*Specializing in FDA Regulatory Matters*

# Demystifying FSMA and the FSVP

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|---|---|
| Section 103 – Hazard Analysis and Risk-Based Preventive Controls | Final rules within 18 months |
| | Guidance (no time specified) |
| | Become effective in 18 months, even without regulations or guidance |
| Section 206 – Mandatory Recall Authority | Limited to Class 1 recalls |
| | Effective immediately |
| Section 207 – Administrative Detention of Food | Effective as July 1, 2011 |
| Section 301 – Foreign Supplier Verification Program | Regulations and guidance within one year |
| | Effective in 2 years, even without regulations or guidance |

| | |
|---|---|
| Section 304 – Prior notice of imports | Completed and in effect |
| Section 306 – Inspection of Foreign Food Facilities | Import to be refused if foreign facility refuses inspection |
| Section 307 – Accreditation of Third-Party Auditors | Applies only to imported food<br>Within 2 years, FDA to establish accreditation of third-party auditors, recognition of accreditation bodies and model accreditation standards.<br>FDA may accredit third-party auditors after 2 years if no accreditation bodies recognized to to do so |
| Section 309 – Smuggled Foods | FDA strategy required within 180 days |

# Seven (7) Foundation FSMA Rules

1. **Human Food preventive controls**
2. **Animal Feed preventative controls**
3. **Produce rules – will set standards for farm growing practices**
4. **Foreign Supplier Verification Proposed Rule – importer accountability program to ensure imported foods are produced under the same standards/level of protection, as our new preventative control of produce standards.**
5. **Accredited Third Party Certification of Foreign Suppliers.**
6. **Sanitary Transport of Food**
7. **Intentional Adulteration**

# FDA's Final Timeline

| FSMA Regulation | Size of Business | Industry Compliance Date(s) |
|---|---|---|
| Current GMPs & Preventive Controls for Human Food | Qualified facility (including very small business) (less than $1.0 million on a 3 year average) | September 17, 2018, except that the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2016. |
| | Small Business (less than 500 employees) | September 18, 2017. |
| | Businesses subject to the Pasteurized Milk Ordinance | September 17, 2018. |
| | All other businesses | September 19, 2016. |

# 21 CFR Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food

Subpart A – General Provisions

Subpart B – Current Good Manufacturing Practice

Subpart C – Hazard Analysis and Risk-based Preventive Controls

Subpart D – Modified Requirements

Subpart E – Withdrawal of a Qualified Facility Exemption

Subpart F – Requirements Applying to Records That Must be Established and Maintained

Subpart G – Supply-chain Program

# PCHF Definitions:

**Preventive controls qualified individual:** A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

**Qualified individual**: A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

# Preventive Controls Qualified Individual Responsibilities (§ 117.180(a))

- Oversees or performs
  - Preparation of the Food Safety Plan
  - Validation of the preventive controls
  - Review of records
  - Reanalysis of the Food Safety Plan

# Preventive Controls Qualified Individual (§ 117.180(c)(1))

- Must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA – PCQI Certificate
- Or be otherwise qualified through job experience to develop and apply a food safety system.
- Can be an external consultant
- Training must be documented in records – date, type of training, person(s) trained

# § 117.4 Qualifications of Individuals

## Who Manufacture, Process, Pack, or Hold Food

- Must have the education/ training/ experience necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties
- *Must receive training in the principles of food hygiene and food safety*, as appropriate to the food, the facility and the individual's assigned duties
- Records required for food hygiene and food safety training, as appropriate

# Training Requirements

- **Appropriate training provided for personnel carrying out tasks critical to effective implementation and maintenance of food safety and quality**
- **Documented and implemented**
- **Outline competencies for specific duties and training methods:**
- **Identify and implement refresher training needs of organization**

- ***Note: Be able to show summary of training completed for each employee***

# Foreign Supplier

- For an article of food, the establishment that:
  - Manufactures/processes the food
  - Raises the animals
  - Grows the food that is exported to the United States
  - Without further manufacturing/processing by another establishment, except for the further manufacturing/processing that consist solely of the addition of labels or any similar activity of a de minimis nature

# FSVP Required?

Unless exempt, the FSVP requirements apply to all food that is imported or offered for import into the US and to the importers of such food

