AFDO Annual Educational Conference

FSMA Imports and Systems Recognition

Sharon Lindan Mayl, JD
Senior Advisor for Policy
Office of Foods and Veterinary Medicine
Food and Drug Administration

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FSMA Import Provisions

- **Sec. 301. Foreign Supplier Verification Program (Sec. 805 of FD&C Act)**
- **Sec. 302. Voluntary Qualified Importer program (Sec. 806 of FD&C Act)**
- Sec. 303. Certification for Food Imports (Sec. 801(q) of FD&C Act)
- Sec. 304. Prior notice of imported food shipments (Sec. 801(m)(1) of FD&C Act)
- Sec. 305. Capacity building
- Sec. 306. Inspection of foreign food facilities (Sec. 807 of FD&C Act)
- **Sec. 307. Accreditation of third-party auditors (Sec. 808 of FD&C Act)**
- Sec. 308. Foreign Offices of the Food and Drug Administration.
- Sec. 309. Smuggled Food
- Sec. 404. Compliance with International Agreements

FSMA Implementation

"A Continuum"

- Phase 1: Set Standards
  - Develop regulations, guidance, policy
- Phase 2: Design Strategies to Promote and Oversee Industry Compliance
  - Identify performance metrics to measure success
- Phase 3: Implement, Monitor, Evaluate, Refresh
  - Transition strategies and performance metrics from design to operational, then evaluate success and make needed changes.

Foreign Supplier Verification Program (FSVP)

Key Principles of FSVP Rule

- Requires importers to share responsibility for ensuring safety of imported food
- Risk-based (according to types of hazards, importers, and suppliers)
- Flexibility in meeting requirements (assessing activities conducted by others)
- Alignment with supply-chain provisions of the Preventive Controls rules

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Purpose of FSVPs

- To provide adequate assurances that:
  - Foreign suppliers produce food using processes and procedures providing same level of public health protection as FSMA preventive controls or produce safety provisions
  - Food is not adulterated or misbranded (as to allergen labeling)

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Who Must Comply?

- "Importer" is U.S. owner or consignee of a food at time of U.S. entry
- If no U.S. owner or consignee at entry, importer is U.S. agent or representative of the foreign owner or consignee, as confirmed in signed statement of consent

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Who Is the Foreign Supplier?

- The foreign supplier of a food is the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature.

Exemptions from FSVP

- Firms subject to juice or seafood HACCP regulations
- Food for research or evaluation
- Food for personal consumption
- Alcoholic beverages and ingredients (when importer uses them to make an alcoholic beverage)
- Food transshipped through U.S.
- Food imported for processing and export
- “U.S. food returned”
- Meat, poultry, and egg products subject to USDA regulation at time of importation

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FSVP Compliance Dates

- Importers will be required to comply with FSVP no earlier than 18 months after issuance of final rule (i.e., May 30, 2017)
- If foreign supplier is subject to preventive controls or produce safety regulations, importer must comply with FSVP 6 months after supplier must comply with the relevant regulations

FSVP Enforcement Discretion

- FDA issued several guidance documents granting enforcement discretion for certain provisions of the FSVP rule:
  - Written assurance requirements in the FSVP, PC Human, PC Animal, and Produce rules
  - FSVP requirements for importers of food contact substances
  - FSVP requirements for importers of grain Raw Agricultural Commodities
  - FSVP requirements for importers of live animals that must be slaughtered and processed at establishments regulated by USDA and subject to HACCP requirements

FSVP

- Key requirements:
  - Hazard analysis
  - Evaluation of Food and Foreign Supplier
  - Verification activities
  - Corrective actions
  - Importer identification at entry
  - Recordkeeping

Modified FSVP Requirements

- Hazards are being controlled after entry into the U.S.
- Dietary supplements
- Very small importers and importers of food from certain small foreign suppliers
- Certain food from suppliers in countries with comparable or equivalent food safety systems

Importers Who Are Subject to the Preventive Controls Regulations

- Importers who are subject to the PC regulations are deemed in compliance with most of the FSVP requirements when they:
  - Comply with PC supply-chain provisions
  - Implement preventive controls under PC regulation for hazards in food they import
  - Are not required to implement a preventive control under certain PC provisions
- Will still need to identify themselves at entry under FSVP

Phase 2:
Key Implementation Principles

- Goal of FSMA is to move food safety system from a reactive to a **preventive** mode.
- FSMA's success depends on bringing about high rates of **compliance**.
- FDA is **committed** to educating before and while we regulate.
- FDA will **engage and communicate** to international community that is consistent with domestic efforts.

