The Accredited Third-Party Certification Program: Questions and Answers: Guidance for Industry

Draft Guidance

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
Office of Regulatory Affairs

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The Accredited Third-Party Certification Program: Questions and Answers: Guidance for Industry[1]

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I. Introduction

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) added section 808 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384d), which directs the U.S. Food and Drug Administration (FDA or Agency) to establish a program for accreditation of third-party certification bodies[2] to conduct food safety audits and to certify that eligible foreign food entities (including registered foreign food facilities) and food produced by such entities meet applicable FDA requirements for purposes of sections 801(q) (21 U.S.C. 381(q)) and 806 (21 U.S.C. 384b) of the FD&C Act. On November 27, 2015, FDA issued the final rule, Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (also referred to as the TPP regulation) (80 FR 74569; 21 CFR Part 1, Subpart M).[3]

This guidance answers frequently asked questions relating to the requirements of the Accredited Third-Party Certification Program (also referred to as the Third-Party Program or TPP) established in 21 CFR Part 1, Subpart M (21 CFR 1.600-1.695, 21 CFR 1.700-1.725). This guidance intends to assist the accreditation bodies', third-party certification bodies', and eligible entities' understanding of the TPP regulation and program requirements.

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[1] This guidance has been prepared by the Center for Food Safety and Applied Nutrition, Office of Compliance, in collaboration with the Office of Regulatory Affairs and Center for Veterinary Medicine at the U.S. Food and Drug Administration.

[2] As defined in 21 CFR 1.600(c), a "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. For consistency with the implementing regulations in 21 CFR Parts 1, 11, and 16, the TPP final rule uses the term "certification body."

[3] For the requirements in 21 CFR Part 1, Subpart M, see https://www.ecfr.gov/cgi-bin/text-idx?SID=829f8115c895b28fef2cb6234b603a05&mc=true&node=sp21.1.1.m&rgn=div6.

In this guidance, the pronouns "you" and "your" are used to refer to the accreditation bodies, certification bodies, or eligible entities, as applicable, applying to, or participating in the Third-Party Program. The pronouns "we" and "our" are used to refer to the FDA.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

Table 1 lists abbreviations and acronyms used in this guidance.

Table 1 – Abbreviations and Acronyms Used in This Guidance

Reference	Abbreviation/Acronym
Accreditation Body	AB
Accredited Third-Party Certification Program	Third-Party Program or TPP
Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications	TPP regulation
Acidified Foods	AF
Current Good Manufacturing Practices	CGMPs
FDA Food Safety Modernization Act	FSMA
FDA's Unified Registration and Listing System	FURLS
Federal Food, Drug, and Cosmetic Act	FD&C Act
Foreign Supplier Verification Program	FSVP
Guidance for Industry: FDA's Voluntary Qualified Importer Program	VQIP Guidance
Juice Hazard Analysis and Critical Control Points	Juice HACCP
Low-Acid Canned Foods	LACF
Preventive Controls for Animal Food	PCAF
Preventive Controls for Human Food	PCHF
Raw Agricultural Commodity	RAC
Regulatory Audit Report	RAR
Seafood Hazard Analysis and Critical Control Points	Seafood HACCP
Third-Party Certification Body	CB
U.S. Food and Drug Administration	FDA
Voluntary Qualified Importer Program	VQIP

II. Background

The TPP regulation implements section 808 of the FD&C Act by establishing the framework, procedures, and requirements for the accreditation of "third-party certification bodies" (CBs) to conduct food safety audits and issue food or facility certifications to eligible entities. "Accreditation bodies" (ABs) apply to FDA to be recognized under TPP. Once recognized by FDA, an AB may begin assessing CBs for accreditation and accrediting CBs that meet our program requirements. In turn, the accredited CBs under TPP conduct consultative and/or regulatory food safety audits of eligible entities that produce food for humans or animals. An "eligible entity" is 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 conducted by an accredited CB under TPP (21 CFR 1.600(c) (definition of "eligible entity")).

The certifications issued under TPP are based on a determination of whether the food or facility meets the food safety requirements of the FD&C Act and FDA regulations. Audits and certifications issued under TPP provide the Agency with useful information regarding the operations of an eligible entity. They do not preclude the Agency from performing inspections of eligible entities that fall under our jurisdiction. The TPP regulation also provides that FDA may refuse to accept any certification for purposes of section 801(q) or 806 of the FD&C Act if the agency determines that the certification is not valid or reliable (21 CFR 1.653(b)(3)). For example, if a certification was issued without reliable demonstration regarding the basis for issuance, we may determine that the certification is not valid or reliable (21 CFR 1.653(b)(3)(iii)).[4]

Section 808(c)(2)(B) of the FD&C Act specifies two uses for the certifications issued by accredited CBs under this program. First, a "facility certification" will be used by importers to establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP), which allows for expedited review and entry of foods from importers in the program under section 806 of the FD&C Act (21 U.S.C. 384b). One condition of participation in VQIP is importation of food from facilities audited and certified by accredited CBs under TPP. The second use of a certification issued under TPP is for the purposes of section 801(q) of the FD&C Act (21 U.S.C. 381(q)) where FDA can require, in specific circumstances, that a food offered for import be accompanied by certification or other assurances that the food complies with applicable FD&C Act requirements, as provided under section 801(q) of the FD&C Act.

The TPP regulation is part of FSMA's paradigm shift toward a modern, preventive, and risk-based approach to food safety. The TPP regulation establishes requirements for the competence and independence of CBs who are accredited to conduct foreign food safety audits to examine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. The program requirements help ensure the integrity of the TPP certificates that are used for the purposes of VQIP under section 806 of the FD&C Act and the safety of imported food subject to import certification under section 801(q) of the FD&C Act. FDA maintains oversight and management of TPP through routine monitoring and periodic assessments of the participating

[4] See also 21 CFR 1.664(f); 21 CFR 1.665(c).

ABs and CBs, with the main focus of our regulatory oversight on the ABs, who are responsible for overseeing the accredited CBs and ensuring that they are in compliance with the TPP requirements.

III. Questions and Answers

A. Definitions Applying to the Third-Party Program

A.1 What are consultative audits and regulatory audits?

Consultative audits and regulatory audits are the two types of "food safety audits" that are conducted under TPP to determine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations.

"Consultative audits" are conducted by accredited CBs to determine if the eligible entity complies with applicable food safety requirements of the FD&C Act, FDA regulations, and industry standards and practices (21 CFR 1.600(c) (definition of "consultative audit")). The audits are conducted to help eligible entities prepare for a regulatory audit. Consultative audit reports do not have to be submitted to FDA, but CBs must maintain records of the consultative audit. The consultative audit records must also be made available to FDA in accordance with FDA's records access authority under section 414 of the FD&C Act (21 U.S.C. 350c) (21 CFR 1.658(b)).

"Regulatory audits" are conducted to determine if the eligible entity is in compliance with the applicable food safety requirements under the FD&C Act and FDA regulations. Only the results of a regulatory audit can determine eligibility for issuing food or facility certification under sections 801(q) or 806 of the FD&C Act (21 CFR 1.600(c) (definition of "regulatory audit")). An accredited CB must, no later than 45 days after completing a regulatory audit, prepare and submit electronically, in English, to FDA and to its recognized AB, a report of such regulatory audit (see 21 CFR 1.652(b) and Responses F.2.3-F.2.6).

A.2 What is an audit agent?

An "audit agent" is defined as an individual who is an employee or other agent of an accredited CB who, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited CB. An audit agent includes a contractor of the accredited CB but excludes subcontractors, or other agents under outsourcing arrangements for conducting food safety audits without direct control by the accredited CB (21 CFR 1.600(c) (definition of "audit agent")).

It is the responsibility of the accredited CB that uses audit agents to conduct food safety audits to ensure that each audit agent has the required qualifications (see 21 CFR 1.650(a)). The accredited CB exercises adequate oversight of its audit agents under TPP, such that the CB accepts the result of the audit agents as its own (80 FR 74569 at 74580) and exercises adequate

control and oversight over a contractor that is used as an audit agent such that the accredited CB accepts the result of the contractor's audit as its own (80 FR 74569 at 74581).

A.3 How are "days" defined in the Third-Party Program regulation?

The TPP regulation uses both the terms "days" and "business days". Unless specified as business days, FDA interprets "days" in 21 CFR Part 1, Subpart M as calendar days.

B. Circumstances Requiring Certification Under the Third-Party Program

B.1 Is certification under the Third-Party Program mandatory for all FDA-regulated products offered for import into the United States?

No. There is no general requirement for foreign firms to obtain a certification by an accredited CB under TPP. Food or facility certification under TPP is only required under specific circumstances:

> (1) to establish eligibility for participation of importers in VQIP, which offers expedited review and entry of food from a facility that has been certified by an accredited CB (section 806 of the FD&C Act) and;
>
> (2) in specific circumstances, where FDA can require that a food offered for import be accompanied by a certification issued by a CB accredited under this program (or by a representative of a foreign government, if designated by FDA to issue such certifications) that the food meets applicable requirements of the FD&C Act to prevent potentially harmful food from reaching U.S. consumers. (For a complete explanation of the circumstances under which FDA may require such certifications, see section 801(q) of the FD&C Act).

Under section 806(d) of the FD&C Act, an entity seeking VQIP benefits needs to have a facility certification issued consistent with TPP for each foreign supplier's facility.[5] Additional information on the eligibility criteria for participation in VQIP is available in the FDA Guidance for Industry: FDA's Voluntary Qualified Importer Program (VQIP Guidance).[6]

Additional information on how audits under TPP can be used to meet the supplier verification requirements of other FDA regulations is available in Response H.2.2.

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[5] Although participation in VQIP allows for expedited review and entry of foods from importers in the program, a VQIP food may nevertheless be subject to "for cause" examination when FDA determines the food is or may be associated with a risk to public health. VQIP food may, at times, also be subject to microbiological sampling related to specific risk-based surveillance assignments. For additional information on circumstances under which FDA may examine or sample a VQIP food, see https://www.fda.gov/media/92196/download.

