FDA-FSMA Foreign Supplier Verification Program (FSVP) & Voluntary Qualified Importer Program (VQIP)

FDA has established a voluntary program for the expedited review and importation of foods from importers who achieve and maintain a high level of control over the safety and security of their supply chains. This control includes importation of food from facilities that have been certified in accordance with FDA's program for Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications as well as other measures that support a high level of confidence in the safety and security of the food they import.

Voluntary Qualified Importer Program (VQIP) is applicable only to the importer of food into the U.S. Importers participating in VQIP will receive expedited entry into the United States for all foods included in an approved VQIP application (VQIP foods). FDA will set screening in its Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) import-screening system to recognize shipments of food, which are the subject of an approved VQIP application to expedite the entry of such food.

For the purposes of VQIP, the importer is defined as the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States (section 806(g) of the FD&C Act). A VQIP importer can be located outside the United States. Persons who may be a VQIP importer include the manufacturer, owner, consignee, and importer of record of a food, provided that the importer can meet all the criteria for participation described in this guidance.

Perry Johnson Registrar Food Safety Inc., (PJRFSI) offers certification under section 806(d) of the FD&C Act and other certification services to importers and foreign facilities under the FSMA Rules.

This includes,

a. Doing assessment or audits of the importers against FSVP Rules and issuing a certificate;
b. Doing audits of the foreign suppliers of importers against the applicable preventive control rules and certifying them under VQIP; or,
c. Doing the facility or product certification of foreign suppliers when FDA requires under specified conditions.

1 References

1.1. Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications

1.2. Foreign Supplier Verification Programs for Importers of Food for Human and Animals
1.3. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Food For Humans
1.4. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Food For Animals
1.5. Sanitary Transport of Human and Animal Food
1.6. Focused Mitigation Strategies to Protect Food Against Intentional Adulteration
1.7. 21 CFR Part 11 Electronic Records
1.8. ISO/IEC 17065: Conformity Assessment – Requirements for Bodies Certifying Products, Processes and Services (latest revision)
1.9. #FS-1fsma – Food Safety Certification Questionnaire/Client Application
1.10. #F-207 – Food Safety Quote Approval and Audit Justification Checklist
1.11. #F-3fsma – Certification Agreement
1.12. #F-3tc – Terms and Conditions
1.13. #F-71fs65 – Certification Personnel Statement of Availability Form
1.14. #F-163fsi – Audit Scheduling Acknowledgement Form
1.15. #F-27fsi – Auditor Assignment Form
1.16. #WBfs65 – Auditor Workbook with Opening/Closing Meeting Minutes
1.17. #F-184fs65-A – Onsite Audit Plan
1.18. #F-67fs65 - Audit Package Review Form – Food Safety Programs
1.19. #F-67fs65-A, Audit Report Review Form - Food Safety Programs
1.20. #F-144fsi Transfer of Certification Body Checklist
1.21. #F-108FSMA Stage 1 FSMA Readiness Confirmation
1.22. # FS-0102FSMA Mandatory CFR Reference Sheet
1.23. #SOP-10 Dispute/Appeal Procedure
1.24. PJView – PJRFSI's client database and project management system
1.25. Sharepoint – PJRFSI document portal

2 Definitions

2.1 Accredited third-party certification body – a third-party certification body that a recognized accreditation body (or, in the case of direct accreditation, FDA) has determined meets the applicable requirements of this subpart and is accredited to conduct food safety audits and to issue food or facility certifications to eligible entities. An accredited third-party certification body has the same meaning as accredited third-party auditor as defined in section 808(a)(4) of the FD&C Act.

2.2 Accreditation – a determination by a recognized accreditation body (or, in the case of direct accreditation, by FDA) that a third-party certification body meets the applicable requirements of this subpart. Accreditation body means an authority that performs accreditation of third-party certification bodies.

2.3 Assessment (with respect to an accreditation body) – an evaluation by FDA of the competency and capacity of the accreditation body under the applicable requirements of this subpart for the defined scope of recognition. An assessment of the competency and capacity of the accreditation body involves evaluating the competency and capacity of the operations of the accreditation body that are relevant to decisions on recognition and, if recognized, an evaluation of its performance and the validity of its accreditation decisions under the applicable requirements of subpart M.

2.4 Assessment (with respect to a third-party certification body) – an evaluation by a recognized accreditation body (or, in the case of direct accreditation, FDA) of the competency and capacity of a third- party certification body under the applicable requirements of this subpart for the defined scope of accreditation. An assessment of the competency and capacity of the third-party certification body involves evaluating the competency and capacity of the operations of the third-party certification body that are relevant decisions on accreditation and, if accredited, an evaluation of its performance and the validity of its audit results and certification decisions under the applicable requirements of subpart M.

2.5 Audit – the systematic and functionally independent examination of an eligible entity under this subpart

by an accredited third-party certification body or by FDA. An audit conducted under subpart M is not considered an inspection under section 704 of the FD&C Act.

2.6 Audit agent – an individual who is an employee or other agent of an accredited third-party certification body who, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party certification body. An audit agent includes a contractor of the accredited third-party certification body but excludes subcontractors or other agents under outsourcing arrangements for conducting food safety audits without direct control by the accredited third-party certification body

2.7 Consultative audit – an audit of an eligible entity: (i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and industry standards and practices; (ii) The results of which are for internal purposes only; and (iii) That is conducted in preparation for a regulatory audit; only the results of a regulatory audit may form the basis for issuance of a food or facility certification under this subpart.

2.8 Direct accreditation – accreditation of a third-party certification body by FDA

2.9 Eligible entity – a foreign entity in the import supply chain of food for consumption in the United States that chooses to be subject to a food safety audit under this subpart conducted by an accredited third-party certification body. Eligible entities include foreign facilities required to be registered under subpart H of this part

2.10 Facility – any structure, or structures of an eligible entity under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, holds, grows, harvests, or raises animals for food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. 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. The private residence of an individual is not a facility. Non-bottled water drinking water collection and distribution establishments and their structures are not facilities. Facilities for the purposes of this subpart are not limited to facilities required to be registered under subpart H of this part.

2.11 Facility certification means an attestation, issued for purposes of section 801(q) or 806 of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a facility complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

2.12 Food has the meaning given in section 201(f) of the FD&C Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

2.13 Food certification – an attestation, issued for purposes of section 801(q) of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a food of an eligible entity complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

2.14 Food safety audit – a regulatory audit or a consultative audit that is conducted to determine compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and for consultative audits, also includes conformance with industry standards and practices. An eligible entity must declare that an audit is to be conducted as a regulatory audit or consultative audit at the time of audit planning and the audit will be conducted on an unannounced basis under this subpart.

2.15 Foreign cooperative – an autonomous association of persons, identified as members, who are united through a jointly owned enterprise to aggregate food from member growers or processors that is intended for export to the United States.

2.16 Recognized accreditation body – an accreditation body that FDA has determined meets the applicable requirements of this subpart and is authorized to accredit third-party certification bodies under this subpart.

2.17 Regulatory audit – an audit of an eligible entity: (i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations; and (ii) The results of which are used in determining eligibility for certification under section 801(q) or under section 806 of the FD&C Act.

2.18 Relinquishment (With respect to an accreditation body) – a decision to cede voluntarily its authority to accredit third-party certification bodies as a recognized accreditation body prior to expiration of its recognition under this subpart; and (With respect to a third-party certification body) – a decision to cede voluntarily its authority to conduct food safety audits and to issue food and facility certifications to eligible entities as an accredited third-party certification body prior to expiration of its accreditation under this subpart.

