Accredited Third-Party Certification Program (TPP)

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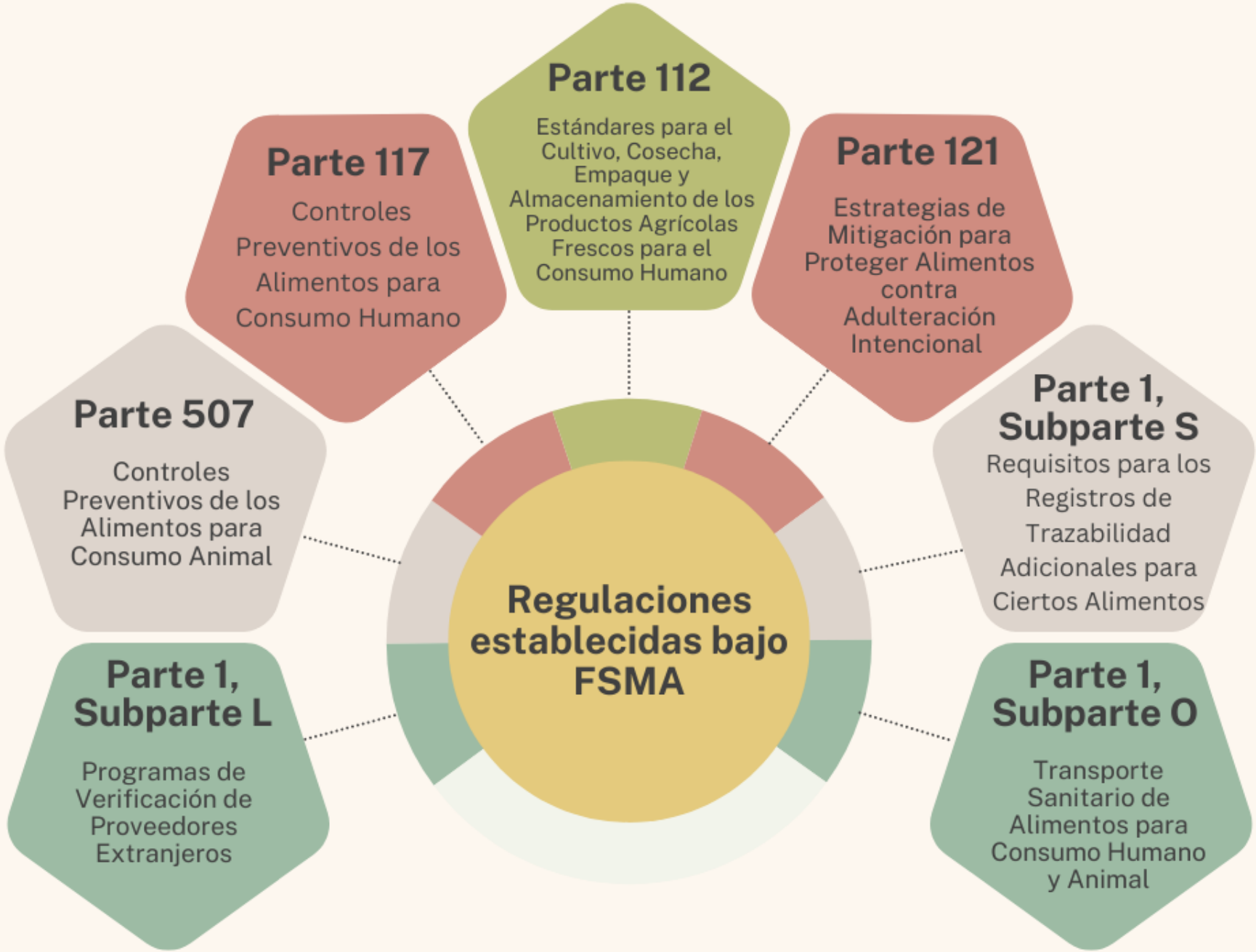