[6] See U.S. Food and Drug Administration, Guidance for Industry: FDA's Voluntary Qualified Importer Program, Final Guidance, November 2016, (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-voluntary-qualified-importer-program).

C. Requirements for Accreditation Bodies Seeking Recognition Under the Third-Party Program

C.1 Who is eligible to be a recognized accreditation body under the Third-Party Program?

Interested parties, such as private third-parties, foreign governments, or foreign agencies, may apply to FDA to become recognized ABs under TPP. Such parties must meet the requirements established in the regulation for the legal authority, competency, capacity, conflict of interest safeguards, quality assurance, and records procedures that ABs must demonstrate to be eligible for recognition (see 21 CFR 1.610-1.615).

C.2 Where and how can you apply for recognition?

An AB can apply for recognition through FDA's electronic portal dedicated to TPP within the FDA's Unified Registration and Listing System (FURLS) page. In addition, you can use this portal to manage the AB's account and submit reports and notifications to FDA.

Users must first create an online account at the FURLS page to gain access. Only those organizations seeking recognition by FDA as an AB may submit an application. Users may access detailed application instructions in a document titled "U.S. Food and Drug Administration, Accredited Third-Party Certification Program Portal, Step-by-Step Instructions for an Accreditation Body to Apply for and Manage Recognition Status in the Program", available at https://www.fda.gov/media/119119/download. This instruction guide can also be accessed from FDA's Accredited Third-Party Certification Program Web site at https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program.

C.3 What are the scopes of recognition under the Third-Party Program?

FDA has implemented 11 scopes of food or process categories for which the Agency will recognize ABs under TPP. Each scope represents a set of overarching food safety requirements of the FD&C Act and FDA regulations for the respective food or process category. We refer to the 11 scopes as scopes of recognition for ABs and scopes of accreditation for CBs (see Response E.4 for more detail about how the scopes of accreditation correspond to the facility, process(es), or food to be audited).

The 11 scopes include the following:

- Acidified Foods (AF) scope
- Dietary Supplements scope
- Infant Formula scope
- Juice Hazard Analysis and Critical Control Points (Juice HACCP) scope
- Low-Acid Canned Foods (LACF) scope
- Medicated Feed Current Good Manufacturing Practices (Medicated Feed CGMPs) scope

- Preventive Controls for Animal Food (PCAF) scope
- Preventive Controls for Human Food (PCHF) scope
- Produce Safety scope
- Seafood Hazard Analysis and Critical Control Points (Seafood HACCP) scope
- Shell Eggs scope

ABs select the scope(s) of recognition for which they are seeking recognition during the application process in FURLS. As part of the application review, FDA evaluates the competency and capacity of the operations of the AB for each scope selected in the application (21 CFR 1.600(c) (definition of "assessment")). FDA may recognize an applicant and recognize all scopes in the application, some of the scopes, or may deny the application in whole.

A recognized AB can only accredit a CB for the scope(s) for which FDA has recognized them. That means, for example, that an AB recognized for the Juice HACCP and PCHF scopes can accredit a CB for the Juice HACCP scope, the PCHF scope, or both scopes but cannot accredit a CB for the other nine scopes.

We also note that recognized ABs may have additional restrictions in place for the scopes as part of their management of accredited CBs within the program and may make CB accreditation decisions based on FDA's TPP requirements and their own restrictions.

Additional information about the scopes is available in Responses C.4, E.3, and E.4.

C.4 How do the scopes of recognition correspond with the food safety requirements of the FD&C Act and FDA regulations?

As discussed in Response C.3, the scopes of recognition and accreditation represent sets of the overarching food safety requirements under the FD&C Act and FDA regulations.

The titles of the scopes correspond with specific FDA regulations, but the TPP regulation requires that food safety audits examine compliance with all applicable food safety requirements of the FD&C Act and FDA regulations. Therefore, additional FDA food safety requirements may also apply to the audit that are not in the specific regulation that corresponds with the title of the scope. For example, for processors of acidified foods that are subject to the Acidified Foods regulation (21 CFR Part 114), the processors are also subject to the requirements of the Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food regulation (21 CFR Part 117). So, a food safety audit of an acidified food would be conducted under the AF scope and would consider the FDA regulations that are specific to acidified foods, i.e., the food safety requirements in 21 CFR Part 114, Emergency Permit Control (21 CFR Part 108), as well as the food safety requirements in 21 CFR Part 117.

The applicable food safety requirements from the FD&C Act and FDA regulations would depend on the type of eligible entity and the specific facility, process, or food being audited.[7] Even when an audit is conducted under a single scope (for example, the LACF scope), the food safety audit may need to examine compliance with multiple different applicable food safety requirements of the FD&C Act and FDA regulations. For example, consider a food safety audit of a low-acid canned food that would be conducted under the LACF scope (see Response E.4 for more detail about how to determine the appropriate scope for an audit). Manufacturers of low-acid canned foods, while exempt from the requirements of subparts C and G of 21 CFR Part 117 for biological hazards controlled under 21 CFR Part 113,[8] still must meet all the other applicable requirements of Part 117.[9] Therefore, in addition to considering the FDA regulations that are specific to low-acid canned foods --- i.e., the Low-Acid Foods Packaged in Hermetically Sealed Containers regulation (21 CFR Part 113) and 21 CFR Part 108 --- an audit conducted under the LACF scope would also consider the applicable requirements of 21 CFR Part 117. In addition, these audits may need to also consider additional applicable food safety requirements of the FD&C Act and FDA regulations. For example, food additive requirements,[10] which are generally not addressed in 21 CFR Parts 113 and 117, may be applicable to the low-acid canned food being audited under the LACF scope.

As another example, a medicated animal food audit would be conducted under the Medicated Feed CGMPs scope. Audits conducted under that scope would consider the applicable food safety requirements in the Current Good Manufacturing Practice for Medicated Feeds regulation (21 CFR Part 225) and in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals regulation (21 CFR Part 507), along with the food safety requirements of any additional applicable FDA regulations and the FD&C Act.

Additionally, even when a general scope such as the PCHF scope is the appropriate scope, audits may still need to consider product-specific food safety requirements. For example, a bottled water product would be audited under the PCHF scope. Such an audit would need to assess compliance with the applicable food safety requirements under the Processing and Bottling of Bottled Drinking Water regulation (21 CFR Part 129) in addition to 21 CFR Part 117, as well as other applicable food safety requirements of the FD&C Act and FDA regulations.

In addition, sometimes the title of the most appropriate scope may refer to a regulation to

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[7] The descriptions of the scopes of recognition and accreditation are listed in Response E.4 to assist CBs in identifying the appropriate scope for an audit of a specific type of facility, process, or food.

[8] See 21 CFR 117.5(d), which exempts the processing activities of processors of low-acid canned foods from the requirements of 21 CFR Part 117 subpart C, Hazard Analysis and Risk-Based Preventive Controls, and subpart G, Supply Chain Program, for biological hazards and their controls, if the processor of low-acid canned foods is in compliance with 21 CFR Part 113.

[9] For a more complete discussion of how the FSMA requirements apply to processors of low-acid canned foods, see "Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF) Regulation and the FDA Food Safety Modernization Act: Guidance for Industry," available at https://www.fda.gov/media/106721/download.

[10] Food additive requirements are set forth in section 409 of the FD&C Act (21 U.S.C. 348). See also 21 CFR Parts 170-189.

which the particular food is not subject. For example, the most appropriate scope for produce that FDA has determined to be "rarely consumed raw" is the Produce Safety scope, even though such "rarely consumed raw" produce is not subject to FDA's Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption regulation (21 CFR Part 112) in accordance with 21 CFR 112.2(a)(1). (See 21 CFR 112.2(a)(1) for identifying the specific produce items that are exempt from the requirements in 21 CFR Part 112 because they are "rarely consumed raw").[11]

FDA developed templates that ABs may voluntarily choose to use to help develop evaluation criteria for food safety requirements of certain FDA regulations to ensure that accredited CBs conduct food safety audits that adequately evaluate the applicable FDA food safety requirements (see Response D.1). Additional food safety requirements beyond those for which FDA has developed templates may need to be considered, as appropriate.

Additional information about the scopes is available in Responses C.3, E.3, and E.4.

D. Requirements for Recognized Accreditation Bodies Under the Third-Party Program

D.1 Is there information available to assist accreditation bodies in developing criteria for evaluating the food safety audits?

FDA developed templates that ABs may voluntarily use to help develop evaluation criteria for food safety requirements of certain FDA regulations to ensure that accredited CBs conduct food safety audits that adequately evaluate the FDA food safety requirements. The audit templates present certain food safety requirements in a table format, which can be used to more easily compare third-party food safety audit standards to these FDA food safety requirements. ABs are not required to use the FDA templates. ABs and CBs may use other means to determine that audits meet the requirements of TPP.

Food safety audits must consider all applicable FDA food safety requirements, such that CBs may need to consider additional food safety requirements beyond those for which FDA has developed templates, as appropriate. The templates are available at https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program-voluntary-audit-templates and at FDA's Accredited Third-Party Certification Program Web site (https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program).

D.2 What factors should be considered when a recognized accreditation body determines the appropriate number of onsite audits to observe prior to accrediting a certification body?

[11] Because audits need only consider the applicable food safety requirements of the FD&C Act and FDA regulations, an audit for produce that FDA has determined to be "rarely consumed raw" would not assess compliance with the Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption regulation in 21 CFR Part 112. In this example, the audit would consider the applicable food safety requirements of the FD&C Act.

In accordance with 21 CFR 1.620(a)(3), a recognized AB evaluating a CB seeking accreditation must observe a representative sample of onsite audits examining compliance with applicable food safety requirements of the FD&C Act and FDA regulations conducted by the applicant CB or its agents. The recognized AB should use these observations as part of its evaluation to determine whether the CB meets the requirements for accreditation under TPP.