2.19 Self-assessment – an evaluation conducted by a recognized accreditation body or by an accredited third-party certification body of its competency and capacity under the applicable requirements of this subpart for the defined scope of recognition or accreditation. For recognized accreditation bodies this involves evaluating the competency and capacity of the entire operations of the accreditation body and the validity of its accreditation decisions under the applicable requirements of this subpart. For accredited third-party certification bodies this involves evaluating the competency and capacity of the entire operations of the third-party certification body and the validity of its audit results under the applicable requirements of this subpart.

2.20 Third-party certification body has the same meaning as third-party auditor as that term is defined in section 808(a)(3) of the FD&C Act and means a foreign government, agency of a foreign government, foreign cooperative, or any other third party that is eligible to be considered for accreditation to conduct food safety audits and to certify that eligible entities meet the applicable food safety requirements of the FD&C Act and FDA regulations. A third-party certification body may be a single individual or an organization. Once accredited, a third-party certification body may use audit agents to conduct food safety audits.

2.21 Certificate - A certificate and associated documents affirming that the Facility has, as a result of the documented assessment procedure conducted by PJRFSI, been found to be in accordance with the applicable Federal Requirement.

2.22 Executive Committee – the PJRFSI committee comprised of individuals who are competent to review audit results and render certification recommendations.

2.23 Designee – a PJRFSI employee who is designated and trained to complete specific procedural functions on behalf of another PJRFSI position. Throughout this SOP-1FSMA procedure, functions which may be completed by a designee will include the following references: “[position] or designee…” or “[position]/designee…”

3 Request for Certification

3.1 The Applicant initiates the application for certification process via a written or verbal request.

3.2 In response, a PJRFSI Project/Sales Manager or the Food Safety Program Coordinator or designee or appropriate International Division Manager provides the Applicant with the #FS-1fsma – Food Safety Certification Questionnaire/Client Application.

3.3 Duly Authorized representatives of the Applicant must complete and sign the Questionnaire/Application to provide PJRFSI with sufficient information required for providing a quote. This should include,

- Scope and purpose of food safety audits, including facility, process or food to be audited;
- Consultative or regulatory audit
- If regulatory the type of certification (VQIP, FSVP compliance, PC Rules of Human or Animal food, or produce)

- 30-day operating schedule relevant to scope and purpose of audit

3.4 Upon receipt of the signed application, PJRFSI's Food Safety Program Accreditation Manager or designee trained in quoting procedures conducts an application review to ensure that:

a. certification requirements are clearly defined, documented, and understood; and the requested scope is within the scope of accreditation; and PJRFSI has the contractual authority to conduct the audit;
b. any differences in understanding between PJRFSI and the Applicant are resolved; and
c. PJRFSI has the technical resource and competencies to perform the certification services sought by the applicant, and if not, PJRFSIs Food Safety Program Accreditation Manager or designee in consultation with the Technical Specialist will reject the application.

The record of this review is the Food Safety Program Accreditation Manager or designee's signature at the bottom of the #FS-1FSMA Food Safety Certification Questionnaire/Client Application and a completed #F-207FSMA – Food Safety Quote Approval and Audit Duration Justification Checklist. Applications received by International Division Managers will be sent to PJRFSI's Food Safety Program Accreditation Manager or designee trained in quoting procedures for an application review.

3.5 Based on the information furnished by the Applicant and the input from the application review process, the Food Safety Program Accreditation Manager or designee completes an #F-207FSMA which is a record of: the determination of scope including exclusions; the justification for quoted audit days; and the overall quote approval.

3.5.1 PJRFSI may conduct FSMA audits combined with other certification system audits or audit elements, if all program rules are met and the integrity of any one component of the combined audit is not compromised. PJRFSI does not, however, conduct any consulting or training in combination with FSMA audit activity. Details of combined audits are specified on the audit report. Regulatory type third party audits can only be combined with other food safety audits if both audits are unannounced.

3.6 Based on the information from the application review (#FS-1FSMA) and quote approval process (#F-207FSMA), the Food Safety Program Accreditation Manager or designee completes a quotation in the form of a Certification Agreement (#FS-3FSMA) to cover the costs of the proposed audit activity and any associated fees.

3.7 A PJRFSI Project/Sales Manager or designee or appropriate International Division Manager provides the Applicant with a duly authorized copy of the Certification Agreement (#FS-3FSMA), the Terms and Conditions (#FS-3tc), and a summarized version of the Certification Procedure (#SOP-01FSMA). (In some cases, the Certification Agreement and Terms and Conditions are forwarded directly to the Applicant by PJRFSIs Sales Coordinator or the Food Safety Program Accreditation Manager/designee.) The Applicant then signs and returns a copy of the Certification Agreement bearing an original signature.

3.8 Signatures by both parties indicate mutual agreement of Certification Agreement including the scope of certification and any exclusions, the certification costs, and the associated Terms and Conditions. After the Certification Agreement is signed, amendments, agreed upon by both parties, may be made as necessary.

3.9 Receipt of the signed Certification Agreement taken by PJRFSI as an instruction to proceed in accordance with the FSMA Certification Agreement and the Terms and Conditions. The Food Safety Program Accreditation Manager or designee sends the Applicant, hereafter referred to as the Facility, any other guidance documents describing the audit process, as appropriate.

3.10 The Food Safety Program Accreditation Manager or designee is responsible for monitoring and verifying the progress of the Facility's certification program including but not limited to audit/certification status, and timeline/due date performance for both Facility and Certification Body (PJRFSI) activities.

3.11 If the requirements for certification change at any time and need retroactive implementation, PJRFSIs Food Safety Program Accreditation Manager or designee will ensure that the Facility is notified as soon as possible by the most appropriate means and that the new requirements are followed/implemented at the next onsite audit activity or sooner if necessary.

4 Scheduling Audits

4.1 Once the signed Certification Agreement (#FS-3FSMA) is received, the Technical Specialist or designee confirms the audit scope and approves facility's applicable and non-applicable CFRs using the Mandatory CFR Reference Sheet (#FS-0102FSMA). The Mandatory CFRs are recorded as applicable and non-applicable in the client's scope.

4.2 The Food Safety Program Accreditation Manager or designee and assigns a FSMA auditor to the audit after verifying needed competencies and that the Auditor has had no prior relationship with the Facility which would present a conflict of interest. The Auditor will confirm this by signing a Certification Personnel Statement of Availability (#F-71FSMA) before completing the audit.

4.3 Audit protocols. PJRFSI must conduct a food safety audit in a manner consistent with the identified scope and purpose of the audit and within the scope of its accreditation. With the exception of records review, which may be scheduled, the regulatory audit must be conducted without announcement during the 30-day timeframe identified under paragraph (a)(1)(ii) (Provide a 30-day operating schedule for such facility that includes information relevant to the scope and purpose of the audit) and must be focused on determining whether the facility, its process(es), and food are in compliance with applicable food safety requirements of the FD&C Act and FDA regulations.

4.4 For consultative audits, also includes conformance with applicable industry standards and practices that are within the scope of the audit.

4.5 The Facility is assigned to an Audit Program Coordinator (Scheduler) who will contact the availability of the assigned Auditor pre-selected by the Food Safety Program Accreditation Manager or designee. The Scheduler sends the Scheduled Audit Form to the auditor when the dates are confirmed and entered into PJview.

4.5.1 The Scheduler then sends the Facility an Audit Scheduling Acknowledgement form (#F-163fsi) or equivalent document for the Facility to sign and return by fax which indicates:

a. Facility's acceptance of the announced consultative audit or unannounced regulatory audit;
b. Facility's acceptance of the proposed audit team whose background information is available upon request. The Facility has the right to object in writing to the appointment of any particular auditor or technical expert providing the objection is valid, i.e. employee of a competitor, personal differences, etc.
c. Facility's confirmation that all processes/procedures/activities will be ready by the proposed audit date.