- Natural State Food
- Processed Food
- Additives and Colors
- Dietary Supplements
- Animal Feed

- Food Contact Substance a Food?
  A food contact substance is any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food – May, 2019

Am I Subject to FSVP?
https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472461.pdf

# Partial Exemptions from Preventive Controls

- Low Acid Canned Foods
- Dietary Supplements
- Juice HACCP
- Seafood HACCP
- Infant Formula

NOTE:

1. All above food safety plants must address radiological hazards
2. All food safety plans are required to be overseen by a Preventive Controls Qualified Individual
3. 21 CFR 117
   - Subparts “C – Risk-Based Preventive Controls” & “G – Supply Chain Management” do not apply
   - Subparts “A”, “B”, “D”, “E” and “F” do apply

# Foods Exempt Under Section §1.501 from the FSVP Regulations

- Firms subject to juice or seafood HACCP regulations
- Any raw materials or other ingredients imported for use by the importer in the manufacturing/processing of juice, fish, or fishery products
- 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. goods returned” without further manufacturing / processing
- Meat, poultry, and egg products subject to USDA regulation at time of importation

# The "Canadian, Australia or New Zealand" Connection

Officially Recognized or equivalent Food Safety System
Certain Foods must comply with **modified standards**…not required to comply with the requirements in §§ 1.504 through 1.508

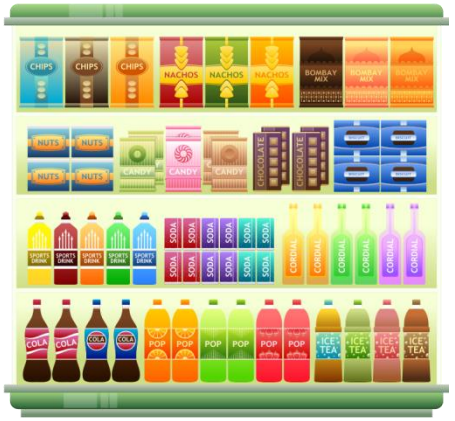
- Hazard analysis
- Foreign supplier evaluation
- Corrective action

Still be required to comply with the requirements in §§ 1.503, 1.509, and 1.510 (Develop an FSVP, Identify FSV Importer at Entry & Recordkeeping)

# FSVP – What Is Not Changing

- Prior Notice for importations of food
- Definitions of food or food products
- Registration - Domestic and foreign facilities that manufacture, process, pack, or hold food, as defined 21 CFR 1.227.
- No fee to register or update
- Registration required to be renewed every two years from Oct 1 to Dec 31 each even numbered year
- Facilities exempt from registration
- Who may register a facility, information required, and the methods of registration
- FDA Refusal of imported food manufactured by a non-registered facility

# Samples ,Trade Show, Unsold Goods…




- Samples…
  - Research
  - Evaluation
  - Should not be for public consumption (such as a trade show or exhibition)

- Trade show goods would generally not be considered to be samples as it would be expected that they would be offered for consumption and would be required to comply with all applicable FSVP standards

- Under definition as outlined in the FSVP, unsold goods would not have an FSV Importer and must therefore engage the services of an agent, in writing, to fulfil the responsibilities of the importer

# FSMA Foreign Supplier Verification Requirements

***Good compliance standing with a foreign food safety authority*** means that the foreign supplier

(1) Appears on the current version of a list, issued by the food safety authority of the country in which the foreign supplier is located and which has regulatory oversight of the supplier, of food producers that are in good compliance standing with the food safety authority; or

(2) Has otherwise been designated by such food safety authority as being in good compliance standing.

# FSMA Foreign Supplier Verification Requirements

**Audit -** the systematic, independent, and documented examination (through observation, investigation, discussions with employees of the audited entity, records review and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

***Foreign supplier -*** 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 deminimis nature.

**Importer** - 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 this subpart.

# FSMA Foreign Supplier Verification Requirements

*Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients.