Education, Outreach, and Technical Assistance for Industry

- Facilitate industry compliance with prevention oriented standards through guidance, developing tools/resources for education, outreach and technical assistance
  - Website
  - Guidance Documents
  - Alliances
  - Technical Assistance Networks

FSVP Guidance Documents

- Compliance Guide: Draft Published 1/18
- Small Entity Compliance Guide: Published 1/18
- Recognition of Acceptable UFI: Published 3/17
- Compliance with UFI: Published 5/17
- Considerations for Determining Whether A Measure Provides the Same Level of Public Health Protection: Draft Published 1/18 (also relevant to PC and Produce rules)

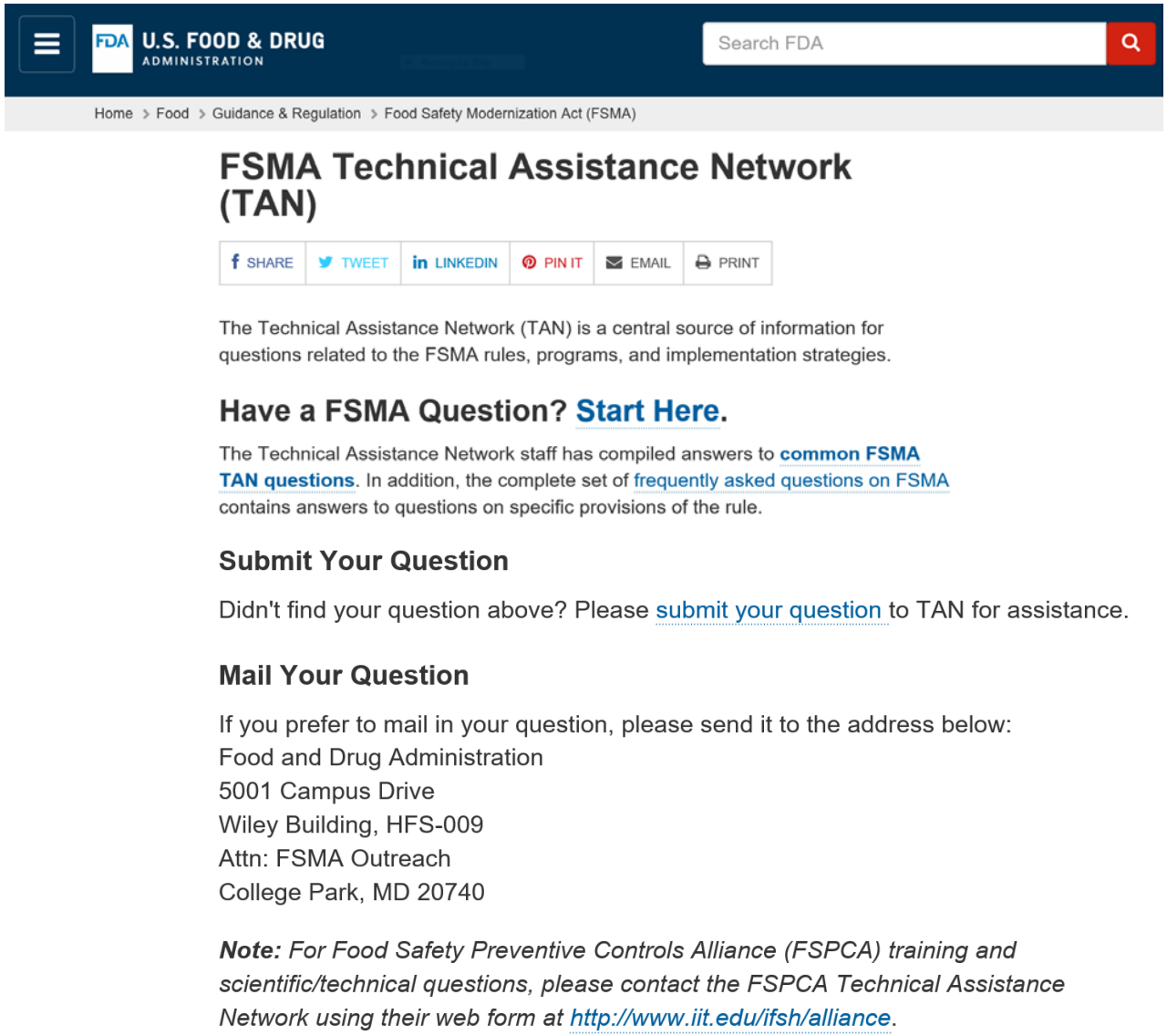
FSVP Industry Training - Alliance

- Food Safety Preventive Controls Alliance (FSPCA)
  - Curriculum to train importers subject to the FSVP rule
  - Released updated version 1.1
- Modules for the Preventive Controls and Produce Safety Curricula