4.5.2 The Scheduler then creates an Auditor Assignment Form (#F-27fsi) and forwards it to the Auditor(s) after approval by relevant Customer Service Personnel.

4.5.3 The International Divisions will be responsible for scheduling audits in their respective countries.

4.6 The regulatory audit must include an announced Stage I records review prior to the onsite examination. The regulatory audit must also include an onsite examination of the facility, its process(es), and the food that results from such process(es).

4.7 Authority to audit. In arranging a food safety audit with an eligible entity, the certification body must ensure it has authority, whether contractual or otherwise, to:

a. Conduct a regulatory, unannounced audit to determine whether the facility, process(es), and food of the eligible entity (within the scope of the audit) comply with the applicable food safety requirements of the FD&C Act and FDA regulations and, for non-regulatory type voluntary audits against the applicable FSMA rules (PC rules for Human Food, PC

Rules for Animal Food, Produce Safety Rule conformance with applicable industry standards and practices;

b. Access any records and any area of the facility, process(es), and food of the eligible entity relevant to the scope and purpose of such audit;

4.8 When, for a regulatory audit or when FDA requires certification of specific products, sampling and analysis is conducted, the certification body must use a laboratory that is accredited in accordance with:

a. ISO/IEC 17025:2005; or (ii) Another laboratory accreditation standard that provides at least a similar level of assurance in the validity and reliability of sampling methodologies, analytical methodologies, and analytical results.

b. Notify FDA immediately if, at any time during a food safety audit, the certification body (or its audit agent, where applicable) discovers a condition that could cause or contribute to a serious risk to the public health;

4.9 The audit must be sufficiently rigorous to allow PJRFSI to determine whether the eligible entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. For both regulatory type and non-regulatory type voluntary audits against the applicable FSMA rules (PC rules for Human Food, PC Rules for Animal Food, Produce Safety Rule conformance with applicable industry standards and practices, at the time of the audit must be demonstrated by the Facility. PJRFSI (or its audit agent, where applicable) that identifies a deficiency requiring corrective action may verify the effectiveness of a corrective action once implemented by the eligible entity but must not recommend or provide input to the eligible entity in identifying, selecting, or implementing the corrective action.

4.10 Audit observations and other data and information from the examination, including information on corrective actions, must be documented and must be used to support the findings contained in the audit report.

4.11 Prepare reports of audits as follows:

a. For non-regulatory type voluntary audits against the applicable FSMA rules (PC rules for Human Food, PC Rules for Animal Food, Produce Safety Rule conformance with applicable industry, prepare reports and maintain such records, subject to FDA access in accordance with section 414 of the FD&C Act; and

b. For regulatory audits, prepare and submit them to the Facility and to its recognized accreditation body. Allow FDA and ANSI that accredited PJRFSI, to observe any food safety audit conducted under this subpart for purposes of evaluating PJRFSI's performance or, where appropriate, the ANSI's performance.

c. Audit protocols. The certification body (or its audit agent, where applicable) must conduct a food safety audit in a manner consistent with the identified scope and purpose of the audit and within the scope of its accreditation.

5 Voluntary FSMA Audits

5.1 The voluntary, non-regulatory type audits against the applicable FSMA rules (PC rules for Human Food, PC Rules for Animal Food, Produce Safety Rule, FSVP) are conducted in preparation for a regulatory audit and is for the Facility's internal use. This type of audit assesses the Facility's compliance to the applicable FSMA rules and other federal standards and considers how the Facility meets industry standards and practices.

5.2 The Auditor is responsible for completing the appropriate Audit Workbook (#WBfsma) and creating an Audit Plan using the #F-184fs65-A Audit Plan Template, which will be forwarded to the Facility at least one week in advance of the audit.

5.3 The Facility's senior management personnel, who have the appropriate authority to ensure that corrective actions will be implemented in response to any non-conformities found, are expected to attend the opening and closing meetings for all audit activity. In particular, the most senior operations manager

onsite or their nominated deputy shall be available at the audit and attend the opening and closing meetings. All of the Facility's personnel are expected to fully assist the Auditor at all times.

5.4 The Auditor should audit the Facility's processes and products where they occur. Audit evidence gathered through interviews should be verified by acquiring supporting information from independent sources, such as observations, records, and results of existing measurements. The names, job titles, and working shifts of those interviewed are to be recorded. The Auditor must record copious notes of conformity and nonconformity, including the nature and severity of any nonconformity. These notes serve as the basis for the audit report and will be submitted to PJRFSI with the audit package. Should objective evidence exist to support writing a nonconformity, the following format is used:

a. Citation of the requirement(s) not being met
b. Statement of nonconformity
c. Objective evidence observed that supports the statement of nonconformity

5.5 For multiple day audits, the Auditor must hold a daily wrap-up meeting with the PJRFSI audit team and the Facility's key personnel to discuss a summary of the findings of that day.

5.6 On the last day of the audit, the Auditor will hold a closing meeting using the Closing Meeting Agenda. During this meeting, the Auditor reviews the audit findings, including the non-conformities, with the Facility's senior management personnel.

5.7 At the close of the audit or within one working day of the last day of the audit, the Auditor provides the Facility with a written summary of the non-conformities discussed at the closing meeting.

5.8 The certification body must prepare a report not later than 45 days after completing such audit and must provide a copy of such report to the eligible entity and must maintain such report subject to FDA access in accordance with the requirements of section 414 of the FD&C Act.

5.9 Any deficiencies observed that relate to or may influence a determination of compliance with the applicable food safety requirements of the FD&C Act and FDA regulations that require corrective action, the corrective action plan, and the date on which such corrective actions were completed. Such audit reports must be maintained as a record and must be made available to FDA, if required.

6 Regulatory Audits

6.1 Eligibility (only VQIP): To be eligible to participate in VQIP, importers should meet all of the following criteria:

a. At least a 3-year history of importing food into the United States. Import history may be based on the shared importation history of previous or parent companies, such as those that have been involved in a merger. Import history is based on importation of all foods, including food that may not be covered under VQIP.
b. Have a Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number.
c. Use paperless filers/brokers who received acceptable results during their last FDA Filer Evaluation. The filer/broker is the person responsible for (1) submitting entry and entry summary data on the food into the Automated Commercial System (ACS) or Automated Commercial Environment (ACE) and (2) submitting import documents into the International Trade Auxiliary Communication System (ITACS) or through CBP's Document Imaging System (DIS).
d. No food you import, including a food you do not intend to include under VQIP, is subject to detention without physical examination under an Import Alert or a Class 1 recall at the time you submit your application.
e. Neither you as the importer nor the non-applicant entities associated with a VQIP food are subject to an ongoing FDA administrative or judicial action (e.g., Import Alert, injunction, debarment), or have a history of significant non-compliances relating to food safety (e.g., an "Official Action Indicated" (OAI) FDA inspection classification with no documentation of appropriate corrective actions; one or more voluntary Class 1 recalls relating to food safety). "Non-applicant entities" are those entities associated with a VQIP food that conduct activities

throughout the supply chain necessary for ensuring that the eligibility requirements of VQIP are met. Non-applicant entities associated with a VQIP food include, but are not limited to, the FSVP or HACCP importer of the food (if other than you), the foreign supplier of the food, and the filer/broker.

f. If you are the FSVP or HACCP importer 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 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.

g. You have a current facility certification issued in accordance with FDA's third-party certification program for each foreign supplier of food you intend to import under VQIP.

h. You develop and implement a VQIP Quality Assurance Program (QAP). Your written QAP is submitted with your VQIP application.

i. Within the past 3 years, you have not been the subject of any CBP penalties, forfeitures, or sanctions that are related to the safety or security of any FDA-regulated product that you imported or offered for import.

j. You pay the annual VQIP user fee before October 1 of the year in which you intend to participate. (See Question J.2.)