Examples of manufacturing/processing activities include:

Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding (of animal food), formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging, pasteurizing, peeling, pelleting (of animal food), rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

# CRITERIA FOR FSVP QUALIFIED INDIVIDUAL & QUALIFIED AUDITOR

- A **Qualified Individual** must develop your FSVP and perform each of the activities required under this subpart. A qualified individual must have the education, training, or experience (or a combination thereof) necessary to perform their assigned activities and must be able to read and understand the language of any records that must be reviewed in performing an activity.
- A **Qualified Auditor** must:
  - Conduct onsite audits, when required
  - Have technical expertise obtained by education, training and experience in the auditing function with training documented in records – date, type of training, person(s) trained

# Who is a "Qualified Individual"

1.503 requires that the importer use a **qualified individua**l to perform all FSVP activities, which includes the following:

- Develop FSVP
- Conduct Hazard Analysis
- Evaluate Risks Posed by a Food and Performance of the Foreign Supplier
- Approval of Foreign Supplier
- Foreign Supplier Verification Activities
- Corrective Actions
- Maintenance of Records

# FSVP Qualified Individual Training

- **FSPCA FSVP Lead Instructor or FSVP Workshop with official FSPCA Certification**
- **“Appropriate” training and/or experience to be able to determine if the foreign supplier of food is compliant with all applicable FSMA requirements.**
- **Documented and implemented**

# Foreign Supplier Initial FSMA PC Qualification

(a) Use of approved foreign suppliers.

(1) Importer must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). Importer must document these procedures.

(c) Requirement of supplier verification. The foreign supplier verification activities must provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented.

# § 1.505 Importer Requirements - Evaluation of Foreign Supplier

(a) *Evaluation of a foreign and the risk posed by a food.*

(iv) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) You must document the evaluation you conduct under paragraph (a)(1) of this section.

(b) *Approval of foreign suppliers.* You must approve your foreign suppliers on the basis of the evaluation that you conducted under paragraph (a) of this section or that you review and assess under paragraph (d) of this section, and document your approval.

# § 1.505 Evaluation for Foreign Supplier Approval and Verification

(a) *Evaluation of a foreign supplier's performance and the risk posed by a food.*

(1) Except as specified in paragraphs (d) and (e) of this section, in approving your foreign suppliers and determining the appropriate supplier verification activities that must be conducted for a foreign supplier of a type of food you import, you must consider the following:

(i) The hazard analysis of the food conducted in accordance with § 1.504, including the nature of the hazard requiring a control.

(ii) The entity or entities that will be significantly minimizing or preventing the hazards requiring a control or verifying that such hazards have been significantly minimized or prevented, such as the foreign supplier, the foreign supplier's raw material or other ingredient supplier, or another entity in your supply chain.

# § 1.505 Evaluation for Foreign Supplier Approval and Verification

(iii) Foreign supplier performance evaluation includes:

(A) The foreign supplier's food safety procedures, processes, and practices;

(B) Assessing compliance with FDA food safety regulations relevant to the foreign supplier's compliance, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations); and

(C) The foreign supplier's food safety history, including available information about results from testing foods for hazards, audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems.

# ALTERNATIVES TO ON-SITE AUDIT CONDUCTED BY QUALIFIED AUDITOR

- (1) The written results of an **appropriate inspection of the foreign supplier** for compliance with applicable FDA food safety regulations conducted **by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies**; or
- (2) The written results of an inspection of the foreign supplier by the **food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent** to that of the United States, provided that the food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country.

# Foreign Supplier On-Going Follow-up

- If at the end of any 3-year period, the importer has not reevaluated the concerns associated with the factors in paragraph (a)(1) of this section in accordance with paragraph (c)(1) of this section, a reevaluation of those concerns must be conducted.
- The FSVP Importer must document said reevaluation and any subsequent actions taken by the Importer and the Foreign Supplier

# Compliance Dates

# FDA's Most Recent Timeline

| FSMA Regulation | Final Publica-tion | Industry Compliance Date(s) |
|---|---|---|
| Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animal | 11/27/15<br><br>5/27/16<br><br>5/30/17 | Final rule published<br><br>Effective date<br><br>Entry Process Changes in the US Customers & Border Protection Automated Commercial Environmental (ACE) System |
| FSVP Importers | Generally must be in compliance 6 months after their foreign suppler must be in compliance with the Preventive Controls rules | |

# Compliance Date Dependencies for FSVP

- Dates for compliance with FSVP depend on the size of the **foreign supplier**, not the **importer**
- Importers typically have **six months** to comply, **after** their foreign supplier must comply with the Preventive Control Rule(s) or Produce Safety Rule