FDA Industry TAN

- Established an FDA FSMA Technical Assistance Network (TAN) to provide central, consistent, sources of outreach and technical assistance
- Launched on September 10, 2015
  - Provide technical assistance to industry, academia, and consumers regarding FSMA
  - Address questions related to FSMA rules, programs, and implementation
  - Submit inquiries via the web form or by mail
  - To submit a question about FSMA, visit www.fda.gov/fsma and go to "Training and Technical Assistance" menu

FDA Industry TAN



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FSMA Technical Assistance Network (TAN)

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The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

Have a FSMA Question? Start Here.

The Technical Assistance Network staff has compiled answers to **common FSMA TAN questions**. In addition, the complete set of frequently asked questions on FSMA contains answers to questions on specific provisions of the rule.

Submit Your Question

Didn't find your question above? Please submit your question to TAN for assistance.

Mail Your Question

If you prefer to mail in your question, please send it to the address below:
Food and Drug Administration
5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

Note: *For Food Safety Preventive Controls Alliance (FSPCA) training and scientific/technical questions, please contact the FSPCA Technical Assistance Network using their web form at http://www.iit.edu/ifsh/alliance.*

Regulator Training

- Invest in regulator training/continuing education, on-going calibration of regulators to promote consistent inspections and decision making
- FDA Food Safety Staff are expected to participate in:
  - FSMA Rule Readiness Webinar Series and FSMA Chats
  - Alliance courses with industry and state counterparts
  - FSVP Regulator Training Curriculum
  - Mentors and Regulator TAN
  - Focus on “Systems Thinking”

FSVP Inspection Program

- Initiated June 2017
- Preannounced
- Evaluating FSVP importer's compliance with the FSVP requirements
- Consistent with PC inspections for supply chain provisions

FSVP Inspections

- FY17: 285 FSVP inspections completed
  - No warning letters issued
  - 0 OAI
  - 179 VAI (with 174 483a forms issued)
  - 106 NAI
- FY18: Significant increase over FY17; 222 completed (as of 5/21/18)
  - 142 VAI (with 483a forms issued)
  - 80 NAI

FSVP Inspections

- Significant observations:
  - Failure to have any FSVP
  - Failure to establish written procedures to ensure that foods are imported only from approved foreign suppliers
  - Failure to have a written analysis to identify and evaluation known or reasonable foreseeable hazards.
  - Failure to document the approval of foreign suppliers
  - Incorrect entry data

Voluntary Qualified Importer Program (VQIP)

VQIP Overview

- FDA required to establish a program to provide for the expedited review of food imported by voluntary participants.
- Participation is limited to importers who meet all eligibility criteria, including offering food from a facility certified under FDA's Accredited Third-Party Certification Program
- Final Guidance issued November 2016

VQIP Benefits

- Expedited entry into the U.S.
- Examination and/or sampling generally limited to "for cause" situations
- Any sampling or examination done at location chosen by the importer
- Expedited laboratory analysis if sampled
- VQIP Importers Help Desk
- FDA will post approved VQIP importers, if desired

VQIP Eligibility Criteria

- Quality Assurance Program (QAP)
- Assurance of compliance with the supplier verification and other importer responsibilities under the applicable FSVP or HACCP regulations
- Current facility certification, including farms, issued under FDA's Accredited Third-Party Certification regulations for each foreign supplier of food in VQIP

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Draft VQIP Guidance Eligibility Criteria (cont.)

- 3+ year history of importing food to the United States
- No ongoing FDA administrative or judicial action (e.g., import alert, injunction, recall), or other history of non-compliance with food safety regulations by the importer, other entities in the supply chain (e.g., foreign suppliers, filers/brokers, and FSVP and HACCP importers), or food

Other Elements of the VQIP Guidance

- Application (e.g., submission, timing, amendments, FDA review)
- User Fees
- Revocation Process
- Reinstatement Process

Timing of the VQIP Program

- Applications accepted between January 1st and May 31st, annually
  - Portal opened on 1/31/18
  - Up to 200 applications
- Annual benefit period between October 1st and September 30th, following application approval
- User fee notice will publish annually in August
  - 2015 estimate of annual fee was $16,400

Accredited Third-Party Certification Program

FDA's Accredited Third-Party Certification Program

- Establishes a **voluntary, fee-based program** for the recognition of accreditation bodies that accredit third-party auditors to conduct food safety audits and, where appropriate, to issue certifications of foreign facilities and the foods for humans and animals they produce.
- These certifications can be used for 2 purposes:

  1. Voluntary Qualified Importer Program
  2. Import Certification

- Not required for FSVP and PC rules

FDA's Accredited Third-Party Certification Program At-A-Glance

FDA

FDA would recognize accreditation bodies based on certain criteria such as competency and impartiality.