Regulaciones establecidas bajo FSMA
Parte 112
Estándares para el Cultivo, Cosecha, Empaque y Almacenamiento de los Productos Agrícolas Frescos para el Consumo Humano
Parte 117
Controles Preventivos de los Alimentos para Consumo Humano
Parte 121
Estrategias de Mitigación para Proteger Alimentos contra Adulteración Intencional
Parte 507
Controles Preventivos de los Alimentos para Consumo Animal
Parte 1, Subparte S
Requisitos para los Registros de Trazabilidad Adicionales para Ciertos Alimentos
Parte 1, Subparte L
Programas de Verificación de Proveedores Extranjeros
Parte 1, Subparte O
Transporte Sanitario de Alimentos para Consumo Humano y Animal


PROGRAMA DE CERTIFICACIÓN POR TERCEROS ACREDITADOS
Parte 1, Subparte M
PROGRAMA VOLUNTARIO DE IMPORTADORES CALIFICADOS
Programas establecidos bajo FSMA
PROGRAMA DE ACREDITACIÓN DE LABORATORIOS PARA ANÁLISIS DE ALIMENTOS
Parte 1, Subparte R
CERTIFICACIÓN DE IMPORTACIÓN

Eligibility requirements

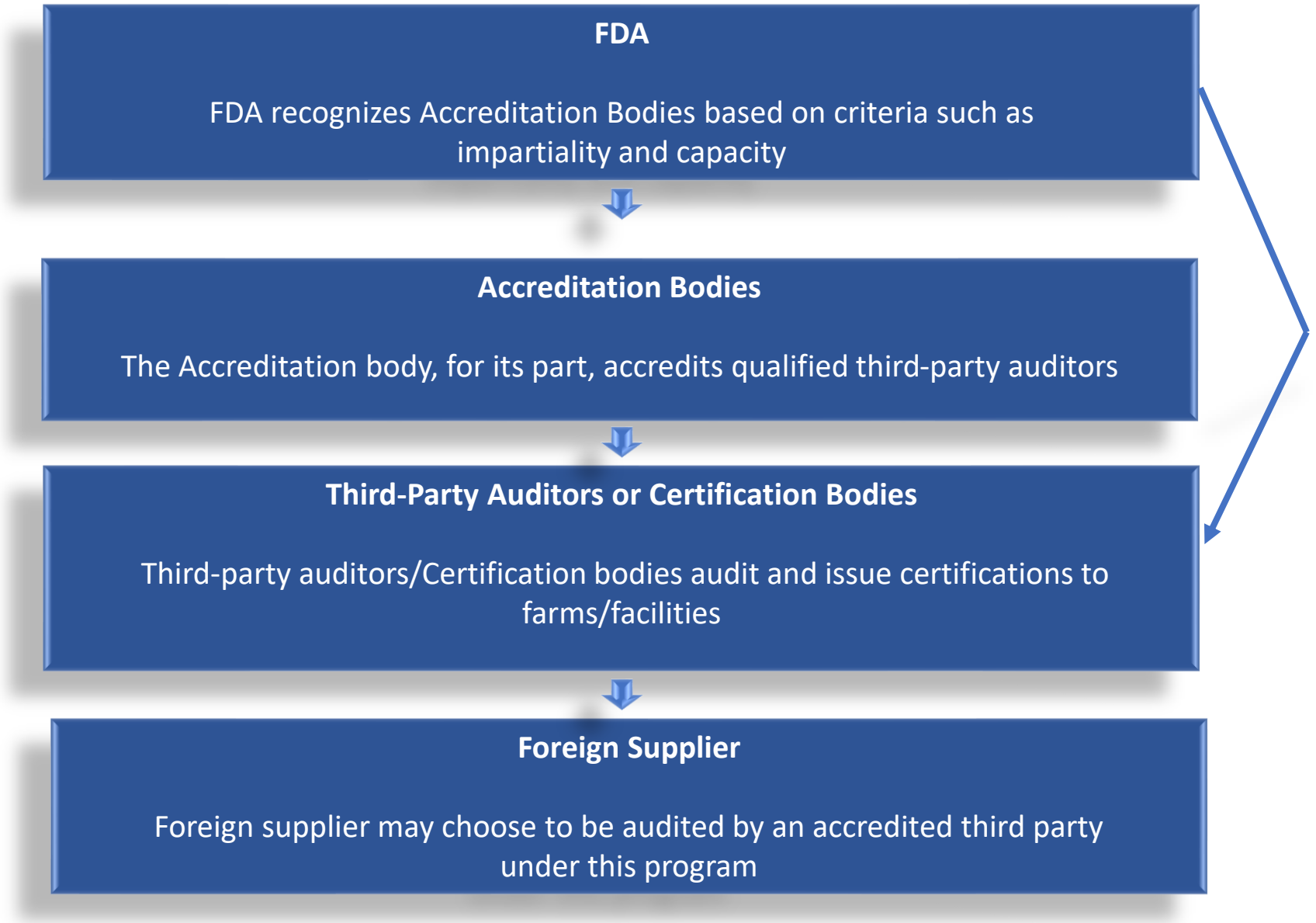
- Authority
  - Accreditation Body: Authority to evaluate a third-party certification body for accreditation
  - Certification body: Authority to perform audits and review records
- Capacity and competence
- Quality control
- Protection against conflicts of interest
- Record keeping