The size of the representative sample will vary on a case-by-case basis and will depend on a number of factors including the scope(s) of accreditation sought by the CB, whether the CB is an individual who will conduct audits and make certification decisions, or whether the CB uses agents to conduct audits and, if so, whether such agents are centrally managed, conducting similar types of audits, under a single set of operating procedures or whether the agents are managed from various locations, perform different types of audits, or follow different procedures such that these various locations, activities, or practices must be observed to ensure that the sample is sufficiently representative.

For example, to ensure that the CB adequately demonstrates its qualifications to conduct food safety audits, a recognized AB may need to conduct more onsite audits to evaluate accreditation for the PCHF scope as compared to the accreditation for the Juice HACCP scope because of the diverse types of facilities and foods subject to the PCHF scope as compared to that of the Juice HACCP scope.

Additionally, a CB seeking accreditation with audit agents managed from three different locations may require more onsite audits than a CB with audit agents managed from one central location in order to ensure a representative review. The recognized AB should consider how many locations the CB manages and whether the sample includes audit agents from each location.

D.3 What reports and notifications must a recognized accreditation body submit to FDA?

A recognized AB must electronically submit the following information to FDA:

- Assessments of an accredited CB's performance. The recognized AB must submit to FDA electronically, in English, a report of the results of any assessment conducted under 21 CFR 1.621, no later than 45 days after completing such assessment. The report must include an up-to-date list of any audit agents used by the accredited CB to conduct food safety audits under TPP (see 21 CFR 1.623(a)).

- Self-assessments. An AB must electronically submit to FDA, in English, reports of the recognized AB's self-assessments. Specifically, the reports must be of the annual self-assessment required under 21 CFR 1.622, and must be sent to FDA no later than 45 days after completing such self-assessment (see 21 CFR 1.623(b)(1)). For a recognized AB subject to 21 CFR 1.664(g)(1) because FDA withdraws the accreditation of a CB that the AB accredited, the AB must submit a report of a self-assessment under 21 CFR 1.622 no later than 60 days after the CB's withdrawal. A recognized AB may use a

report prepared for conformance to ISO/IEC 17011:2004, supplemented as necessary, in meeting the requirement related to self-assessment reports (see 21 CFR 1.623(b)).

- Immediate notification to FDA. The AB must immediately submit electronic notifications to FDA, in English, upon accrediting a CB, expanding the scope of accreditation of a CB, withdrawing, suspending, or reducing the scope of an accreditation, determining that an accredited CB failed to comply with 21 CFR 1.653 when issuing a certificate, when denying accreditation, or when making significant changes that would affect the manner in which the recognized AB complies with the TPP requirements (21 CFR 1.623(c)). See 21 CFR 1.623(c) for the specific information that must be provided.

A recognized AB should submit the information required in 21 CFR 1.623 through FDA's electronic portal dedicated to TPP in FURLS. This portal in FURLS is the primary system for managing the AB's account and submitting reports and notifications to FDA (see Response C.2). Within this portal, there are tabs for Supplemental Documentation and a Reports and Notification Directory where the various reports and notifications required in 21 CFR 1.623 should be electronically submitted to FDA through the data or text entry fields or as attachments, as applicable. Note that the information required in 21 CFR 1.623 must be submitted in English. Users may access instructions for submitting the reports and notifications at https://www.fda.gov/media/119119/download.

D.4 Can a recognized accreditation body apply to FDA for recognition of additional scopes of recognition?

Yes. There are 11 scopes of recognition under TPP. A recognized AB may apply for any scope of recognition that they are not currently recognized for under TPP. The request for additional scopes would be submitted in FURLS as a report and notification and would include the additional scope(s) of recognition being sought along with the information necessary to demonstrate the recognized AB's qualifications for the new scope(s). Specifically, the recognized AB would submit information supporting the competency, capacity, and quality assurance requirements under TPP for the requested scope(s).

D.5 When may an accreditation body accept payment from a certification body for accreditation services?

A recognized AB may accept the payment of fees for accreditation services and the reimbursement of direct costs associated with assessment of a CB only after the date on which the report of such assessment was completed or the date on which the accreditation was issued, whichever comes later (21 CFR 1.624(b)). Such payment is not considered a conflict of interest for purposes of 21 CFR 1.624(a).

If a recognized AB determines that a CB should not be accredited, the recognized AB may accept fees for accreditation services and reimbursement of direct costs when the recognized

AB completes its assessment report documenting the decision that the CB will not be accredited.

If the CB withdraws from the application process, the recognized AB may accept fees for accreditation services and reimbursement of direct costs when the CB withdraws from the application process.

D.6 Can an employee of a recognized accreditation body serve as an audit agent for a certification body that the recognized accreditation body has accredited under the Third-Party Program?

A recognized AB must implement a written program to protect against conflict of interest between the recognized AB and any CBs seeking accreditation from, or accredited by, such recognized AB (21 CFR 1.624(a)). This includes prohibiting officers, employees, or other agents involved in accreditation activities under the program from accepting any money, gift, gratuity, or item of value from a CB seeking accreditation from, or accredited by, the recognized AB (21 CFR 1.624(a)(2)).

An employee of a recognized AB that serves as an audit agent for a CB that the AB has accredited would likely receive compensation from the CB and therefore would be in receipt of money or an item of value from the CB. If the employee is involved in TPP-related accreditation activities of the accredited CB, such a relationship would therefore be prohibited.

If an officer, employee, or other agent that is not involved in any TPP-related accreditation activities, with respect to the AB's accreditation of CBs, serves as an audit agent for an accredited CB, the recognized AB should document how it is maintaining the required conflict of interest protections such that the employee's activities remain separate from TPP-related accreditation activities.

D.7 Do the financial interests of the spouses and children of a recognized accreditation body's officers, employees, and agents involved in accreditation activities need to be considered in the written program to protect against conflicts of interest?

Yes. The financial interests of the spouses and children younger than 18 years of age of a recognized AB's officers, employees, and other agents involved in accreditation activities will be considered the financial interests of such officers, employees, and other agents involved in accreditation activities (21 CFR 1.624(c)). Therefore, the written program under 21 CFR 1.624(a) to protect against conflicts of interest between the recognized AB and any CB seeking accreditation from, or accredited by, the recognized AB must protect against conflicts of interest related to the financial interests of their spouses and children younger than 18.

D.8 What types of records should be maintained to meet the requirements in 21 CFR 1.625(a)(8) regarding records for fee payments and reimbursement of direct costs?

An AB must maintain records related to fee payments and reimbursement of direct costs to demonstrate compliance with this program (21 CFR 1.625(a)(8)).

The records needed to demonstrate compliance include the amount paid and the date(s) on which the accredited CB paid any fees or reimbursements of direct costs. The records could also include any fee schedules or standard operating procedures to describe what costs are considered and how the fee payments and reimbursement of direct costs are determined. Recognized ABs are required to electronically maintain the records of fee payments and reimbursement of direct costs for five years (21 CFR 1.625(a)).

The records that the recognized AB maintains in accordance with 21 CFR 1.625(a)(8) may also be used to document the AB's compliance with 21 CFR 1.624(b) (regarding when a recognized AB may accept the payment of fees for accreditation services) and 21 CFR 1.624(d) (regarding the requirement to maintain a Web site with an up-to-date list of accredited CBs and the date(s) on which the accredited CB paid any fee or reimbursement associated with the accreditation).

D.9 Is the recognized accreditation body notified of FDA's response when a certification body they accredited requests a waiver for the 13-month limit for audit agents conducting regulatory audits?

Yes. An accredited CB cannot use an audit agent to conduct a regulatory audit at an eligible entity if such audit agent conducted a consultative audit or regulatory audit for the same eligible entity in the preceding 13 months, except that such limitation may be waived if the accredited CB demonstrates to FDA, under 21 CFR 1.663, there is insufficient access to audit agents in the country or region where the eligible entity is located. Once the Agency makes a determination for the waiver or waiver extension request in accordance with 21 CFR 1.663, the point of contact from the recognized AB would be copied on the FURLS automatic system notification that is sent to the point of contact from the accredited CB. See Response F.1.1 for additional information about the FDA waiver for the 13-month limit.

E. Requirements for Certification Bodies Seeking Accreditation from Recognized Accreditation Bodies Under the Third-Party Program

E.1 Who is eligible to be an accredited certification body under the Third-Party Program?

A CB can be a foreign government, agency of a foreign government, foreign cooperative, or any other third-party (foreign or domestic) 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. An individual may also be accredited as a CB (21 CFR 1.640). All such entities and individuals will only be accredited if they can meet the requirements of 21 CFR 1.641 through 1.645. Additional information for CBs seeking

accreditation under TPP is available in FDA's guidance entitled "Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards."[12]

E.2 Where and how can you apply to be an accredited certification body?

Interested CBs can seek accreditation from an AB recognized under TPP. FDA maintains a public registry of recognized ABs along with their Web site and contact information (as discussed in Response H.1.1).

CBs will not be able to transmit any information to FDA until they have been accredited by a recognized AB. FURLS is the primary system for managing the CB's account, issuing food safety certifications, and submitting reports and notifications to FDA. Users may access detailed instructions on creating and managing an account in FURLS from a document titled "U.S. Food and Drug Administration, Accredited Third-Party Certification Program Portal, Instructions for a Certification Body to Manage Accreditation Status in the Program", available at https://www.fda.gov/media/143888/download. This instruction guide can also be accessed from the FDA's Accredited Third-Party Certification Program Web site at https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program.

E.3 What are the scopes of accreditation under the Third-Party Program?