# FSVP Compliance Dates

- FSVP importer whose foreign supplier is not subject to the PC or produce safety rules →May 30, 2017
- FSVP importer whose foreign supplier is required to comply with the PC rule for human food:
  - Qualified Facilities →March 18, 2019
  - Suppliers subject to the Pasteurized Milk Ordinance →March 18, 2019
  - “All Other” Businesses Suppliers → May 30, 2017

# FSVP Compliance Dates

- FSVP importer of animal food whose foreign supplier is subject to the CGMP requirements in the PC rule for animal food:
  - Small Businesses →March 19, 2018
  - Qualified Facilities →March 18, 2019
  - “All Other” Businesses → May 30, 2017

# FSVP Compliance Dates

- FSVP importer whose foreign supplier is required to comply with the produce safety rule:
  - Small Businesses →July 29, 2019
  - Very Small Businesses →July 27, 2020
  - “All Other” Businesses → July 26, 2018

# Extended Compliance Dates

- Importing food contact substances, earliest compliance date for large facilities → May 28, 2019
- Includes packaging, utensils/napkins, etc.

# Extended Compliance Dates

- The PC Rules allow a manufacturer that does not control a hazard requiring a preventive control to rely on its customer to control the hazard
- Affected manufacturers have an additional two years to comply
  - First PC Rule compliance for large facilities → September 19, 2018
  - Corresponding FSVP compliance date → March 19, 2019

# FSVP Implementation

## May 30th, how did it go?

- CBP only allowed access to the new FSVP data requirements in its certification system about a week before the new data set became mandatory
- FDA provided a wealth of information on their website/outreach
- Many were prepared some were caught unawares
- “I don’t want to be the FSVP”….

# Declaring FSV in ACE

- FSVP-related details are **mandatory** for all Entry Lines with FDA Program Code "FOO- Food", **unless Industry Codes 16(Fishery/Seafood Prod) or 32(Alcoholic Beverage)** are present in the FDA Product Code
- **Exemption** is declared in the **Affirmations of Compliance** (AoC) Field using either**:**
  - **FSX (FSVP Exempt)**
  - **RNE (Research and Evaluation)**
- **Supplier with fewer than 500 employees**
  - Global number not by facility
  - Must qualify as a small business as defined under 21 CFR 117.3
  - Must comply with FSVP standards by March 19, 2018
  - Recommend a statement with entry documentation

# FSVP Implementation

## What exactly do I need to provide to my broker?

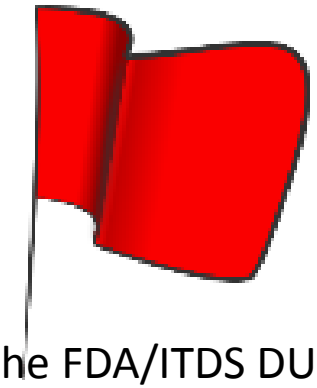
- Name & address of the FSV Importer
- Email address
- DUNS number
- Name (optional)
- Telephone number (optional)

## Methods of Providing Information

- Transactional
- Blanket
- EDI

# So…what about the DUNS number?

- The FSVP requires the importer's unique facility identifier
- At the moment the only data element which satisfies this requirement is the DUNS (Dun and Bradstreet number)
- **The number provided should refer to facility where FDA would physically go to in the event that they wished to inspect records**
- "UNK" – Limited / Temporary and a red flag



Need a DUNS number or need to verify your DUNS
http://www.dnb.com/government/duns-request.html

Step-by-Step Guide on How to Look up a DUNS Number in the FDA/ITDS DUNS Portal:
https://www.fda.gov/downloads/ForIndustry/ImportProgram/EntryProcess/ImportSystems/UCM483657.pdf

# FSVP Implementation

## Who is ultimately responsible?

For the purposes of FSVP, an importer is the U.S. owner or consignee/buyer of a food offered for import into the United States. If there is no U.S. owner or consignee, the importer is the U.S. agency or representative of the foreign owner of consignee at the time of entry, as confirmed in a signed statement of consent

## …but my broker is requiring a signed document

Brokers are not required to police the FSVP for FDA but are required to ensure that they have verified the information that they are transmitting is accurate to the best of our ability