FDA Accredited Third-Party Certification Program

- TPP is a **voluntary program** for the accreditation of third-party auditors, also known as third-party certification bodies, to conduct food safety audits and issue certifications of foreign facilities and the human and animal foods they produce.

- Final Rule on Accredited Third Party Certification– At a glance– in English https://www.fda.gov/media/175615/download
- Accreditation of Third-Party Certification Bodies - 21CFR, Part 1,Subpart M https://www.gpo.gov/fdsys/pkg/CFR-2017-title21-vol1/pdf/CFR-2017-title21-vol1-part1-subpartM .pdf

Certification Program by Accredited Third Parties



Audit Requirements

Carry out audits of properties and facilities without prior notice

Notify FDA if you discover a condition that may cause or contribute to a serious risk to public health

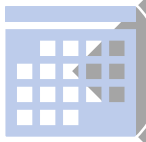
Submit regulatory audit reports to the FDA

Keep a record of consultation audit reports

Certification Requirements

Issued based on regulatory audit in accordance with TPP

If deficiencies are observed, corrective actions must be verified before issuing certification



Certification duration up to 12 months

Any certification issued under TPP must be submitted to the FDA

FDA U.S. FOOD & DRUG ADMINISTRATION
DATA DASHBOARD

Data Dashboard Home | Compliance Dashboards > | FSMA Data Search > | Resources >

FDA Data Dashboard

Compliance Dashboards

Inspections

Compliance Actions

Recalls

Imports Summary

Import Refusals

Imports Entry

FSMA Data Search

Find firm compliance and enforcement information.

Search Firm Information

LAAF Participants

TPP Participants

Approved VQIP Importers

Recursos

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Food

Home › Food › Guidance & Regulation › Food Safety Modernization Act (FSMA)

- **Food Safety Modernization Act (FSMA)**
- The Law, Rules & Guidance
- Frequently Asked Questions on FSMA
- FDA Actions and Meetings
- FSMA Rules & Guidance for Industry
- FSMA Training
- FSMA Technical Assistance Network (TAN)

Industry Resources on Third-Party Audit Standards and FSMA Supplier Verification Requirements