As discussed in Responses C.3 and C.4, FDA implemented 11 scopes of food or process categories for which the CBs will be accredited under TPP:

- Acidified Foods (AF) scope
- Dietary Supplements scope
- Infant Formula scope
- Juice Hazard Analysis and Critical Control Points (Juice HACCP) scope
- Low-Acid Canned Foods (LACF) scope
- Medicated Feed Current Good Manufacturing Practices (Medicated Feed CGMPs) scope
- Preventive Controls for Animal Food (PCAF) scope
- Preventive Controls for Human Food (PCHF) scope
- Produce Safety scope
- Seafood Hazard Analysis and Critical Control Points (Seafood HACCP) scope
- Shell Eggs scope

The scopes represent sets of overarching food safety requirements of the FD&C Act and FDA regulations for respective food or process categories. We refer to the 11 scopes as scopes of recognition for ABs and scopes of accreditation for CBs.

[12] See U.S. Food and Drug Administration, Guidance for Industry and FDA Staff: Model Accreditation Standards for Third-Party Certification Body Accreditation for Food Safety Audits, Final Guidance, December 2016, (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-fda-staff-model-accreditation-standards-third-party-certification-body).

As part of the assessment to evaluate a CB seeking accreditation, a recognized AB evaluates the competency and capacity of the CB for the specific scope(s) of accreditation being sought under TPP that correspond to the specific scopes for which the AB is recognized. An AB can only accredit a CB for scopes for which the AB has been recognized (see Response C.3). Once a recognized AB accredits a CB, the AB also conducts annual comprehensive assessments of the accredited CB for each scope of accreditation (21 CFR 1.621).

Additional information about the scopes is available in Responses C.3, C.4, and E.4.

E.4 How do the scopes of accreditation correspond to the facility, process(es), or food to be audited under the Third-Party Program?

As discussed in Response E.3, a recognized AB evaluates the competency and capacity of the CB for the specific scope(s) of accreditation being sought under TPP (that correspond to the specific scopes for which the AB is recognized). During the evaluation of a CB seeking accreditation, the recognized AB observes a representative sample of onsite audits examining compliance with the applicable food safety requirements of the FD&C Act and FDA regulations as conducted by the CB or its agents (21 CFR 1.620(a)(3)). The recognized AB must use these observations as part of its evaluation to determine whether the CB meets the requirements for accreditation under TPP (21 CFR 1.620(a)(3)).

Table 2 describes the 11 scopes of recognition and accreditation. We are providing this description to assist CBs in identifying the appropriate scope for an audit of a specific type of facility, process, or food. Recognized ABs and CBs seeking accreditation should consider this information when identifying appropriate audits for the ABs to observe while evaluating a CB's accreditation request. In addition, accredited CBs should consider this list in determining the appropriate scope of food safety audits to conduct under TPP.

Table 2 – Description of the Scopes of Recognition and Accreditation

Scope of Recognition and Accreditation	Description of the Scopes of Recognition and Accreditation
Acidified Foods (AF)	The scope applies to acidified foods packaged in hermetically sealed containers. Acidified food means low-acid food to which acid(s) or acid food(s) are added and that have a finished equilibrium pH of 4.6 or below and a water activity greater than 0.85. (See 21 CFR 114.3 for the complete definition of acidified foods)
Dietary Supplements	The scope applies to dietary supplements as defined in section 201(ff) of the FD&C Act (21 U.S.C. 321(ff)). The term dietary supplement means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, mineral, herb or other botanical,

Scope of Recognition and Accreditation	Description of the Scopes of Recognition and Accreditation
	amino acid, a dietary substance to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredients listed above. (See section 201(ff) of the FD&C Act for the complete definition of dietary supplements)
Infant Formula	The scope applies to infant formula as defined in section 201(z) of the FD&C Act (21 U.S.C. 321(z)). Infant formula means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of simulation of human milk or its suitability as a complete or partial substitute for human milk. (See section 201(z) of the FD&C Act)
Juice Hazard Analysis and Critical Control Points (Juice HACCP)	The scope applies to juice, as defined in 21 CFR 120.1(a). Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree. (See 21 CFR 120.1(a) for a complete description of the applicability of the juice HACCP requirements)
Low-Acid Canned Foods (LACF)	The scope applies to thermally processed low-acid foods packaged in hermetically sealed containers. Low-acid food means foods (other than alcoholic beverages) with a finished equilibrium pH greater than 4.6 and a water activity greater than 0.85. (See 21 CFR 113.3 for the complete definition of low-acid foods)
Medicated Feed Current Good Manufacturing Practices (Medicated Feed CGMPs)	The scope applies to all types of facilities and equipment used in the production (i.e., manufacturing, processing, packing, and holding) of medicated feeds for consumption in the United States, and also applies to instances in which failure to adhere to the regulations has caused nonmedicated feeds that are manufactured, processed, packed, or held to be adulterated (21 CFR 225.1(b)(1)). The scope applies to facilities manufacturing one or more medicated feeds for which an approved medicated feed mill license is required where the requirements in 21 CFR 225.10-225.115 would apply. The scope also applies to facilities manufacturing solely medicated feeds for which an approved license is not required where the requirements in 21 CFR 225.120-225.202 would apply (21 CFR 225(b)(2)). (See 21 CFR Part 225) Medicated feed production is also subject to the Current Good Manufacturing Practice, Hazard Analysis, and

Scope of Recognition and Accreditation	Description of the Scopes of Recognition and Accreditation
	Risk-Based Preventive Controls for Food for Animals regulation (21 CFR 507.1(c)). An audit conducted under the Medicated Feed CGMPs scope should assess compliance with the applicable food safety requirements of 21 CFR Part 225 and 21 CFR Part 507 (along with any other applicable requirements of the FD&C Act and FDA regulations).
Preventive Controls for Animal Food (PCAF)	The scope generally applies to the manufacturing, processing, packing, or holding of animal food. The Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals regulation applies to facilities that are required to register with the FDA under section 415 of the FD&C Act because they manufacture, process, pack, or hold animal food for consumption in the United States (21 CFR 507.5(a)), unless an exemption applies (see 21 CFR 507.5 for exemptions). (See 21 CFR Part 507)
Preventive Controls for Human Food (PCHF)	The scope generally applies to the manufacturing, processing, packing, or holding of human food (unless there is a product-specific scope that is more appropriate). Subparts A, B, and F of 21 CFR Part 117 (the Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food regulation) include requirements for manufacturing, packing, or holding human food. Subparts A, C, D, E, F, and G of Part 117 include requirements for food facilities that are required to register under section 415 of the FD&C Act because they manufacture, process, pack, or hold human food for consumption in the United States. (See 21 CFR Part 117) The scope does not apply when the food being assessed is more appropriately assessed under the LACF, AF, Produce Safety, Dietary Supplement, Juice HACCP, Infant Formula, or Seafood HACCP scopes.
Produce Safety	The scope applies to produce as defined in 21 CFR 112.3. Produce means any fruit or vegetable (including mixes of intact fruit and vegetables) and includes—but is not limited to—mushrooms, sprouts, peanuts, tree nuts, and herbs. The scope only applies to produce that is a raw agricultural commodity (RAC) as defined in section 201(r) of the FD&C Act (21 U.S.C. 321(r)), which means any food in its raw or natural state. The scope may apply to produce that is not subject to the

Scope of Recognition and Accreditation	Description of the Scopes of Recognition and Accreditation
	Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption regulation (21 CFR Part 112), such as RAC produce that has been designated as rarely consumed raw in accordance with 21 CFR 112.2(a)(1). (See 21 CFR 112.3 for the complete definition of produce and section 201(r) of the FD&C Act for the complete definition of RAC)
Seafood Hazard Analysis and Critical Control Points (Seafood HACCP)	The scope applies to fish or fishery products as defined in 21 CFR 123.3, where fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life other than birds or mammals, and all mollusks, where such animal life is intended for human consumption and fishery products means any human food product in which fish is a characterizing ingredient. (See 21 CFR 123.3(d) and (e) for the complete definitions of fish and fishery products)
Shell Eggs	The scope applies to shell eggs as defined in 21 CFR 118.3, which means the egg of a domesticated chicken. (See 21 CFR 118.3)

The descriptions of the scopes in Table 2 are to assist CBs in determining the appropriate scope for an audit of a specific type of facility, process, or food. The scopes apply to the manufacturing, processing, growing, or other related activities pertaining to the food subject to the applicable scope. Along with determining the appropriate scope for a specific audit, the CB is also responsible for determining the applicable food safety requirements of the FD&C Act and FDA regulations that should be assessed. An audit conducted under a single scope may need to examine compliance with food safety requirements from more than one food safety regulation (see Response C.4).

Identifying the specific facility, process(es), or food to be audited is important in determining the appropriate scope of accreditation for the audit (see Response F.1.5 for information on how to determine what should be assessed as part of a food safety audit). The appropriate scope for an audit may depend not just on the product being audited, but also on the specific activity or process being examined during the audit. For example, a food safety audit of the packing of avocados that are RACs would be conducted under the Produce Safety scope, while a food safety audit of the processing of avocado oil would be conducted under the PCHF scope.

Further, there may be multiple appropriate scopes of accreditation in the case of a facility that manufactures multiple types of products at one location. For example, suppose the following conditions exist: an eligible entity that manufactures an acidified food that meets the definition of 21 CFR 114.3(b) and manufactures a dietary supplement that meets the definition of section 201(ff) of the FD&C Act requests a regulatory audit from an accredited CB. The CB is accredited for the AF and Dietary Supplement scopes under TPP and during the audit planning, the CB determines that the dietary supplement product is not an acidified food. In the case

where the request was for a regulatory audit focusing on only the production of the acidified food product, the appropriate scope of accreditation would be the AF scope. In the case where the request was for a regulatory audit focusing on only the production of the dietary supplement product, the appropriate scope of accreditation would be the Dietary Supplement scope.

However, if the request was for a regulatory audit focusing on the production of both the acidified food and the dietary supplement products, the regulatory audit would be conducted under both the AF and Dietary Supplement scopes of accreditation. In this regulatory audit, the physical locations, activities, and processes related to the production of the acidified food would be assessed for compliance with the FDA food safety requirements that apply to acidified foods (e.g., 21 CFR Parts 114, 108, and 117). In addition, the physical locations, activities, and processes related to the production of the dietary supplement would be assessed for compliance with the FDA food safety requirements that apply to dietary supplements (e.g., 21 CFR Parts 111 and 117).