6.2 PJRFSI undertakes the Regulatory Audits to certify foreign processing/manufacturing/packing/storing/producing facilities to verify the effectiveness of the foreign supplier's food safety system.

6.3 A facility certification is an attestation, issued for purposes of section 801(q) or 806 of the FD&C Act by PJRFSI, after conducting a regulatory audit and any other activities necessary to establish whether a facility complies with the applicable food safety requirements of the FD&C Act and FDA regulations. Any food that an importer wishes to be covered under VQIP should be within the scope of the facility certification.

6.4 An announced document audit referred to as the Stage 1 audit, is conducted prior to the unannounced Regulatory audit. The Stage 1 is conducted offsite and the facility is required to fill out the FSMA Stage 1 Readiness Confirmation Form F-108FSMA and send in a copy of their documentation and records to PJRFSI in advanced of the scheduled audit activity.

6.5 PJRFSI undertakes the Stage 1 audit to verify that the facility's documentation meets the requirements of the applicable FDA regulations and to confirm scope of certification and the products processed.

6.6 If during the Stage 1 or at any time the facility's FDA registration information is incorrect changes must be submitted to the FDA immediately through the FDA Industry System. If changes were submitted to the FDA Industry System but the registration does not reflect those changes,instruct the food facility operator to contact FDA Industry Systems to assure that their registration is correct. They can be reached at:

Phone: 1-800-216-7331 or 240-247-8804 7:30 a.m.-11:00 p.m. Eastern Time
Fax: 301-436-2804 or 1-866-573-0846

6.7 The Auditor is responsible for completing the appropriate Audit Workbook (example, WB-FSMA HF for preventive controls for human food) and any applicable CFR checklist(s). Mandatory CFR must be submitted with the audit report and if they are not applicable, auditor must mark Not Applicable.

6.8 The Facility's senior management personnel, who have the appropriate authority to ensure that corrective actions will be implemented in response to any non-conformities found, are expected to attend the opening and closing meetings for all audit activity. In particular, the most senior operations manager onsite or their nominated deputy shall be available at the audit and attend the opening and closing meetings. All of the Facility's personnel are expected to fully assist the Auditor at all times.

6.9 The unannounced onsite facility audit consists of the following:

a. Opening meeting to confirm the scope and process of the audit. The Auditor will utilize the Opening Meeting Agenda found in the Auditor Workbook Supplement (#WBfsmaSupp).
b. Access any records and any area of the facility, process(es), and food of the eligible entity relevant to the scope and purpose of the audit.
c. Closing meeting to review audit findings with the Facility's management personnel.

6.10 When sampling and analysis is conducted, PJRFSI must use a laboratory that is accredited in accordance with ISO/IEC 17025:2005 or another laboratory accreditation standard that provides similar level of assurance.

6.11 The Auditor should audit the supplier's processes where they occur. Audit evidence gathered through interviews should be verified by acquiring supporting information from independent sources, such as observations, records, and results of existing measurements. The names, job titles, and working shifts of those interviewed are to be recorded. The Auditor must record copious notes of conformity and nonconformity, including the nature and severity of any nonconformity. These notes serve as the basis for the audit report and will be submitted to PJRFSI with the audit package. Should objective evidence exist to support writing a nonconformity, the following format is used:

a. Citation of the requirement(s) not being met
b. Statement of nonconformity
c. Objective evidence observed that supports the statement of nonconformity

6.12 For multiple day audits, the Auditor must hold a daily wrap-up meeting with the PJRFSI audit team and the supplier's key personnel to discuss a summary of the findings of that day.

6.13 On the last day of the audit, the Auditor will hold a closing meeting using the Closing Meeting Agenda. During this meeting, the Auditor reviews the audit findings, including the non-conformities, with the Facility's senior management personnel. When discussing the findings, the Auditor should never comment on the likely outcome of the certification process.

6.14 At the close of the audit or within one working day of the last day of the audit, the Auditor provides the Supplier with a written summary of the non-conformities discussed at the closing meeting.

6.15 The certification body must, no later than 45 days after completing a regulatory (VQIP) audit, prepare and submit electronically, in English, to the Facility or to its recognized accreditation body and must provide a report of such an audit. Whether any sampling and laboratory analysis (e.g., under a microbiological sampling plan) is performed in or used by the facility; and

- Whether the eligible entity has made significant changes to the facility, its process(es), or food products during the 2 years preceding the regulatory audit.

6.16 Submission of VQIP (regulatory) audit report. PJRFSI must submit a completed regulatory audit report regardless of whether PJRFSI issued a food or facility certification to the eligible entity.

6.17 Notice and appeals of adverse regulatory audit results. PJRFSI must notify an eligible entity of a denial of certification and must establish and implement written procedures (SOP-10) for receiving and addressing appeals from eligible entities challenging such adverse regulatory audit results and for investigating and deciding on appeals in a fair and meaningful manner. The appeals procedures must provide similar protections to those offered by FDA.

a. Make the appeals procedures publicly available;
b. Use competent persons, who may or may not be external to the certification body, who are free from bias or prejudice and have not participated in the certification decision or be subordinate to a person who has participated in the certification decision, to investigate and decide appeals;
c. Advise the eligible entity of the final decision on its appeal; and
d. Maintain records of the appeal, the final decision, and the basis for such decision

7 Nonconformities and Corrective Actions

7.1 Once the Auditor has made an observation during the audit, the Supplier, if possible, may take corrective action during the audit. However, the audit report must reflect the condition or status prior to the Facility's corrective actions.

7.2 Regardless of the severity of findings, the Auditor is expected to complete the audit except when extreme circumstances would not allow him/her to do so.

7.3 For Regulatory Audits, the findings, as well as the full audit report, are always subjected to a full technical review by PJRFSIs Executive Committee. If the technical review process results in any change in the findings, the Facility will be notified.

7.4 If during the course of the audit, the Auditor identifies findings which could cause or contribute to a serious risk to public health must notify PJRFSI Technical Specialist to discuss the findings and PJRFSI's Technical Specialist will notify the importer, accreditation body and FDA.

7.5 In the event of a failure to achieve or maintain certification, foreign Facility's, where required by their customers, must notify their customers of the circumstances and the Facility's intended corrective actions.

7.6 No certificate shall be issued until the Facility has corrected all nonconformities permanently or via a temporary solution as accepted by the Technical Specialist or designee.

7.7 For any nonconformity identified, the Facility must:
a. take corrective action to remedy the immediate issue; and
b. undertake a root cause analysis of the nonconformity; and
c. develop a corrective action plan and timeline to address the root cause.

7.8 For all non-conformities, the Facility should submit satisfactory objective evidence to the Auditor within 28 calendar days of the last day of the audit to allow the Auditor time to close the nonconformities by 30 calendar days of the last day of the audit.

7.9 If satisfactory evidence to close out nonconformities is not provided within the 30 calendars days of the first day of the audit, PJRFSI will not grant certification or will withdraw certification as appropriate and the Facility will require an additional full audit to be considered for certification.

7.10 Any required onsite revisit audit will primarily review the effectiveness of the corrective action taken for nonconformities. However, if new nonconformities are identified during the course of the revisit, these nonconformities must also be satisfactorily resolved before a certificate can be issued.