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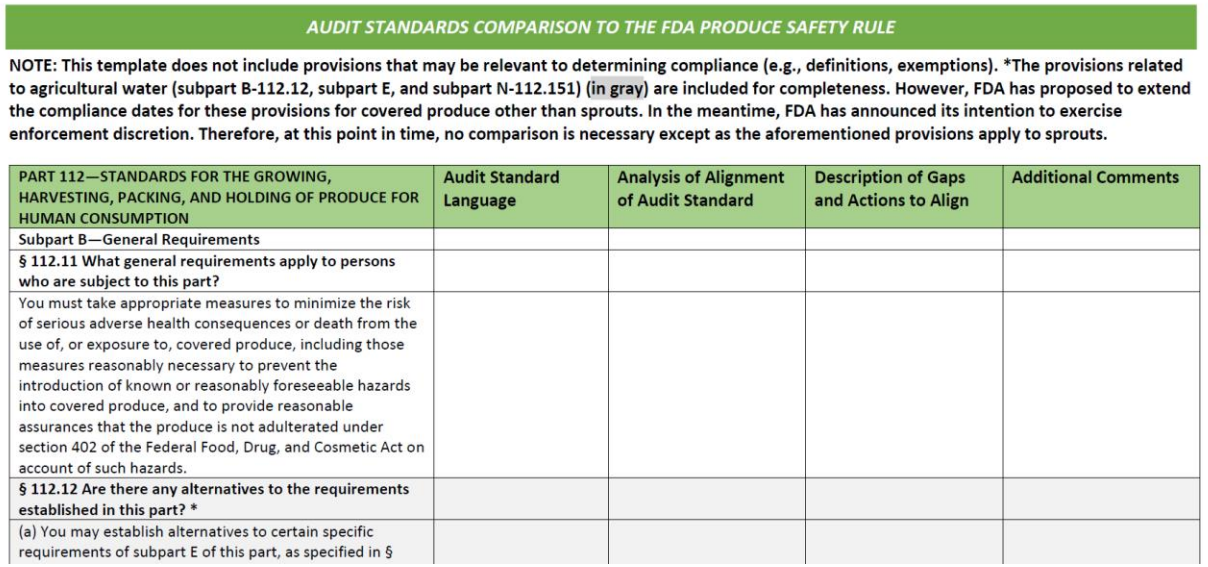
Under the Preventive Controls for Human Food (PCHF) regulation (21 CFR part 117), Preventive Controls for Food for Animals (PCAF) regulation (21 CFR part 507), and Foreign Supplier Verification Programs (FSVP) regulation (21 CFR Part 1, Subpart L), receiving facilities and importers may need to conduct onsite audits to determine if their suppliers are producing food in compliance with FDA food safety standards, including the new standards promulgated under the FDA Food Safety Modernization Act (FSMA). An annual onsite audit is required under the PCHF, PCAF, and FSVP regulations when the hazard will result in a serious adverse health consequences or death to humans or animals (SAHCODHA) and is controlled by the supplier, unless the receiving facility or importer has made a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate verification.



AUDIT STANDARDS COMPARISON TO THE FDA PRODUCE SAFETY RULE

NOTE: This template does not include provisions that may be relevant to determining compliance (e.g., definitions, exemptions). *The provisions related to agricultural water (subpart B-112.12, subpart E, and subpart N-112.151) (in gray) are included for completeness. However, FDA has proposed to extend the compliance dates for these provisions for covered produce other than sprouts. In the meantime, FDA has announced its intention to exercise enforcement discretion. Therefore, at this point in time, no comparison is necessary except as the aforementioned provisions apply to sprouts.

PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
Subpart B—General Requirements				
§ 112.11 What general requirements apply to persons who are subject to this part?				
You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act on account of such hazards.				
§ 112.12 Are there any alternatives to the requirements established in this part? *				
(a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in §				