# FDA FSVP Inspection Strategy

- Onsite & Electronic record review
- Records must be produced promptly
- Initial inspection “education”
- FDA to take action only in limited circumstances (e.g., public health risk, fraud)
- Subsequent inspections “enforcement”

# Failing to Comply

- Article of food is subject to refusal of admission
- The importation or offering for importation into the US of an article of food without the importer having an FSVP is prohibited
- In the context of FSVP, including the FSVP requirements, providing false information related to the identification of the importer at the time of entry into the US., might be a criminal offense

# FSVP Implementation

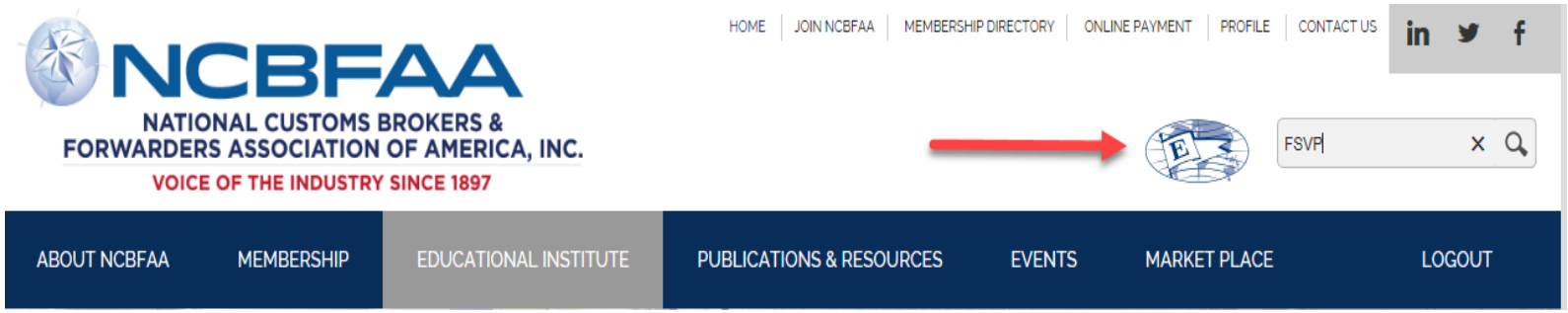
- FDA still owes trade and industry a guidance document
- It is FDA's goal to "educate while we regulate"…there will be more of a focus on education than enforcement
- For those relying upon the small supplier exemption, remember that March 19, 2018 is just around the corner
- FDA will be performing FSVP audits beginning in FY 2018

# Best Practices

- Provide Broker with written instruction of FSVP Importer/Contact/ DUNS
- Verify DUNS Number provided is location where FSVP records are kept
- Include FSVP details on commercial document
- Commercial Documents should indicate applicable exemption
- ACE Portal or Broker Reports to review FSVP Importer, DUNS and contact email declared
- Consider email distribution i.e. FSVPContact@importerinc.com
- How do I know I am being designated as the FSVP Importer?