There are also foods where the descriptions of two of the scopes may apply. For example, suppose the following conditions exist: a CB accredited for both the AF and Juice HACCP scopes conducts a regulatory audit at an eligible entity that manufactures an acidified juice and the CB issues a certificate to the eligible entity as a result of the audit. The regulatory audit for an acidified juice would have considered the food safety requirements in the FDA regulations applicable to both acidified foods in 21 CFR Part 114 and juice in 21 CFR Part 120. When submitting the RAR and certificate information to FDA through FURLS, the CB would need to identify either the AF or Juice HACCP scopes, because FURLS is designed so that the accredited CB selects a single scope of accreditation (and then submits the product codes for the products observed during the regulatory audit). In this example, we recommend that the accredited CB identify the Juice HACCP scope, because juice is the more specific category of food, and the acidification describes the processing method of the juice product. See Response F.2.7 for more information about the use of the FDA product codes in FURLS under TPP.

The eligible entity seeking a food safety audit should work with the CB to ensure that they have identified the appropriate scope and purpose of the food safety audit, including the facility, process(es), or food to be audited by the accredited CB. The CB, in turn, should determine whether the requested audit is within its scope of accreditation during the audit planning (21 CFR 1.651(a)).

Additional information about the scopes is available in Responses C.3, C.4, and E.3.

E.5 Where can certification bodies locate the audit criteria to evaluate eligible entities?

The TPP regulation establishes the framework, procedures, and applicable procedural requirements for accredited CBs participating in the program, including requirements regarding how accredited CBs must conduct food safety audits of eligible entities (see 21 CFR 1.651). Audits must be focused on determining whether the facility, its process(es), and food are in compliance with the applicable food safety requirements of the FD&C Act and FDA

regulations, and, for consultative audits, also includes conformance with applicable industry standards and practices that are within the scope of the audit (21 CFR 1.651(c)(1)). The criteria that accredited CBs will use in auditing eligible entities for compliance with the applicable FDA food safety requirements appear in the FD&C Act and applicable FDA regulations.

As discussed in Response D.1, FDA has provided templates that recognized ABs and accredited CBs may voluntarily use to help ensure that CBs conduct audits to adequately evaluate the food safety requirements in certain FDA regulations.

CBs may need to consider additional food safety requirements beyond those for which FDA has developed templates, as appropriate. The templates are provided as a tool as a starting point for developing evaluation criteria and are not required to be used. The voluntary audit templates are available at https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program-voluntary-audit-templates and at FDA's Accredited Third-Party Certification Program Web site (https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program).

We note that recognized ABs under TPP may have their own audit criteria requirements beyond the TPP requirements as part of their management systems and processes.

E.6 How could a certification body demonstrate capability to meet the requirements for accreditation if the certification body has not previously issued certifications based on food safety programs?

A CB is not required to have previously issued certificates based on food safety programs to become accredited under TPP.

A CB seeking accreditation under TPP must establish its eligibility by demonstrating it has the legal authority, competency, capacity, quality assurance procedures, records procedures, and conflict of interest protections to meet the TPP requirements (see 21 CFR 1.641-1.645). A CB may use documentation of its conformance with ISO/IEC 17021:2011 or ISO/IEC 17065:2012, supplemented as necessary, to demonstrate that it meets the requirements under the program (21 CFR 1.640(a)). Conformance with other standards may be used, but are not required, to support some of the requirements.

E.7 Can the onsite audits that a recognized accreditation body observes before accrediting a certification body serve as a basis for issuing a food or facility certification to an eligible entity?

As discussed in Response D.2, prior to accrediting a CB, a recognized AB evaluating a CB seeking accreditation must observe the CB or its agents conduct a representative sample of onsite audits examining compliance with applicable food safety requirements of the FD&C Act and FDA regulations (21 CFR 1.620(a)(3)). The onsite audits that the AB observes as part of the evaluation process are conducted prior to the recognized AB accrediting the CB. As a result, the TPP requirements for accredited CBs conducting food safety audits in 21 CFR 1.651

do not apply. Because the basis for food and facility certifications is a regulatory audit that meets the requirements of 21 CFR 1.651, and section 1.651 only applies to accredited CBs, onsite audits conducted prior to the CB's accreditation cannot serve as the basis for issuing a food or facility certification (see 21 CFR 1.653(a); 21 CFR 1.651).

F. Requirements for Accredited Certification Bodies Under the Third-Party Program

F.1 Accredited Certification Bodies Conducting Observed Onsite Audits and Food Safety Audits

F.1.1 Can the same certification body conduct both consultative audits and regulatory audits for an eligible entity?

Yes, an accredited CB may conduct both regulatory audits for certification purposes and consultative audits for internal purposes of the same eligible entity.

There are restrictions on an accredited CB's ability to use an audit agent to conduct a regulatory audit of an eligible entity if the same agent conducted a consultative or regulatory audit of the same eligible entity in the preceding 13 months, unless FDA waives the limitation (see 21 CFR 1.650(c)).

An accredited CB can request an FDA waiver or waiver extension for the 13-month limit for audit agents conducting regulatory audits. The accredited CB seeking the FDA waiver must demonstrate that there is insufficient access to audit agents in the country or region where the eligible entity is located (21 CFR 1.663(a)). Accredited CBs that are comprised of an individual may also request the FDA waiver under 21 CFR 1.663.

F.1.2 For a regulatory audit, can advanced notice be given to the eligible entity's key food safety employees if they are based in another site that is several hours away?

Before beginning to conduct a food safety audit under TPP, an accredited CB must engage in audit planning that requires the eligible entity seeking certification to identify the scope and purpose of the food safety audit and provide a 30-day operating schedule with information relevant to the scope and purpose (21 CFR 1.651(a)(1)). The availability of the key employees could be discussed during the audit planning, but with the exception of records review, which may be scheduled, the audit must be conducted without announcement during the 30-day timeframe identified (21 CFR 1.651(c)(1)-(2); section 808(c)(5)(C)(i) of the FD&C Act).

F.1.3 Are there any restrictions that prohibit accredited certification bodies from auditing and certifying eligible entities outside the countries of the certification bodies?

The TPP regulation does not set geographic limitations regarding where an accredited CB could audit and certify eligible entities. However, accredited CBs must have the authority, whether contractual or otherwise, to perform such audits at the location of the eligible entity in accordance with the requirements of TPP (21 CFR 1.651(b)). We are aware that some

recognized ABs may include geographic restrictions in their contracts with their accredited CBs, but any such restrictions are beyond the TPP requirements.

F.1.4 Who issues food or facility certificates to eligible entities and makes the determination of whether to issue such certificates?

Under TPP, accredited CBs issue food or facility certificates after conducting a regulatory audit and any other activities necessary to establish whether a food or facility complies with the applicable food safety requirements of the FD&C Act and FDA regulations (see, e.g., 21 CFR 1.600(c) (definitions of "accredited third-party certification body" and "regulatory audit")). Where a CB uses an audit agent to conduct a regulatory audit of an eligible entity, the CB, not the audit agent, must make the determination of whether to issue certification based on the results of the regulatory audit (21 CFR 1.653(a)(5)). In the circumstance where the accredited CB is an individual, the same individual would conduct the food safety audit and determine whether to issue certification.

F.1.5 How should an accredited certification body determine what should be assessed as part of a food safety audit?

Prior to issuing a food or facility certification to an eligible entity, an accredited CB (or, where applicable, audit agent(s) on its behalf) must complete a regulatory audit that meets the requirements of 21 CFR 1.651 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 (21 CFR 1.653(a)). The audit must be sufficiently rigorous to allow the accredited CB to determine whether the eligible entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. A regulatory audit must also be sufficient to determine whether the eligible entity, given its food safety system and practices, would be likely to remain in compliance with the applicable FDA food safety requirements of the FD&C Act and FDA regulations for the duration of any certification issued under TPP (21 CFR 1.651(c)(3)).

The eligible entity identifies the scope and purpose of the audit, including the facility, process(es), or food to be audited and the type of certification(s) being sought for a regulatory audit during the audit planning (21 CFR 1.651(a)). When the accredited CB conducts the resulting audit, the CB should ensure that the audit covers the appropriate physical locations, activities, and processes to be audited, and information collected during the audit must be relevant to the purpose and criteria, including information related to interfaces between functions, activities, and processes of the food safety system (80 FR 74569 at 74610).

For example, suppose the following conditions exist: an eligible entity requests a regulatory audit for a processed food product (that is within the accredited CB's scope of accreditation) for the purposes of seeking a facility certification. The eligible entity had requested the regulatory audit because they are working with an importer that is trying to establish eligibility for VQIP. The eligible entity only identifies one building that should be audited. The accredited CB conducts a record review prior to the onsite examination of the facility and

determines that the handling and processing of the raw materials, filling, and packaging of the food product occur at the eligible entity in different buildings. In this scenario, the accredited CB should ensure that its record review and the onsite examination for the regulatory audit includes an evaluation of all of the buildings, activities, and processes involved in the manufacturing and production of the processed food product.

We encourage eligible entities, importers, and accredited CBs to consult the VQIP guidance for information about the program, eligibility criteria for VQIP applicants, and the use of the facility certificates in VQIP.[13]

F.1.6 Can a certification be issued for a food that was not directly observed during the onsite examination of the regulatory audit?

In some circumstances, yes. An accredited CB may issue a certification that covers food for which the CB did not directly observe the manufacturing/processing if the operations that the CB did observe are applicable to that food.

For example, suppose the following conditions exist: an eligible entity contacts an accredited CB requesting a regulatory audit of the processing of frozen vacuum-packed tilapia and salmon fillets. The accredited CB determines that the regulatory audit is within its scope of accreditation, Seafood HACCP in this case. For the regulatory audit, the accredited CB reviews the records pertaining to the processed frozen vacuum-packed tilapia and salmon fillets. During the onsite examination, only the frozen vacuum-packed tilapia fillets are being processed.