User Fee

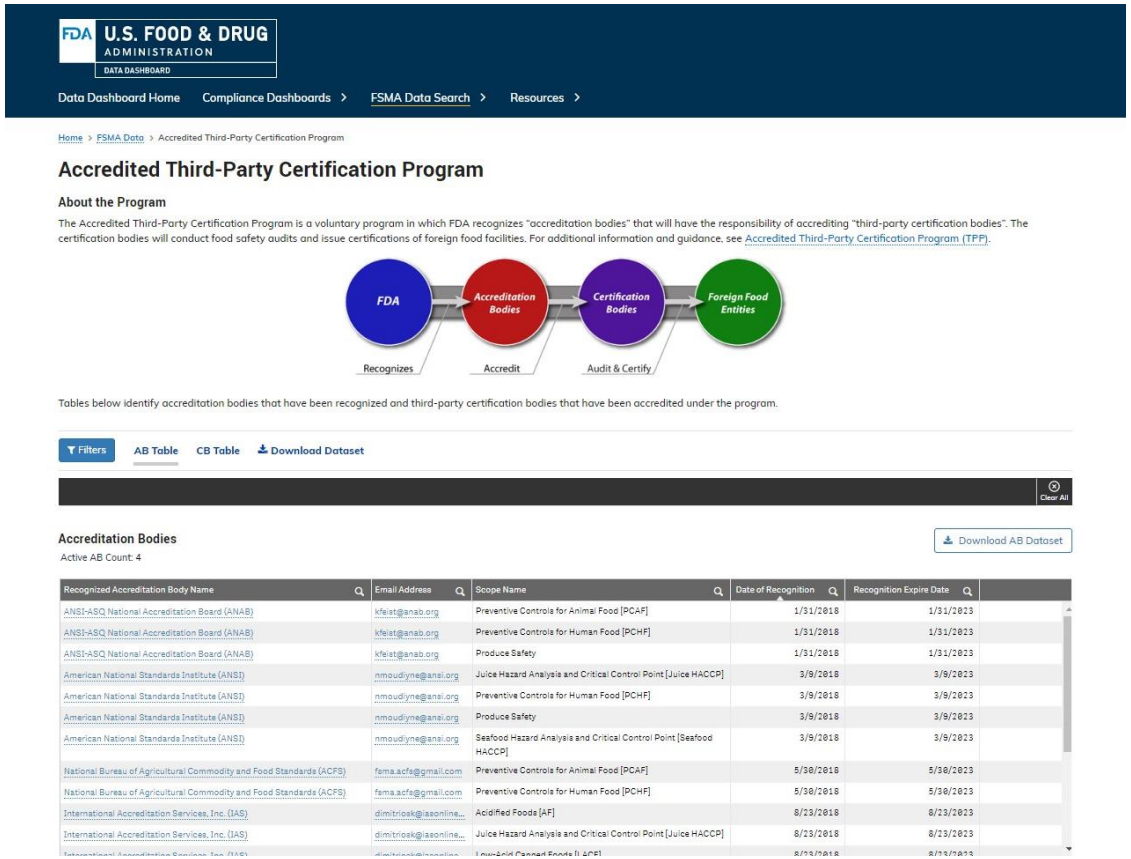
- On or before August 1 of each year, the FDA publishes a notice in the Federal Register announcing user fees for the upcoming fiscal year. User fee rates for the current fiscal year and past years can be found at the following link: https://www.fda.gov/industry/fda-user-fee-programs/accredited-third-party-certification-program-user-fees

- User fees are recalculated each US fiscal year .

List of TPP participants

- FDA Data Dashboard
  - List of recognized accreditation bodies
  - List of accredited external certification bodies

- Available at : https://datadashboard.fda.gov/ora/fd/tpp.htm



Resources

- Final Guide to the Accreditation Standards Model
  - Contains recommendations on qualifications that certification bodies and their employees should have in areas such as education and their experience. https://www.fda.gov/food/newsevents/constituentupdates/ucm531731.htm

- User guide for certification bodies
  - Document with step-by-step instructions so that certification bodies can provide their certifications to the FDA and can manage their accreditation status in the TPP. https://www.fda.gov/media/143888/download?attachment

- Final regulation establishing user fees for accreditation and certification bodies
  - http://www.fda.gov/ForIndustry/UserFees/

Use of Certifications Issued Pursuant to TPP

FSMA specifies that certifications issued under TPP will be used for:

- Voluntary Qualified Importer Program (VQIP)
- Import Certification (FD&C Act, Section 801(q))

Use of Certifications Issued Pursuant to TPP

Voluntary Qualified Importer Program (VQIP)

- Voluntary program established by the FDA for importers
- Provides expedited review and import entry of imported foods under the VQIP
- Eligibility is limited to importers who demonstrate a high level of control over the safety of their supply chains
- Eligibility criteria include that each foreign supplier added to the VQIP by an importer must have a current certification issued in accordance with the TPP