7.11 PJRFSI must notify FDA and ANSI of any changes in a Facility's certified status.

8 Audit Reporting and the Certification Decision

8.1 The Auditor documents the results of the audit using the latest version of the FSMA Audit Report/checklist (WB-FSMA-PR; WB-FSMA-HF; or WB-FSMA-AF) and the WB-FSMA-Supp. The report must be produced or translated into English.

Within thirty (30) calendar days from the last day of the audit, the Auditor submits the preliminary audit report, audit notes, auditor working documents, and Facility's action plan to PJRFSIs Food Safety Program Accreditation Manager or designee to forward to a Technical Reviewer for a preliminary technical and grammatical review. The audit report must include:

Regulatory audits:

- Identity of the site or location where regulatory audit was conducted, including name and address and FDA Establishment Identifier of the facility;
- FDA registration number assigned to the facility under subpart H;
- Name and telephone number of person responsible for compliance;

- Date and scope of regulatory audit
- Process and food observed during regulatory audit;
- Any deficiencies observed during the regulatory audit that present a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death to humans and animals or may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences or death to humans or animals is remote;
- The corrective action plan for addressing each deficiency unless corrective action was implemented immediately and verified onsite by PJRFSI (or its audit agent, where applicable);
- Whether any sampling and laboratory analysis (e.g., under a microbiological sampling plan) is performed in or used by the facility; and (9) Whether the eligible entity has made significant changes to the facility, its process(es), or food products during the 2 years preceding the regulatory audit.

Consultative audits:

- Identity of the site or location where consultative audit was conducted, including name and address and FDA Establishment Identifier of the facility;
- FDA registration number assigned to the facility under subpart H;
- Name and telephone number of person responsible for compliance;
- Date and scope of consultative audit
- Process and food observed during consultative audit;
- Any deficiencies observed and corrective action plans

8.2 PJRFSIs Executive Committee Technical Reviewers are required to sign the #F-71FSMA – Certification Personnel Statement of Availability prior to beginning a review of an audit report or package in order to confirm that they are impartial and free from any conflict of interest. Note: the Auditor who carried out the evaluation may not serve as the Technical Reviewer.

8.3 The PJRFSI Technical Reviewer conducts a preliminary technical and grammatical review of the audit package and documents the review on the Audit Report Review Form (#F-67FSMA), or an equivalent format. If needed the report is returned to the Auditor for clarification or revision. A record of reviews is maintained using the Audit Package Review Form (#F-67FSMA-AP).

8.4 The Auditor submits the final audit report and complete audit package, including the Facility's corrective actions by day 30 after the last day of the audit to the Food Safety Program Accreditation Manager or designee to forward to a Technical Reviewer for the final technical review and certification recommendation.

8.5 The Technical Reviewer completes the final technical review and documents it and certification recommendation on the Audit Report Review Form (#F-67FSMA) or an equivalent format.

8.6 In cases where the Technical Reviewer rejects the package, s/he or the Food Safety Program Accreditation Manager or designee is responsible for contacting the Auditor or Facility for resolution. As appropriate, the Technical Reviewer or other competent designee is responsible for providing any clarification or any additional training to the Auditor.

8.7 FSMA Certification is awarded to foreign Facility's opting for regulatory audits with no outstanding non-conformities, meaning all nonconformities have been corrected and verified by PJRFSI by onsite visit or by other appropriate means. Similarly, certificates will be issued for non-regulatory compliance audits also after all nonconformities have been corrected and verified by PJRFSI by onsite visit or by other appropriate means.

8.8 PJRFSI's Technical Specialist will take certification decision. When the audits are done by PJRFSI's Technical Specialist then the certificate decision is taken by the technical reviewer.

8.9 PJRFSI will submit a completed regulatory audit report to the FDA and Accreditation Body regardless

of whether PJRFSI issued a food or facility certification to the eligible entity.

8.10 If Certification is granted, PJRFSIs Food Safety Program Accreditation Manager or designee notifies PJRFSIs Certificate Department.

8.11 The Certificate Department creates a draft certificate conforming to FSMA requirements and obtains approval of the certificate from the Facility.

8.12 By 45 calendar days following the last day of the audit, PJRFSIs Food Safety Program Accreditation Manager or designee issues the certificate. Delivery of the Certificate and other documents may be delayed until all outstanding invoices have been paid by the Facility.

8.13 For consultative audit reports will be submitted to the Facility by 45 calendar days following the last day of the audit, PJRFSI's Food Safety Program Accreditation Manager or designee will submit the report electronically to the Facility.

8.14 For Regulatory Audits, by 45 calendar days following the last day of the audit, PJRFSIs Food Safety Program Accreditation Manager or designee will submit the audit report electronically, in English, to the FDA and to its recognized accreditation body, and to the Facility.

8.15 Basis for issuance of a food or facility certification.

a. Prior to issuing a food or facility certification to an eligible entity, PJRFSI must complete a regulatory audit and any other activities that may be necessary to determine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations.

b. If, as a result of an observation during a regulatory audit, an eligible entity must implement a corrective action plan to address a deficiency, the certification body may not issue a food or facility certification to such entity until after the certification body verifies that eligible entity has implemented the corrective action plan through methods that reliably verify the corrective action was taken and as a result the identified deficiency is unlikely to recur, except onsite verification is required for corrective actions required to address deficiencies.

c. PJRFSI must consider each observation and the data and other information from a regulatory audit and other activities conducted to determine whether the entity was in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations at the time of the audit and whether the eligible entity, given its food safety system and practices, would be likely to remain in compliance for the duration of any certification.

d. A single regulatory audit may result in issuance of one or more food or facility certifications under this subpart, provided that the requirements of issuance are met as to each such certification. Where the PJRFSI uses an audit agent to conduct a regulatory audit of an eligible entity under this subpart, PJRFSI (and not the audit agent) must make the determination whether to issue a food or facility certification based on the results of such regulatory audit.

e. Any food or facility certification issued under this subpart must be submitted to FDA electronically and in English. PJRFSI may issue a food or facility certification under this subpart for a term of up to 12 months.

f. PJRFSI will maintain on www.PJRFSI.com website an up-to-date list of the eligible entities to which it has issued food or facility FSMA certifications. For each such eligible entity, the Website will identify the duration and scope of the food or facility certification and date(s) on which the eligible entity paid PJRFSI any fee or reimbursement associated with such audit or certification.

8.16 A food or facility certification must contain, at a minimum, the following elements:

a. The name and address of the certification body and the scope and date of its accreditation;
b. The name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, of the eligible entity to which the food or facility certification was issued;
c. The name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, of the facility where the regulatory audit was conducted, if different than the eligible entity;
d. The scope and date(s) of the regulatory audit and the certification number;
e. The name of the audit agent(s) (where applicable) conducting the regulatory audit; and
f. The scope of the food or facility certification, date of issuance, and date of expiration.

8.17 FDA may refuse to accept any certification for purposes of section 801(q) or 806 of the FD&C Act, if FDA determines, that such food or facility certification is not valid or reliable because, for example:
a. The certification is offered in support of the admissibility of a food that was not within the scope of the certification;
b. The certification was issued by PJRFSI acting outside the scope of its accreditation or
c. The certification was issued without reliable demonstration that the requirements of this section were met.

9 Ongoing Audit Frequency and Maintenance of Certification

9.1 In order to maintain Certification, a Facility is required to ensure all nonconformities are corrected within specified timeframes.

9.2 All audits are due within the 45-day window in advance of the certificate expiration. Annual recertification audit will be conducted by PJRFSI.