In this example, the accredited CB could consider issuing a certificate for the frozen vacuum-packed salmon fillets along with the frozen vacuum-packed tilapia fillets based on their assessment during the records review, onsite observations, and visual examination of the processing of the frozen vacuum-packed tilapia fillets. For a regulatory audit of both the frozen vacuum-packed tilapia and salmon fillets, the records review would include records related to the processing of both types of fish fillets to assess compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. The onsite examination would also cover the appropriate physical locations, activities, and processes for both the frozen vacuum-packed tilapia and salmon fillets, even if only the tilapia fillets are in production at the time of the onsite examination. After the onsite examination, the accredited CB would need to consider the results of the records review, onsite observations, and visual examination to determine if the food or facility certificate should be issued to the eligible entity in accordance with 21 CFR 1.653(a)(3), and if so, which products should be included in the certificate.

F.1.7 Can the onsite audits that a recognized accreditation body observes to evaluate an accredited certification body seeking accreditation for a new scope serve as a basis for issuing a food or facility certification to an eligible entity?

[13] See U.S. Food and Drug Administration, Guidance for Industry: FDA's Voluntary Qualified Importer Program, Final Guidance, November 2016, (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-voluntary-qualified-importer-program).

Since the basis for food and facility certifications is a regulatory audit that meets the requirements of 21 CFR 1.651, and audits conducted under section 1.651 must be within the scope of a CB's accreditation, an accredited CB cannot provide a food or facility certification for a scope that is not part of the CB's accreditation (See 21 CFR 1.653(a); 21 CFR 1.651; and Response E.7). Therefore, when a recognized AB is observing audits pertaining to an accredited CB's request for a new scope, the onsite audits that the AB observes as part of the evaluation process for the new scope cannot be a basis for issuing a food or facility certification.

F.1.8 Can an accredited certification body be evaluated for a new scope while their recognized accreditation body is onsite conducting monitoring activities for an already-accredited scope?

Yes, provided that all of the requirements of TPP are met. As discussed in Response C.3, the AB would need to be recognized for both the scope which the CB is already accredited and the scope for which it is seeking accreditation. The recognized AB must also observe a representative sample of onsite audits for both the scope for which the CB is already accredited and for which it is seeking accreditation (21 CFR 1.620(a)(3); 21 CFR 1.621(b)).

For example, consider a scenario where a CB accredited for the PCHF scope is seeking accreditation for the PCAF scope. The accredited CB has previously issued a facility certificate to an eligible entity for the production of a dry vegetable soup mix. The eligible entity is seeking recertification, and the accredited CB plans to conduct a regulatory audit of the vegetable soup mix operations under the PCHF scope to support the recertification. The recognized AB plans to conduct onsite observations of the CB's regulatory audit in accordance with its obligation under 21 CFR 1.621(b) to conduct onsite observations of a representative sample of regulatory audits performed by the accredited CB. In an adjacent building of the same facility, the eligible entity also manufactures a baked pet treat subject to the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals regulation (21 CFR Part 507). The recognized AB also plans to observe the CB conduct an onsite audit of the baked pet treat operations under the PCAF scope for which the CB is seeking accreditation.

In this scenario, the recognized AB could observe the accredited CB's food safety audit of the vegetable soup mix operations under the PCHF scope in conjunction with also observing the CB's audit of the baked pet treat operations under the PCAF scope. The AB would observe the food safety audit under the PCHF scope to meet its obligations under 21 CFR 1.621(b) to conduct onsite observations of a representative sample of regulatory audits conducted by the CBs it has accredited. The AB would observe the audit under the PCAF scope as part of its obligation when evaluating a CB seeking accreditation to observe the CB or its agents conduct a representative sample of onsite audits examining compliance with applicable food safety requirements of the FD&C Act and FDA regulations under 21 CFR 1.620(a)(3).

The accredited CB would consider the results of the regulatory audit under the PCHF scope to determine if the eligible entity would be issued a new facility certificate for the production of

the dry vegetable soup mix under the PCHF scope of accreditation. As discussed in Response F.1.7, the CB could not use that audit as a basis for issuing a food or facility certification for the pet treat operations because the audit of the eligible entity's pet treat operations was conducted prior to the CB being accredited for the PCAF scope of accreditation. In addition, the regulatory audit report requirements for CBs under 21 CFR 1.651 would not apply to the audit of the baked pet treats conducted under the PCAF scope, because those requirements only apply to accredited CBs and the CB was not accredited for the PCAF scope at the time of the audit. The recognized AB would consider its observations from the CB's audit of the baked pet treat operations in determining whether to grant the CB's request to be accredited for the PCAF scope.

F.2 Reports and Notifications Accredited Certification Bodies Submit to FDA

F.2.1 What reports and notifications must an accredited certification body submit to FDA?

An accredited CB must electronically submit the following information to FDA:

- Regulatory audit reports (RARs). The accredited CB must submit an RAR electronically, in English, to FDA to report the results of a regulatory audit no later than 45 days after completing such audit (21 CFR 1.656(a); see Responses F.2.3 and F.2.6 for additional information about the RARs). The RAR should be submitted to FDA via FURLS.

- Self-assessments. If the accredited CB is subject to an FDA request for cause, or as required in 21 CFR 1.631(f)(1)(i) (after FDA's issuance of the notice of the denial of recognition renewal to any CB accredited by the AB whose renewal application FDA denied), 21 CFR 1.634(d)(1)(i) (after FDA's issuance of the notice of revocation of the AB that has accredited the CB), or 21 CFR 1.635(c)(1)(i) (after the date of relinquishment or the date of expiration of the recognition of the AB that has accredited the CB), the accredited CB must submit the report of its self-assessment to FDA, electronically, in English. The report of its self-assessment must be submitted to FDA within 60 days of the FDA request, denial of renewal, revocation, or relinquishment of recognition of the AB that granted its accreditation (21 CFR 1.656(b)). The self-assessment should be submitted to FDA via FURLS.

- Serious risk to public health. The accredited CB must immediately notify FDA electronically, in English, if during a regulatory or consultative audit, any of its audit agents or the accredited CB itself discovers a condition that could cause or contribute to a serious risk to the public health (21 CFR 1.656(c)). The notification should be submitted to FDA via FURLS.

- Withdrawing or suspending a food or facility certification. The accredited CB must immediately notify FDA electronically, in English, when withdrawing or suspending any food or facility certification of an eligible entity and the basis for such action (21 CFR 1.656(d)). The notification should be submitted to FDA via FURLS.

There are additional requirements in 21 CFR 1.656 for when accredited CBs must provide reports or notifications to their recognized AB or eligible entities.

FDA has an electronic portal dedicated to TPP in FURLS. FURLS is the primary system for managing the CB's account, issuing food safety certifications, and submitting reports and notifications to FDA (see Response E.2). Within the portal dedicated to TPP in FURLS, there are tabs for Supplemental Documentation and a Reports and Notification Directory where the various reports and notifications required under 21 CFR 1.656 are electronically submitted to FDA through the data or text entry fields or as attachments, as applicable. Note that the information required in 21 CFR 1.656 must be submitted in English. Instructions for submitting information in FURLS are available at https://www.fda.gov/media/143888/download (see a related response in D.3 applicable to AB's submission of information to FDA).

F.2.2 Can a company name be used in place of the audit agent(s) name(s) in the food or facility certificate information submitted to FDA?

No. The name(s) of the audit agent(s) who conducted the regulatory audit is required to be included in the certifications that the accredited CB issues and submits to FDA (21 CFR 1.653(b)(2)(v)). An audit agent is an individual, not a company or other corporate entity (see 21 CFR 1.600(c) (definition of "audit agent")). Therefore, the submission of the accredited CB's company name instead of the name(s) of the individual audit agent(s) that conducted the regulatory audit is not permissible. (However, in the case where an individual is accredited as a CB, the audit agent name may match the company name because the individual audit agent is the accredited CB.)

During the certification submission process in FURLS, the accredited CB selects the name(s) of the audit agent(s) that conducted the regulatory audit from a drop-down list. It is critical that the selected name(s) of the audit agent(s) are correct since the FURLS portal uses this information to monitor adherence with the TPP requirements, including the 13-month limit for audit agent(s) conducting a regulatory audit at the eligible entity (see Responses D.9 and F.1.1). Instructions for adding a certificate and managing audit agent information in FURLS are available at https://www.fda.gov/media/143888/download. This instruction guide can also be accessed from the FDA's Accredited Third-Party Certification Program Web site at https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program.

F.2.3 When must an accredited certification body submit a regulatory audit report to FDA and when does FDA consider a regulatory audit to be complete?

An accredited CB must electronically submit a RAR to FDA, in English, no later than 45 days after completing a regulatory audit (21 CFR 1.656(a)). The RAR must be submitted regardless of whether the CB issued a food or facility certification to the eligible entity (21 CFR 1.652(c)).

We consider a regulatory audit to be complete when the accredited CB has completed all activities required under 21 CFR 1.651. Specifically, the accredited CB must consider all information from the regulatory audit and other activities conducted under 21 CFR 1.651, including each observation 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. The activities also include reviewing information that may take place after the onsite audit, such as the verification of effectiveness of corrective actions, and any discussions regarding whether to issue the food or facility certificate.

The 45-day timeframe for submitting the RAR begins once all the pertinent data and information have been considered by the CB.

F.2.4 What must an accredited certification body include in a regulatory audit report?

An RAR must contain all of the data elements required under 21 CFR 1.652(b). RARs are used in TPP for the accredited CBs to provide FDA with a robust executive summary of the regulatory audits and findings that support the decision of whether the eligible entity was issued a food or facility certificate.