Use of Certifications Issued Pursuant to TPP

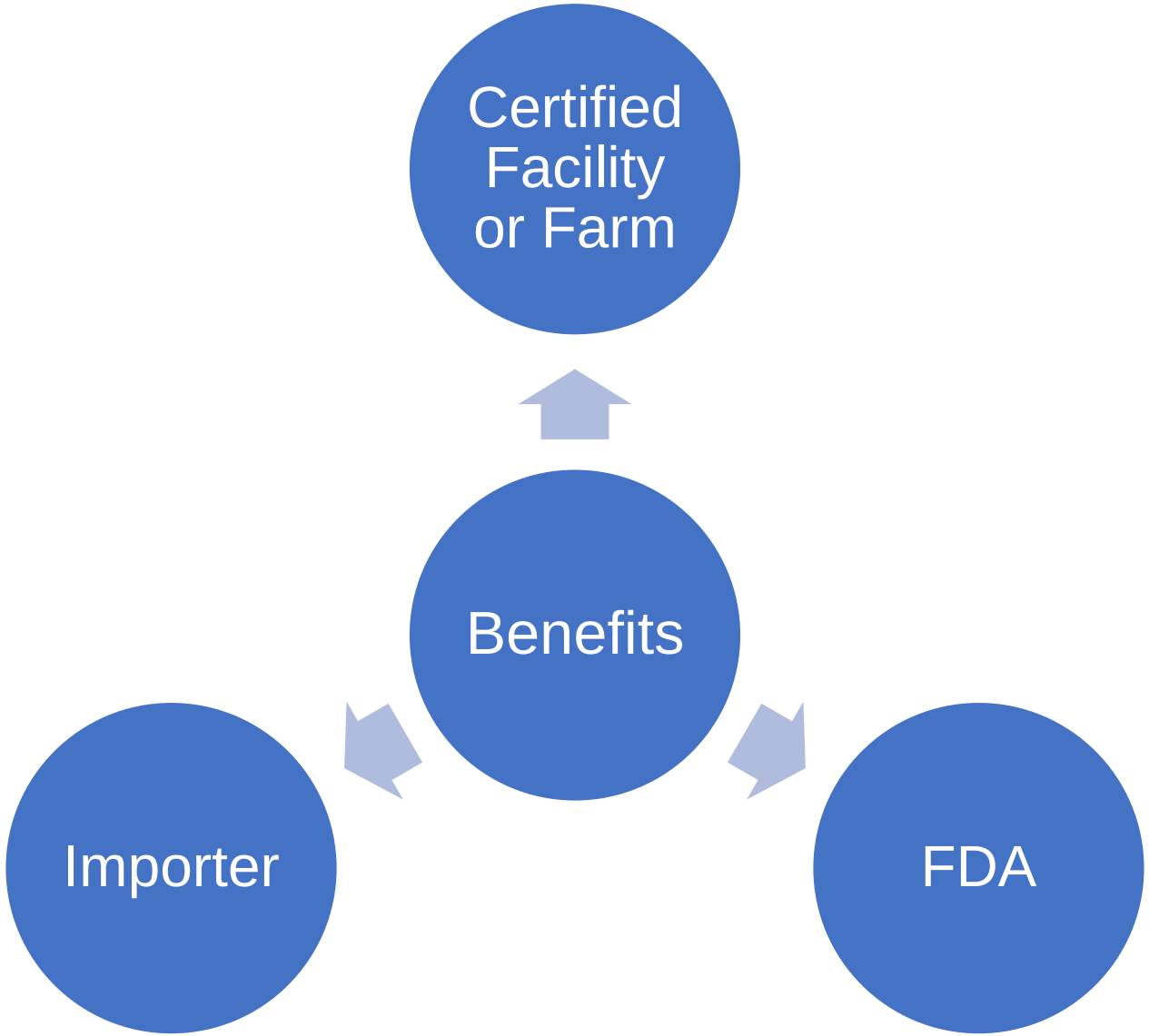
Import Certification (FD&C Act, Section 801(q))

- Compliance tool established through FSMA
- Allows FDA to require certification as a condition of entry for imported foods under certain circumstances
- Such certification is not necessary unless the FDA communicates that it is required.

TPP and other regulations under FSMA

- Audits conducted by TPP-accredited certification bodies can be used to provide evidence of compliance with the standards on
  - *Foreign Supplier Verification Programs* (*FSVP*)
  - Preventive Controls for Human Food (*PCHF*)
  - Preventive Controls for Animal Food (*PCAF*)
  - Standards for the Growing, Harvesting, Packing, and Holding of Sprouts for Human Consumption (*PSR*)
- Certifications under TPP are not required to comply with FSVP or Preventive Control regulations.
  - FSVP and Preventive Controls require that audits used to comply with a verification activity be performed by a “qualified auditor” (as defined in the standard) and that they consider applicable food safety regulations.