10 Conditions for Suspending or Withdrawing Certification

10.1 PJRFSI is responsible for initiating the suspension and withdrawal of the FSMA Certificate.

10.2 If PJRFSI has reason to believe that a Facility to which it issued a food or facility certification may no longer be in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, the PJRFSI must conduct any monitoring (including an onsite audit) of such eligible entity necessary to determine whether the entity is in compliance with such requirements. PJRFSI must immediately notify FDA, under if it withdraws or suspends a food or facility certification because it determines that the entity is no longer in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. PJRFSI must maintain records of such monitoring.

10.3 PJRFSI suspends the FSMA Certificate where:
a. The foreign Facility had a class I recall
b. nonconformities are detected that would be serious risk to public health
c. the Facility fails to have a required audit conducted according to their audit frequency except as justifiably allowed.
d. failure of the client to comply with PJRFSI's terms and conditions (i.e. nonpayment of fees)
e. non-compliance to certification protocol
f. pending complaint investigation
g. major change to the site or its activities that require action
h. a site visit raises doubt to the validity for the current certificate
i. pending appropriate corrective action following an investigation into product recall and/or product withdraw
j. failure to notify PJRFSI of significant changes to the company

10.4 Where the Facility's FSMA Certificate is suspended, the Food Safety Program Accreditation Manager or designee will inform the Facility in writing and sent by certified mail, that their certificate has been suspended, the reasons for doing so, where the condition was discovered, and action required from the Facility including timescale in order to lift the certification. Where the Facility's FSMA Certificate is suspended, PJRFSIs Food Safety Program Accreditation Manager or designee as appropriate immediately removes the Facility's details on the PJRFSI's Directory of Certified Sites.

10.5 PJRFSI will immediately notify ANSI and FDA electronically, in English, upon withdrawing or suspending the food or facility certification of a Facility.

10.6 Where PJRFSI has suspended a Facility's FSMA Certificate, for the duration of the suspension, the Facility:
   a. shall not represent itself as holding a FSMA Certificate;
   b. shall not use any goods, products, packaging, stationery, or other items that contain a PJRFSI Logo that may indicate the Facility holds a FSMA Certificate;
   c. shall notify any customers as required.

10.7 A certificate may be withdrawn by PJRFSI for the following reasons:
   a. failure of the client to adequately comply with the Certification Body's request for action following a complaint investigation
   b. following investigation or a scheduled audit, where a site is not maintaining the standards expected of a FSMA certified site
   c. the company no longer trades
   d. the site no longer undertakes the scope activities e.g. cessation of manufacture due to extensive site damage by fire
   e. a suspended site exceeds the 6 months' time period to demonstrate compliance for recertification

10.8 Where the Facility's Certificate is withdrawn, PJRFSIs Food Safety Program Accreditation Manager or designee as appropriate immediately removes the Facility's details on the PJRFSI's Directory of Certified Sites.
   a. informs the Facility that the FSMA Certificate has been withdrawn, the reason for such action, the date of effect, and in writing sent by certified mail;
   b. instructs the Facility to return the Certificate;
   c. instructs the Facility to return any electronic copies of the PJRFSI Logo and comply accordingly with the PJRFSI Logo Guidelines

10.9 PJRFSI's Food Safety Program Accreditation Manager or designee shall require the client to
   a. withdraw any claim that imply that the site has been certificated;
   b. cease to advertise or use any certification mark issued by PJRFSI;

11 Self-monitoring of Performance by Certification Body

11.1 The certification body must annually conduct a self-assessment that includes evaluation of compliance, including:
   a. The performance of its officers, employees, or other agents involved in auditing and certification activities, including the performance of audit agents in examining facilities, process(es), and food using the applicable food safety requirements of the FD&C Act and FDA regulations;
   b. The degree of consistency among its officers, employees, or other agents involved in auditing and certification activities, including evaluating whether its audit agents interpreted audit protocols in a consistent manner;
   c. The compliance of PJRFSI and its officers, employees, and other agents involved in auditing and certification activities, with the conflict of interest requirements;
   d. Actions taken in response to the results of any assessments conducted by FDA. As requested by FDA, any other aspects of its performance relevant to a determination of whether the certification body is in compliance.

11.2 As a means to assess its performance, PJRFSI may evaluate the compliance of one or more of eligible entities to which a food or facility certification was issued.

11.3 Based on the assessments and evaluations conducted, the certification body must:
   a. Identify any deficiencies in complying with the requirements;
   b. Quickly implement corrective action(s) that effectively address the identified deficiencies;

and

c. Establish and maintain records of such corrective action(s).

11.4 The PJRFSI must prepare a written report of the results of its self-assessment that includes:

a. A description of any corrective action(s) taken;

b. A statement disclosing the extent to which the certification body, and its officers, employees, and other agents involved in auditing and certification activities, complied with the conflict of interest requirements; and

c. A statement attesting to the extent to which the certification body complied with the applicable requirements of this subpart.

11.5 The certification body may use a report, supplemented as necessary, on its conformance to ISO/IEC 17021: 2011 or ISO/IEC 17065: 2012 in meeting the requirements of this section.

11.6 PJRFSI reviews any new information or changes in regard to the FSMA requirements and makes changes to their documented procedures. Documented procedures can be found on the client only site and downloaded by the Facility at any time.

12 Record Requirements for Certification Bodies

12.1 PJRFSI must submit a regulatory audit report, electronically, in English, to FDA and to ANSI no later than 45 days after completing such audit.

12.2 Reporting results of PJRFSI's self-assessments. PJRFSI must submit the report of its annual self-assessment required electronically to ANSI, within 45 days of the anniversary date of its accreditation under this subpart. For an PJRFSI subject to an FDA request for cause, the report of its self-assessment must be submitted to FDA electronically, in English, within 60 days of the FDA request, denial of renewal, revocation, or relinquishment of recognition of the accreditation body that granted its accreditation. Such report must include an up-to-date list of any audit agents it uses to conduct audits.

12.3 Notification to FDA of a serious risk to public health. PJRFSI must immediately notify FDA electronically, in English, if during a regulatory or consultative audit, any of its audit agents or PJRFSI itself discovers a condition that could cause or contribute to a serious risk to the public health, providing the following information:

a. The name, physical address, and unique facility identifier, if designated by FDA, of the eligible entity subject to the audit, and, where applicable, the registration number;

b. The name, physical address, and unique facility identifier, if designated by FDA, of the facility where the condition was discovered (if different from that of the eligible entity) and, where applicable, the registration number assigned to the facility; and

c. The condition for which notification is submitted.

12.4 Immediate notification to FDA of withdrawal or suspension of a food or facility certification. An PJRFSI must notify FDA electronically, in English, immediately upon withdrawing or suspending any food or facility certification of an eligible entity and the basis for such action.

12.5 Notification to ANSI or an eligible entity. After notifying FDA, PJRFSI must immediately notify the eligible entity of such condition and must immediately thereafter notify ANSI. Where feasible and reliable, PJRFSI may contemporaneously notify ANSI and/ or the eligible entity when notifying FDA.

12.6 PJRFSI must notify its ANSI electronically, in English, within 30 days after making any significant change that would affect the manner in which it complies with the requirements and must include with such notification the following information:

- A description of the change; and
- An explanation for the purpose of the change.