The data elements required in the regulatory audit reports under 21 CFR 1.652(b) are:

(1) The identity of the site or location where the regulatory audit was conducted, including:
    (i) The name, address, and FDA Establishment Identifier of the facility subject to the regulatory audit and a unique facility identifier, if designated by FDA; and
    (ii) Where applicable, the FDA registration number assigned to the facility under 21 CFR Part 1, Subpart H;

(2) The identity of the eligible entity, if different from the facility, including the name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, and, where applicable, registration number under 21 CFR Part 1, Subpart H;

(3) The dates and scope of the regulatory audit;

(4) The process(es) and food(s) observed during such regulatory audit;

(5) The name(s) and telephone number(s) of the person(s) responsible for the facility's compliance with the applicable food safety requirements of the FD&C Act and FDA regulations;

(6) Any deficiencies observed during the regulatory audit that present a reasonable probability that the use of or exposure to a violative product:
    (i) Will cause serious adverse health consequences or death to humans and animals; or

(ii) 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;

(7) The corrective action plan for addressing each deficiency identified, unless corrective action was implemented immediately and verified onsite by the accredited CB (or its audit agent, where applicable);

(8) 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 two years preceding the regulatory audit.

All the information in the RAR is important in supporting the decision of whether the eligible entity was issued a certificate and it provides FDA with a robust executive summary of the regulatory audits. For example, the identity or location of the regulatory audit and identity of the eligible entity helps ensure that we have comprehensive, accurate, and up-to-date information on eligible entities and audited facilities that chose to participate in the program (additional information discussed in Response F.2.5). The dates and scope of the regulatory audit and process(es) and food(s) observed during the regulatory audit may help us determine whether the certification matches the scope of the audit and whether the stated scope of audit matches the CB's scope of accreditation (additional information discussed in Response F.2.6). Observed deficiencies and corrective action plan for addressing each deficiency, as well as the facility's use of sampling and laboratory analysis and any significant changes to the facility, its process(es), or food products during the previous two years are important because the elements are related to or influential to a determination of compliance with the applicable food safety standards of the FD&C Act and FDA regulations.

F.2.5 If an eligible entity registered with FDA with one address but the local authority recently changed that address, what address should be submitted in the regulatory audit report?

The accredited CB should use the eligible entity's most current address in the RAR. In accordance with 21 CFR 1.234(a), facilities that are required to register with FDA must update a facility's registration within 60 calendar days of any change to any of the information previously submitted under 21 CFR 1.232, including the address of the facility. Information about updating the registration is available in the Food Facility Registration User Guide on FDA's Web site.[14]

F.2.6 What information about the observed processes and foods should be included in the regulatory audit report?

[14] The Food Facility Registration User Guidance for updating registration information is available at https://www.fda.gov/food/online-registration-food-facilities/food-facility-registration-user-guide-update-registration.

As discussed in Response F.2.4, an RAR must document the process(es) and food(s) observed during the regulatory audit (21 CFR 1.652(b)(4)). The description of the observed process(es) and food(s) in the RAR should contain enough information about the specific process(es) and food(s) that were observed during the audit for FDA and the recognized AB to be able to determine that the certification matches the scope of the audit.

For example, suppose the following conditions exist: an accredited CB completes a regulatory audit of processed mixed vegetables. The description should include details about the process(es) and food such that FDA or the recognized AB can determine the processing steps that were assessed during the records review and onsite examination of the regulatory audit and understand key details about the food that may affect the appropriate scope (e.g., if it was thermally processed and hermetically sealed, frozen, etc.). For example, if the RAR stated only that the CB observed "food manufacturing of processed mixed vegetables," FDA or the recognized AB would not be able to determine the appropriate scope of the audit since any heat-treatments or whether the product is frozen or shelf stable could affect the appropriate scope for the audit (e.g., PCHF scope for a bag of frozen mixed vegetables vs LACF scope for heat-treated product of mixed vegetables that is in a hermetically sealed container, such as canned mixed vegetables). Without detailed descriptions, it is difficult for FDA or the recognized AB to understand what was assessed as part of the regulatory audit.

F.2.7 What is the role of the FDA product codes that accredited certification bodies provide FDA in the certification information in FDA's Unified Registration and Listing System?

Once an accredited CB issues a food or facility certificate to an eligible entity, the CB must electronically submit information to FDA (21 CFR 1.653(b)). When submitting the certificate information through FURLS, the accredited CB selects the FDA product codes to describe the products covered under the certificate. The FDA product codes are used to describe a specific product and contain a combination of five to seven numbers and letters. The product code should match the actual product name and/or invoice description of the product.[15]

It is important for the accredited CB to include the FDA product codes for all products that are covered under the certificate when filling out the information in FURLS. For example, suppose the following conditions exist: an accredited CB completes a regulatory audit of frozen, shredded coconut and dried, shredded coconut at an eligible entity. The eligible entity had requested the regulatory audit because they are working with an importer that is trying to establish eligibility for VQIP. The accredited CB decides to issue a facility certificate for both the frozen and dried shredded coconut products based on the results of the regulatory audit. In order to inform FDA through FURLS that the facility certificate covers both products, the accredited CB would need to include the two FDA products codes for the frozen, shredded

[15] Additional information on FDA product codes and a product code builder are available at https://www.fda.gov/industry/import-program-resources/product-codes-and-product-code-builder.

coconut and the dried, shredded coconut in FURLS.[16] The importer could then include the issued facility certificate for the frozen, shredded coconut and the dried, shredded coconut in their application for VQIP.[17]

The accredited CB may need to coordinate with the eligible entity and the importer interested in applying for VQIP to identify the product codes that should be documented in FURLS for the TPP facility certificate. The FDA product codes in the facility certificates issued by the accredited CB should correspond to the product codes for the products that would be included in the importer's VQIP application so that VQIP benefits can be applied to those products.

F.2.8 Is an accredited certification body required to notify FDA if a condition that could potentially cause or contribute to a serious risk to public health is identified during a non-Third-Party Program audit?

An accredited CB must immediately notify FDA if, during a regulatory or consultative audit, any of its audit agents or the accredited CB itself discovers a condition that could cause or contribute to a serious risk to the public health (21 CFR 1.656(c); see Response F.2.1). This requirement only applies to audits that are conducted as part of TPP. Accredited CBs may conduct audits and issue certificates outside of TPP. Audits that fall outside TPP are not subject to the TPP requirements, including the reporting and notification requirements under 21 CFR 1.656(c) regarding a condition identified during a regulatory or consultative audit that could cause or contribute to a serious risk to public health.

However, under 21 CFR 1.654, if an accredited CB has reason to believe that an eligible entity to which it has already 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 accredited CB must conduct any monitoring (including an onsite audit) of the eligible entity necessary to determine whether the entity is in compliance with such requirements. The accredited CB must immediately notify FDA, under 21 CFR 1.656(d), if it withdraws or suspends a food or facility certification and the basis for such action. The accredited CB must also maintain records of any monitoring it conducted of an eligible entity to which the CB issued a food or facility certification (21 CFR 1.658(a)(6)).

Please see Response G.2 regarding the eligible entity's responsibility to report to FDA regarding a food that could cause serious adverse health consequences or death to humans or animals.

F.3 Conflict of Interest Requirements for Accredited Certification Bodies

[16] Instructions for submitting FDA product codes in FURLS are available at https://www.fda.gov/media/143888/download and additional information on FDA product codes and a product code builder are available at https://www.fda.gov/industry/import-program-resources/product-codes-and-product-code-builder.

[17] See U.S. Food and Drug Administration, Guidance for Industry: FDA's Voluntary Qualified Importer Program, Final Guidance, November 2016, (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-voluntary-qualified-importer-program).

F.3.1 Do the financial interests of the spouses and children of an accredited certification body's officers, employees, and agents involved in auditing and certification activities need to be considered in the written program to protect against conflicts of interest?

Yes. The financial interests of the spouses and children younger than 18 years of age of accredited CB's officers, employees, and other agents involved in auditing and certification activities are considered the financial interests of such officers, employees, and other agents (21 CFR 1.657(c); see related response in D.7 applicable to AB's officers, employees, and agents). Therefore, the written program under 21 CFR 1.657(a)(1) to protect against conflicts of interest between the accredited CB and an eligible entity must protect against conflicts of interests related to the financial interests of their spouses and children younger than 18.

G. Requirements for Eligible Entities Under the Third-Party Program

G.1 Can an eligible entity that is not required to register as a food facility with FDA be issued a certification under the Third-Party Program?

Yes. Eligible entity means 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 conducted by an accredited CB under TPP. Eligible entities include foreign facilities required to be registered under section 415 of the FD&C Act (21 U.S.C. 350d), but for the purposes of section 808 of the FD&C Act, eligible entities are not limited to registered facilities (see 21 CFR 1.600(c) (definition of "eligible entity")).

For example, farms that are not required to register as a food facility under section 415 of the FD&C Act may be eligible entities that could seek certification under TPP. Additionally, a foreign firm that manufactures/processes food that undergoes further manufacturing/processing by another facility outside the United States would not be required to register under section 415 of the FD&C Act (see 21 CFR 1.226(a)) but could seek certification under TPP.

G.2 Should an accredited certification body consider whether an eligible entity is in compliance with FDA registration requirements in determining whether to issue a food or facility certificate?

Yes. When issuing a food or facility certificate, an accredited CB must determine whether an eligible entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations (21 CFR 1.653(a)(3)). We consider FDA registration requirements, such as food facility registration requirements under section 415 of the FD&C Act, to be food safety requirements. Therefore, the accredited CB should assess an eligible entity's compliance with applicable FDA registration requirements. Accredited CBs should not issue certifications to eligible entities that are not in compliance with applicable registration requirements.

The reportable food requirements under section 417 of the FD&C Act (21 U.S.C. 350(f)) also apply to facilities that are required to register with FDA.[18]

H. General Requirements for the Third-Party Program

H.1 General

H.1.1 Where can you locate a list of the recognized accreditation bodies and accredited certification bodies under the Third-Party Program?