Accreditation Bodies

Accreditation bodies would in turn accredit qualified third-party auditors.

Third-Party Auditors or Certification Bodies

Third-party auditors/certification bodies would audit and issue certifications for foreign facilities and foods.

Foreign Facility

Foreign facilities may choose to be audited by an accredited auditor/certification body.

Oversight

- FDA will have oversight at all levels of the program, including:
  - Ability to revoke recognition granted by FDA to an accreditation body
  - Ability to withdraw an accreditation from a third-party certification body, even if it was granted by an FDA-recognized accreditation body
  - FDA does not need to wait for an accreditation body to act before taking action against a problematic certification body

What Is an Accreditation Body?

- An AB can be a foreign government/agency or a private third-party.
- An AB may use documentation of its conformance to ISO/IEC 17011, supplemented as necessary, in meeting FDA requirements.

What Must an Accreditation Body Do?

- FDA requires accreditation bodies to:
  - Assess third-party certification bodies for accreditation
  - Monitor the performance of third-party certification bodies they accredit
  - Assess and correct problems in their own performance
  - Submit reports and other notifications to FDA (e.g. self-assessments, assessments of certification bodies, approved or denied accreditations of certification bodies; lists of certification bodies' audit agents)
  - Maintain and provide FDA access to certain records

What is a Certification Body?

- A certification body can be a foreign government or other third-party entity.
- A certification body may use documentation of its conformance with ISO/IEC 17021 or ISO/IEC 17065, supplemented as necessary, in meeting FDA requirements.

What Must a Certification Body Do?

- FDA requires certification bodies to:
  - Ensure its audit agents are competent and objective.
  - Verify the effectiveness of facilities' corrective actions to address identified deficiencies.
  - Assess and correct any problems in its own performance. Inform their accreditation bodies on their self-assessments.
  - Maintain and provide FDA access to certain records.
  - Submit reports and other notifications to FDA and/or their accreditation body

Audit Requirements

- When performing audits under this program, accredited third-party certification bodies must:
  - Perform facility audits unannounced.
  - Notify FDA on discovering a condition that could cause or contribute to a serious risk to public health.
  - Submit regulatory audit reports to FDA.
  - Maintain consultative audit reports in records, accessed only under section 414.
- Note that the audit criteria for audits conducted under this program are the applicable FDA food safety requirements

Related FDA Actions

- Model Accreditation Standards Final Guidance (December 2016)
  https://www.fda.gov/food/newsevents/constituentupdates/ucm531731.htm
  - Contains recommendations on the qualifications that third-party certification bodies and their agents should have in such areas as education and experience
- Final rule establishing user fees for accreditation and certification bodies (December 2016)
  - FSMA requires that a user-fee program be established to reimburse the agency for its work in establishing and administering the third-party certification program.

User Fees

- The user fees are recalculated each U.S. Fiscal Year.
- On or before August 1 each year, FDA publishes a *Federal Register* notice announcing User Fees rates for the next fiscal year. Current and past Third-Party fiscal year user fee rates will be found at: http://www.fda.gov/ForIndustry/UserFees/

Status of FDA's Accredited Third-Party Certification Program

- FDA has recognized 2 accreditation bodies so far:
  - ANSI-ASQ National Accreditation Board (ANAB)
    - Produce Safety; Preventive Controls for Human Food, Preventive Controls for Animal Food – Jan 31, 2018
  - American National Standards Institute (ANSI)
    - Produce Safety, Preventive Controls for Human Food, Juice HACCP, Seafood HACCP – March 9, 2018
- Several other applications under review
- Public Registry of Recognized Accreditation Bodies: https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm594398.htm

For More Information

- Web site: www.fda.gov/fsma
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us

Systems Recognition

What is Systems Recognition?

- A tool for regulatory partnership with foreign governments
- Systems recognition describes whether a country's food safety system provides a similar, **though not necessarily identical**, system of protections; and the food safety authority provides similar oversight and monitoring.
- It is **not** a market access tool.

Status of Systems Recognition

- FDA has systems recognition agreements with New Zealand, Canada, and Australia.
- FDA and the EU are currently assessing each others' systems, including implementation by the EU member states.


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