13 Facility Requirement to Notify PJRFSI of Special Situations

13.1 The Facility is required to notify PJRFSI in writing and in a timely manner about any significant

change(s), actual or intended, which include but are not limited to:

a. changes in legal or commercial status including changes in name;
b. changes in ownership;
c. changes in key managerial, decision-making or technical staff;
d. changes in the number of employees;
e. changes in location and/or number of sites;
f. damage to the site, e.g., damage by fire or natural disaster such as a flood;
g. changes to the physical building(s) and/or processing operations and equipment;
h. changes to the scope of certification (including expansion or reduction) in terms of products, processes, and/or facilities;
i. changes in the Facility's system or factors influencing the Facility's System; and
j. a food safety incident as described in @12.3

13.2 **If at any time based on available information, the Facility becomes aware that concerns about actual or suspected threats to food safety exist which could require intervention to protect consumers' interests, Facility must notify PJRFSI immediately. Upon identification that a food safety event requires public notification (such as a Class I or Class II recall), the Facility shall, immediately identifying the event, notify PJRFSI in writing and/or by phone call:**

a. **Business hours M-F, 9-5 EST: 248-358-3388**
After hours and weekends: 248-648-0216
b. **Email: foodsafety@pjrfsi.com;**

13.3 When a certified Facility relocates its business premises, the Facility's Certificate is no longer valid until a successful Regulatory Audit of the new premises is conducted.

13.4 A certified Facility must notify PJRFSI of any change in ownership with thirty (30) days of the effective change. When a certified Facility's ownership changes but key staff responsible for the food safety have been retained, PJRFSI confirms the continued effectiveness of the food safety within sixty (60) days of the change of ownership by means of a site audit and upon confirmation. This allows the Facility to retain the existing audit frequency status and certification number. If significant changes in key personnel have occurred with the change in ownership, PJRFSI shall complete a full Facility Audit and the Facility's audit frequency status will be based on this new audit activity.

13.5 PJRFSI reserves the right to conduct special audits during the course of the certification period, and as needed in response to changes/incidents as described above. Where such changes may affect the conformity of the product(s), PJRFSIs Technical Specialist or designee as appropriate determines whether the announced changes require further investigation and schedules a special audit as necessary.

13.6 The Facility must not promote products, processes, and/or facilities/sites which have not been covered in the scope of certification as audited and approved by PJRFSI. Unauthorized promotion will result in the withdrawal of the Certificate.

13.7 Where Facility fails to notify PJRFSI of any of the above changes, PJRFSI may accordingly suspend or withdraw, as deemed appropriate, the Certificate and reserves the right to retroactively invalidate the Certificate effective as of the date the change occurred.

14 Promotion of FSMA Certification by Facility

When providing copies of any certification documents (certificates and audit reports) to interested parties, the Facility shall reproduce those documents in their entirety or otherwise seek permission in writing from PJRFSI. The Facility shall contact the PJRFSI for authorization to use the PJRFSI Logo and shall comply with: the latest Terms and Conditions and Logo Guidelines as published by PJRFSI; and any additional requirements issued by PJRFSI regarding use of certification marks and promotion of certification. The proprietary names and logos of PJRFSI, and any applicable accreditation bodies shall not be used by the Facility in any manner which could be misconstrued or defamatory to the respective parties and/or parties' brands. Any misuse of these proprietary names or logos by a certified Facility or a Facility seeking certification shall be reported to the interested parties and responded to with appropriate actions by PJRFSI.

15 Conditions for Change of Certification Body (Transfers)

15.1 A Certified Facility shall ensure it has a certification body appointed at all times. A Certified Facility may elect to cease being a client of a certification body (Former Certifier) and to have PJRFSI, as a New Certifier, undertake it's FSMA audits.

15.2 Where a Certified Facility elects to transfer its Certificate to PJRFSI, PJRFSIs Food Safety Program Accreditation Manager or designee as appropriate undertakes a pre-transfer review of the Facility's Certification and completes the F-144fsi Transfer of Certification Body Checklist to:

a. confirm the Certificate is current, valid, and relates to the FSMA System so Certified;
b. confirm Certification under Former Certifier is not suspended or under threat of suspension or withdrawal.
c. confirm that the Facility has closed all non-conformities issued by the Former Certifier;
d. review the Facility's Audit history (where the Facility can demonstrate such history to the satisfaction of PJRFSI by way of copies of Audit reports completed by any Former Certifier) and the impact of any outstanding Nonconformities.

15.3 Where a decision is made to proceed with Certification, PJRFSI:

a. Technical Specialist or designee signs off on the completed F-144fsi.
b. PJRFSI conducts the required audit which was described by the Former Certification Body within timelines consistent with the FSMA program audit frequency and certification requirements; and
c. issues a new Certificate under PJRFSI.

16 Appeals

Notice and appeals of adverse regulatory audit results. PJRFSI will notify an eligible entity of a denial of certification. PJRFSI appeal procedures can be found in SOP-10.

PJRFSI will make the appeals procedures publicly available; use competent persons, who may or may not be external to PJRFSI, who are free from bias or prejudice and have not participated in the certification decision or be subordinate to a person who has participated in the certification decision, to investigate and decide appeals;

Advise the eligible entity of the final decision on its appeal; and maintain records under of the appeal, the final decision, and the basis for such decision.

17 Confidentiality

PJRFSI, including all auditors, administrative staff, Executive Committee, Impartiality Committee, and any other employee or contractor, ensures that all records, data, and information received during the execution of any audit activity remain confidential and the property of the Facility. Only with the Facility's authorization will PJRFSI release audit data to any entity other than FDA or ANSI except when mandated by law, statute, or the regulations of accreditation bodies. In the event that disclosure of such information is required by law or statute or accreditation body regulations, PJRFSI will disclose the information as required and inform the Facility of such disclosure in writing in a timely fashion.

18 Third-Party Certification Body Accreditation Requirements

18.1 *Submission of accreditation or renewal application to a recognized accreditation body.* A third-party certification body seeking accreditation must submit its request for accreditation or renewal of accreditation by a recognized accreditation body identified on the Web site described in § 1.690.

18.2 *Notice of records custodian after denial of application for renewal of accreditation.* An applicant whose renewal application was denied by a recognized accreditation body must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of accreditation or denial of the renewal application, of the name and contact information of the custodian who will maintain the records required by § 1.658(a) and make them available to FDA as required by § 1.658(b) and (c). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.658(a) will be located.

18.3 *Effect of denial of an application for renewal of accreditation on food or facility certifications issued to eligible entities.* A food or facility certification issued by an accredited third-party certification body prior to issuance of the denial of its renewal application l will remain in effect until the certification expires. If

FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

18.4 *Public notice of denial of an application for renewal of accreditation.* FDA will provide notice on the Web site described in § 1.690 of the date of issuance of a denial of renewal of accreditation of a third-party certification body that had previous been accredited.

18.5 A recognized accreditation body may grant accreditation to a third-party certification body under this subpart for a period not to exceed 4 years.

19 FDA Monitoring

19.1 FDA will periodically evaluate the performance of each accredited third- party certification body to determine whether the accredited third-party certification body continues to comply with the applicable requirements of this subpart and whether there are deficiencies in the performance of the accredited third-party certification body that, if not corrected, would warrant withdrawal of its accreditation under § 1.664. FDA will evaluate each directly accredited third-party certification body annually. For a third-party certification body accredited by a recognized accreditation body, FDA will evaluate an accredited third-party certification body not later than 3 years after the date of accreditation for a 4-year term of accreditation, or by no later than the mid-term point for accreditation granted for less than 4 years. FDA may conduct additional performance assessments of an accredited third-party certification body at any time.

