, juice HACCP, or seafood HACCP regulations.
- If you are not the FSVP or HACCP importer for a VQIP food, you must identify the FSVP or HACCP importer for the food and ensure that the FSVP or HACCP importer is in compliance with the applicable FSVP or HACCP regulations.

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VQIP Eligibility – Foreign Facility Certification

- VQIP application requires a foreign facility certification for each foreign supplier of the food you intend to import under the VQIP.
- Only a Third Party Certification Body accredited by a recognized body by the FDA can perform the audits and issue the certificates.
- PJRFSI is accredited by American National Standard Institute (ANSI). ANSI is recognized by the FDA.

PJRFSI FSMA Accreditation

FSVP Scope of Accreditation

- Preventive Controls for Human Food (PC) (Part 117)
- HACCP (Juice) (Part 120)
- HACCP (Seafood) (Part 123)
- Produce (Part 112)
- Acidified Foods (Part 114)
- Low Acid Canned Food (Part 113)
- Infant Formula (Part 106)
- Shell Eggs (Part 115, Part 118)
- PC for Animal Food (Part 507)
- Dietary Supplements (Part 111)

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PJRFSI FSMA Accreditation

- PJRFSI is accredited to conduct both consultative audits and regulatory audits

VQIP Regulatory Certification Scope of Accreditation

- Part 112 Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption
- Part 117 Current Good Manufacturing Practice, Hazard Analysis and Risk Based Preventive Controls for Human Food
- Part 120 Hazard Analysis and Critical Control Point (HACCP) [Juice HACCP]
- Part 123 Fish and Fishery Products [Seafood HACCP]

PJRFSI Consultative Audits

- Consultative audits can be used as a gap assessment for the foreign supplier against the applicable FSMA rules

- Consultative audits can also be used supplier verification activity to meet the requirements of FSVP

Regulatory Audits for VQIP

- Regulatory audits can be completed specifically for VQIP application.
- The foreign supplier can have a regulatory audit at any time and the certificate (certificate number) is required to be submitted with the VQIP application.

Regulatory Audits for FSVP Requirements

- Regulatory audits can be requested by the importer or by the foreign food producer.
- The regulatory audit and certificate can be used by the foreign facility to submit to their importer to show compliance to the applicable regulations.
- The certification can be used meet supplier verification FSVP requirements.
- PJRFSI is the only Certification Body accredited by ANSI and approved by FDA to complete these audits and issue a certificate.

Regulatory Audit Information

- 2 Stage Audit
- Stage I – Document audit offsite
- Stage II – Regulatory Unannounced Audit
- Based on 30 day operating window
- Audit Report will be uploaded to the FDA audit portal
- Any non-conformities must be closed out before certification can be granted
- Any serious threat to public health will be reported to PJRFSI immediately and PJRFSI reports to FDA immediately
- Certificate is valid for 1 year

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Any questions?

Thank you for you time