Participation benefits

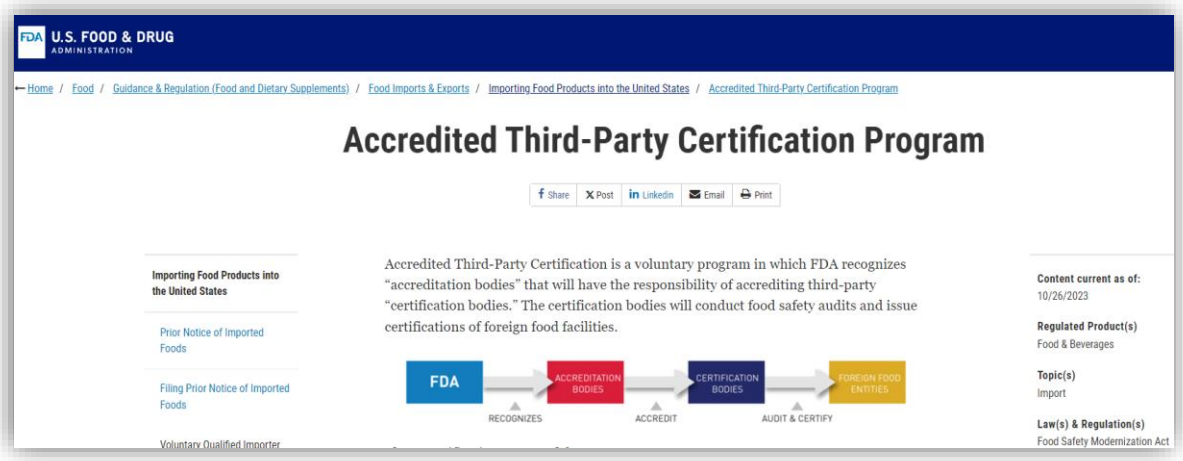


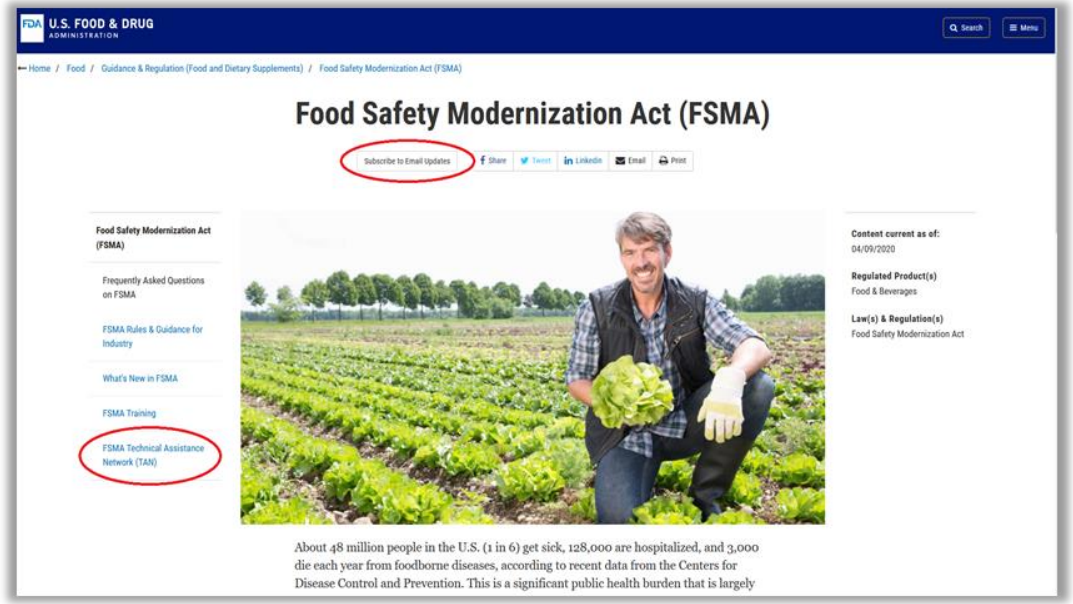
QR Code and TPP Graphic elements

- The following TPP QR code was developed to assist FDA and interested parties in communicating the status of TPP participants.
- TPP graphic elements help program participants communicate their participation in the TPP.

Resources

- TPP website: Accredited Third-Party Certification program
- To submit an inquiry about FSMA, visit www.fda.gov/fsma and go to FSMA Technical Assistance Network (TAN)
- FSMA Frequently Asked Questions: https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma



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