The Agency maintains public registries of the recognized ABs and accredited CBs under TPP. The public registries include a list of the names and contact information for the recognized ABs and accredited CBs along with other information. The public registries of recognized ABs and accredited CBs are available on the FDA Data Dashboard at https://datadashboard.fda.gov/ora/fd/tpp.htm. The information is also available at FDA's Accredited Third-Party Certification Program Web site (https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program).

H.1.2 Are there user fees to participate in the Third-Party Program?

Yes. Section 808(c)(8) of the FD&C Act directs FDA to establish by regulation a reimbursement (user fee) program to assess fees and requires reimbursement for the work performed to establish and administer TPP. The user fee program for TPP was established by the final rule entitled, "Amendments to Accreditation of Third- Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications To Provide for the User Fee Program" (81 FR 90186). The user fees include application, renewal, and annual fees in accordance with 21 CFR 1.700 and 1.705.

A fee notice is published annually in the Federal Register, prior to each fiscal year, to reflect the user fee rates for the upcoming fiscal year and information on how the fees must be paid. The TPP user fee information is available at https://www.fda.gov/industry/fda-user-fee-programs/accredited-third-party-certification-program-user-fees and at FDA's Accredited Third-Party Certification Program Web site (https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program).

H.1.3 Once certification bodies are accredited, can logos or markings be included in their mark of conformity to demonstrate participation in the Third-Party Program?

The TPP regulation does not require the use of a logo or mark of conformity as part of the program. We understand that marks of conformity are included in some industry certification programs.

[18] See U.S. Food and Drug Administration, Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007, Final Guidance, September 2009, (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food-and-drug).

The official FDA logo may not be used by the private sector (see FDA Logo Policy at https://www.fda.gov/about-fda/website-policies/fda-logo-policy). However, FDA's Logo Policy does not apply to the use of non-FDA logos and we do not have a policy against the use of non-FDA logos or markings. In addition, FDA does not approve or endorse private firms' logos or marks of conformity.

We would have concerns with the use of FDA's name in an AB's or CB's promotional materials if such use would likely cause confusion as to the origin or approval of the services of an AB or CB. For example, an accredited CB should not falsely suggest that their food safety audits under TPP are conducted by current FDA employees.

H.2 Third-Party Program and Other FSMA Requirements

H.2.1 What is the relationship between the Voluntary Qualified Importer Program and the Third-Party Program?

Although FDA's TPP and VQIP are two separate programs, FSMA established a link between them. Facility certifications under TPP are used by importers that want to establish eligibility for VQIP.

Section 806(d) of the FD&C Act requires VQIP importers to have a facility certification issued in accordance with TPP for each foreign supplier's facility from which the importer wants to import a food under VQIP. Therefore, foreign establishments may be asked by their importers to obtain a facility certification under TPP for the products they wish to import into the United States under VQIP. Either the importer or the foreign supplier may request the regulatory audit required for facility certification.

We encourage TPP participants and importers interested in VQIP to consult the VQIP guidance for information about the eligibility criteria for VQIP applicants and the use of the facility certificates in VQIP.[19]

H.2.2 Can audits conducted by accredited certification bodies be used to meet the supplier verification requirements of the Foreign Supplier Verification Program and Preventive Controls regulations?

Yes. There are three FSMA regulations that provide for onsite audits of food suppliers in certain circumstances.[20] The three regulations are Current Good Manufacturing Practice,

[19] See U.S. Food and Drug Administration, Guidance for Industry: FDA's Voluntary Qualified Importer Program, Final Guidance, November 2016, (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-voluntary-qualified-importer-program).

[20] See https://www.fda.gov/media/136142/download for the Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency: Guidance for Industry.

Hazard Analysis, and Risk Based Preventive Controls for Human Food (21 CFR Part 117),[21] Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR Part 507),[22] and Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (21 CFR Part 1 Subpart L) ("FSVP regulation").[23]

In circumstances where an onsite audit is an appropriate supplier verification activity under one of those three regulations, receiving facilities and importers are not required to use onsite audits conducted by a CB accredited under TPP, but they may choose to do so. The onsite audits used to meet the supplier verification requirements under the three regulations must meet the applicable requirements of the specific regulations.

We note that audits conducted by an audit agent of an accredited CB to solely meet the requirements of 21 CFR Part 117, 21 CFR Part 507, or the FSVP regulation would not be subject to the requirements of the TPP regulation, including the reporting and notification requirements. However, if a receiving facility subject to 21 CFR Part 117 or Part 507 or an importer subject to the FSVP regulation would like to use a single audit to meet obligations under one of those regulations *and* to apply for participation in VQIP, then the audit would be subject to the requirements of the TPP regulation (because the audit would be used for

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[21] Among other things, subpart G in 21 CFR Part 117 requires the receiving facility to establish and implement a written supply chain-program (21 CFR 117.405(a)-(b)) and approve suppliers for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control (21 CFR 117.415(a)(1)). The receiving facility (or a designee) also must determine and conduct appropriate supplier verification activities (21 CFR 117.425, 21 CFR 117.415(a)(3)(iii)). With some exceptions, one or more supplier verification activities (e.g., onsite audit, sampling and testing, review of food safety records) must be conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter (21 CFR 117.430(a)). Generally, when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death, the appropriate supplier verification activity is an onsite audit of the supplier, and it must be conducted before using the food and at least annually thereafter (21 CFR 117.430(b)(1)). For more information on 21 CFR Part 117, including links to guidance that discusses the requirements mentioned in this document, see https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food.

[22] Subpart E of Part 507 contains supply-chain program requirements for animal food receiving facilities that are comparable to those for human food facilities. For more information on 21 CFR Part 507, including links to guidance that discusses the requirements mentioned in this document, see https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-animal-food.

[23] The FSVP regulation requires importers to conduct a hazard analysis to determine whether there are any hazards that require a control (21 CFR 1.504) and, based on the hazard determine the appropriate type of verification activity as well as the frequency of conducting the activity. The foreign supplier verification activities must provide assurance that the hazards requiring a control in the imported food have been significantly minimized or prevented (21 CFR 1.506(c)). Importers must establish and follow written procedures to ensure they import food only from suppliers they have approved (21 CFR 1.506(a)(1)). Appropriate supplier verification activities may include onsite audits, sampling and testing of a food, and review of the foreign supplier's relevant food safety records (21 CFR 1.506(d)(1)(ii)). When a hazard in a food is controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will cause serious adverse health consequences or death to humans or animals, the default verification activity is to conduct an annual onsite audit before initially importing the food from the supplier and at least annually thereafter (21 CFR 1.506(d)(2)). For more information on the FSVP regulation, including links to guidance that discusses the requirements mentioned in this document, see https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals.

purposes of VQIP eligibility). In those circumstances, the audit would need to be conducted as a regulatory audit in accordance with TPP requirements (21 CFR 1.651).

We also emphasize that receiving facilities and importers subject to 21 CFR Part 117, Part 507, or the FSVP regulation are not required to use accredited CBs under TPP to meet their supplier verification requirements under 21 CFR Part 117, Part 507, or the FSVP regulation. Audits under those regulations must be conducted by "qualified auditors" as defined in 21 CFR 117.3, 21 CFR 507.3, and 21 CFR 1.500, respectively.[24] An example of a potential qualified auditor under those regulations includes, but is not limited to, an audit agent of a CB that has been accredited under TPP.

H.2.3 What are the requirements for conflict of interest if an FDA-recognized accreditation body is also a Foreign Supplier Verification Program importer?

In accordance with 21 CFR 1.624(a), a recognized AB must implement a written program to protect against conflicts of interest between the recognized AB (and its officers, employees, and other agents involved in accreditation activities) and any CB (and its officers, employees, and other agents involved in auditing and certification activities) seeking accreditation from, or accredited by, such recognized AB, including the following:

> (1) Ensuring that the recognized AB (and its officers, employees, or other agents involved in accreditation activities) does not own or have a financial interest in, manage, or otherwise control the CB (or any affiliate, parent, or subsidiary); and
>
> (2) Prohibiting officers, employees, or other agents involved in accreditation activities of the recognized AB from accepting any money, gift, gratuity, or item of value from the CB.

For purposes of FSVP, "importer" means the U.S. owner or consignee of an article of food that is being offered for import into the United States. 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 statement of consent to serve as the importer under the FSVP regulation. The term "U.S. owner or consignee" means 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 (21 CFR 1.500 (definition of "U.S. owner or consignee")). The term "person" includes an individual, partnership, corporation, and association (21 U.S.C. 321(e)).

[24] Additional information on the qualified auditor requirements is available in the draft FSVP guidance at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-foreign-supplier-verification-programs-importers-food-humans-and-animals, draft guidance on Hazard Analysis and Risk-Based Preventive Controls for Human Food (Chapter 15) at https://www.fda.gov/media/110443/download, and draft guidance on Hazard Analysis and Risk Based Preventive Controls for Food and Animals: Supply-Chain Program at https://www.fda.gov/files/animal%20&%20veterinary/published/CVM-GFI--246-Hazard-Analysis-and-Risk-Based-Preventive-Controls-for-Food-for-Animals--Supply-Chain-Program.pdf.

If a recognized AB under TPP is an importer for purposes of FSVP, then the AB must follow the conflict of interest rules that apply to recognized AB and FSVP importers, as applicable. According to 21 CFR 1.506(b), importers must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods they import. As required by 21 CFR 1.506(e)(4), there must not be any financial conflicts of interests that influence the results of the verification activities set forth in paragraph (e)(1) of 21 CFR 1.506, and payment must not be related to the results of the activity.

An example of a FSVP verification activity under 21 CFR 1.506(e)(1) is an onsite audit of the foreign supplier by a qualified auditor where the audit agent is affiliated with a CB that is accredited under TPP. Therefore, if a recognized AB that is also an FSVP importer chooses to use an audit as a verification activity, they would need to abide by the conflict of interest requirements of 21 CFR 1.506(e) and 1.624(a).