19.2 In evaluating the performance of an accredited third-party certification body under paragraph (a) of this section, FDA may review any one or more of the following: (1) Regulatory audit reports and food and facility certifications; (2) The accredited third-party certification body's self-assessments under § 1.655; (3) Reports of assessments by a recognized accreditation body under § 1.621;

19.3 Documents and other information relevant to a determination of the accredited third-party certification body's compliance with the applicable requirements of this subpart; and (5) Information obtained by FDA, including during inspections, audits, onsite observations, or investigations, of one or more eligible entities to which a food or facility certification was issued by such accredited third-party certification body.

19.4 FDA may conduct its evaluation of an accredited third-party certification body through a site visit to an accredited third-party certification body's headquarters (or other location that manages audit agents conducting food safety audits under this subpart, if different than its headquarters), through onsite observation of an accredited third party certification body's performance during a food safety audit of an eligible entity, or through document review.

20 FDA Waiver

20.1 PJRFSI may submit a request to FDA to waive the requirements of §1.650(c) preventing an audit agent from conducting a regulatory audit of an eligible entity if the audit agent (or, in the case that the third-party certification body is an individual, the third-party certification body) has conducted a food safety audit of such entity during the previous 13 months. The accredited third-party certification body seeking a waiver or waiver extension must demonstrate there is insufficient access to audit agents and any third-party certification bodies that are comprised of an individual in the country or region where the eligible entity is located.

20.2 Requests for a waiver or waiver extension and all documents provided in support of the request must be submitted to FDA electronically, in English. The requestor must provide such translation and interpretation services as are needed by FDA to process the request**.**

20.3 The request must be signed by the requestor or by any individual authorized to act on behalf of the requestor for purposes of seeking such waiver or waiver extension.

20.4 FDA will review requests for waivers and waiver extensions on a first in, first out basis according to the date on which the completed submission is received; however, FDA may prioritize the review of specific requests to meet the needs of the program. FDA will evaluate any completed waiver request to determine whether the criteria for waiver have been met.

20.5 FDA will notify the requestor whether the request for a waiver or waiver extension is approved or denied.

20.6 If FDA approves the request, issuance of the waiver will state the duration of the waiver and list any limitations associated with it. If FDA denies the request, the issuance of a denial of a waiver request

will state the basis for denial and will provide the address and procedures for requesting reconsideration of the request under §1.691

20.7 Unless FDA notifies a requestor that its waiver request has been approved, an accredited third-party certification body must not use the audit agent to conduct a regulatory audit of such eligible entity until the 13-month limit in §1.650(c) has elapsed

21 Accreditation Withdrawal

21.1 Mandatory withdrawal. FDA will withdraw accreditation from a third- party certification body: (1) Except as provided in paragraph (b) of this section, if the food or facility certified under this subpart is linked to an outbreak of foodborne illness or chemical or physical hazard that has a reasonable probability of causing serious adverse health consequences or death in humans or animals;

21.2 Following an evaluation and finding by FDA that the third-party certification body no longer complies with the applicable requirements of this subpart;

21.3 Following its refusal to allow FDA to access records under §1.658 or to conduct an audit, assessment, or investigation necessary to ensure continued compliance with this subpart

21.4 Exception. FDA may waive mandatory withdrawal under paragraph (a)(1) of this section, if FDA: (1) Conducts an investigation of the material facts related to the outbreak of human or animal illness; (2) Reviews the relevant audit records and the actions taken by the accredited third-party certification body in support of its decision to certify; and

21.5 Determines that the accredited third-party certification body satisfied the requirements for issuance of certification under this subpart

21.6 Discretionary withdrawal. FDA may withdraw accreditation, in whole or in part, from a third-party certification body when such third-party certification body is accredited by an accreditation body for which recognition is revoked under §1.634, if FDA determines there is good cause for withdrawal, including:

a. Demonstrated bias or lack of objectivity when conducting activities under this subpart; or
b. Performance that calls into question the validity or reliability of its food safety audits or certifications.

21.7 Records access. FDA may request records of the accredited third-party certification body under §1.658 and, where applicable, may request records under §1.625 of an accreditation body that has been recognized under §1.625, when considering withdrawal under paragraph (a)(1), (a)(2), or (c) of this section.

21.8 Notice to the third-party certification body of withdrawal of accreditation. (1) FDA will notify a third-party certification body of the withdrawal of its accreditation through issuance of a withdrawal that will state the grounds for withdrawal, the procedures for requesting a regulatory hearing under §1.693 on the withdrawal, and the procedures for requesting reaccreditation under §1.666

21.9 Within 10 business days of the date of issuance of the withdrawal, the third-party certification body must notify FDA electronically, in English, of the name of the custodian who will maintain the records required by §1.658, and provide contact information for the custodian, which will at least include an email address, and the street address where the records will be located.

21.10 Effect of withdrawal of accreditation on eligible entities. A food or facility certification issued by a third-party certification body prior to withdrawal will remain in effect until the certification terminates by expiration. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

21.11 Effect of withdrawal of accreditation on recognized accreditation bodies. (1) FDA will notify a recognized accreditation body if the accreditation of a third-party certification body it accredited is withdrawn by FDA. Such accreditation body's recognition will remain in effect if, no later than 60 days after withdrawal, the accreditation body conducts a self-assessment under §1.622 and reports the results of the self-assessment to FDA as required by §1.623(b).

21.12 FDA may revoke the recognition of an accreditation body whenever FDA determines there is good cause for revocation of recognition under §1.634.

21.13 Public notice of withdrawal accreditation. FDA will provide notice on the Web site described in §1.690 of its withdrawal of accreditation of a third-party certification body and provide a description of the basis for withdrawal.

21.14 *Notice to FDA of intent to relinquish or not to renew accreditation.* A third-party certification body must

notify FDA electronically, in English, at least 60 days before voluntarily relinquishing accreditation or before allowing accreditation to expire without seeking renewal. The certification body must provide the name and contact information of the custodian who will maintain the records required under § 1.658(a) after the date of relinquishment or the date accreditation expires, as applicable, and make them available to FDA as required by § 1.658(b) and (c). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.658(a) will be located.

21.15 *Notice to recognized accreditation body and eligible entities of intent to relinquish or not to renew accreditation.* No later than 15 business days after notifying FDA under paragraph (a) of this section, the certification body must notify its recognized accreditation body and any eligible entity with current certifications that it intends to relinquish accreditation or to allow its accreditation to expire, specifying the date on which relinquishment or expiration will occur. The recognized accreditation body must establish and maintain records of such notification under § 1.625(a).

21.16 Effect of voluntary relinquishment or expiration of accreditation on food or facility certifications issued to eligible entities. A food or facility certification issued by a third-party certification body prior to relinquishment or expiration of its accreditation will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

21.17 Public notice of voluntary relinquishment or expiration of accreditation. FDA will provide notice on the Web site described in §1.690 of the voluntary relinquishment or expiration of accreditation of a certification body under this subpart.

21.18 Application following withdrawal. FDA will reinstate the accreditation of a third-party certification body for which it has withdrawn accreditation: (1) If, in the case of direct accreditation, FDA determines, based on evidence presented by the third-party certification body, that the third-party certification body satisfies the applicable requirements of this subpart and adequate grounds for withdrawal no longer exist; or

21.19 In the case of a third-party certification body accredited by an accreditation body for which recognition has been revoked under § 1.634: (i) If the third-party certification body becomes accredited by another recognized accreditation body or by FDA through direct accreditation no later than 1 year after withdrawal of accreditation, or the original date of the expiration of accreditation, whichever comes first; or (ii) Under such conditions as FDA may impose in withdrawing accreditation.

21.20 Application following voluntary relinquishment. A third-party certification body that previously relinquished its accreditation under § 1.665 may seek accreditation by submitting a new application for accreditation under § 1.660 or, where applicable, § 1.670.