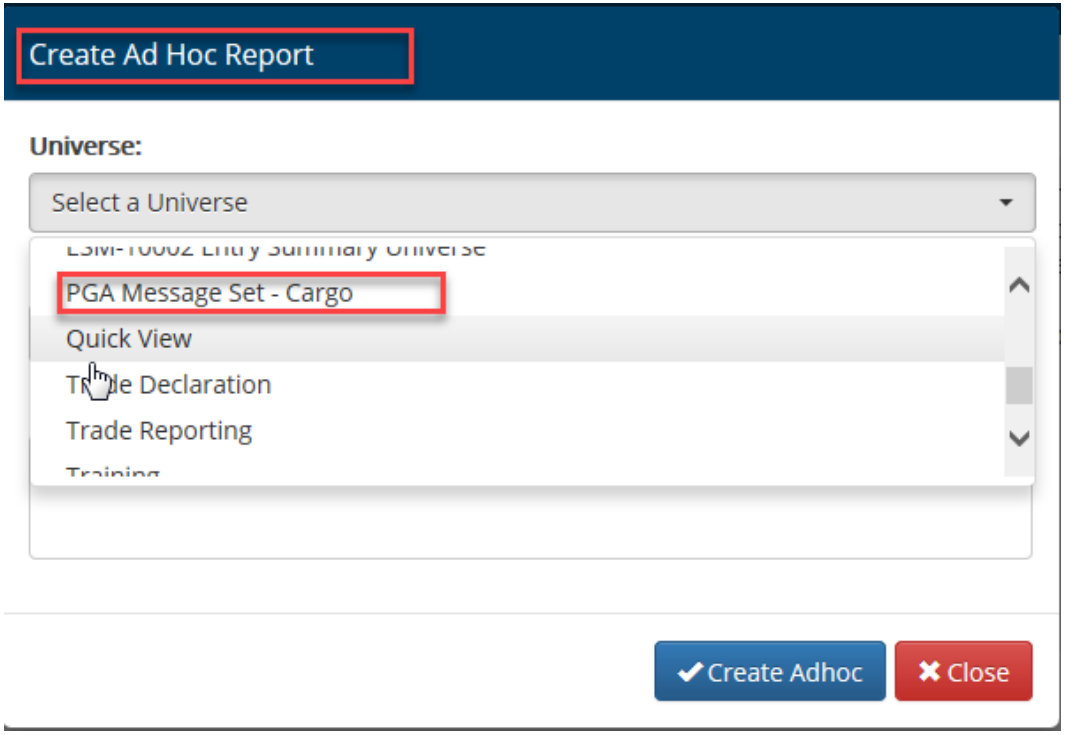
# NCBFAA Resources

- Regulatory Agency Committee
- Monday Morning Briefing
- NEI
- ACE Helpful Links

# ACE Portal

ACE Portal AdHoc Report



# FSVP Toolkit:

Am I Subject to FSVP?
https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472461.pdf

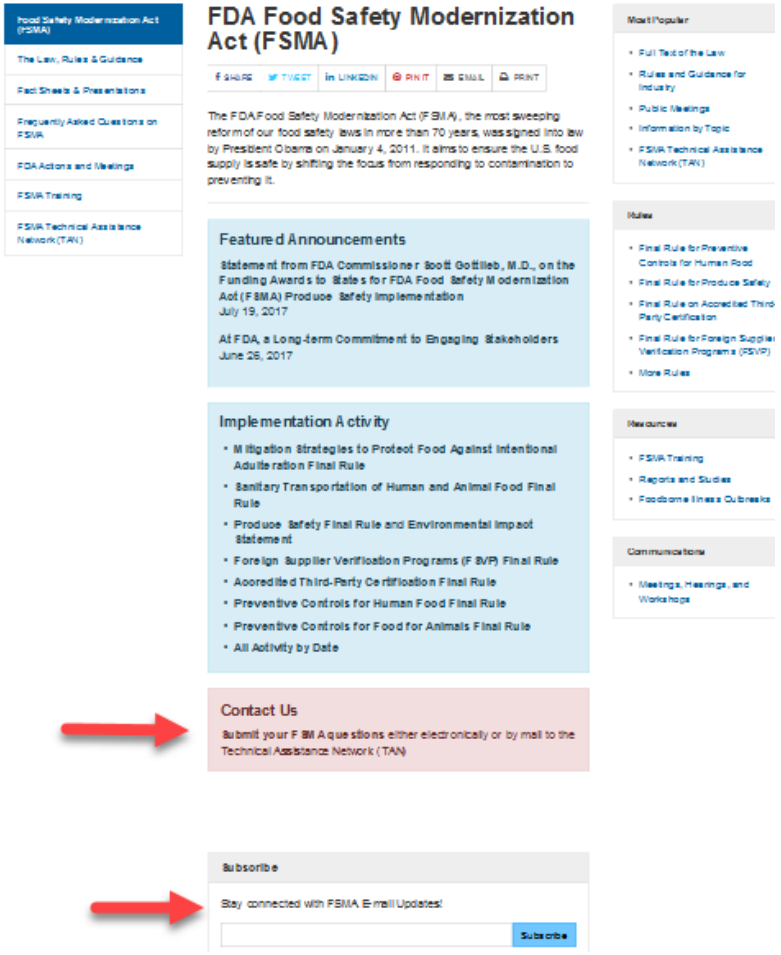
FSVP at-a-glance
https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472890.pdf

FSVP Fact Sheet
https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM502160.pdf

FSVP Final Rule
https://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28158.pdf

# For More Information

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

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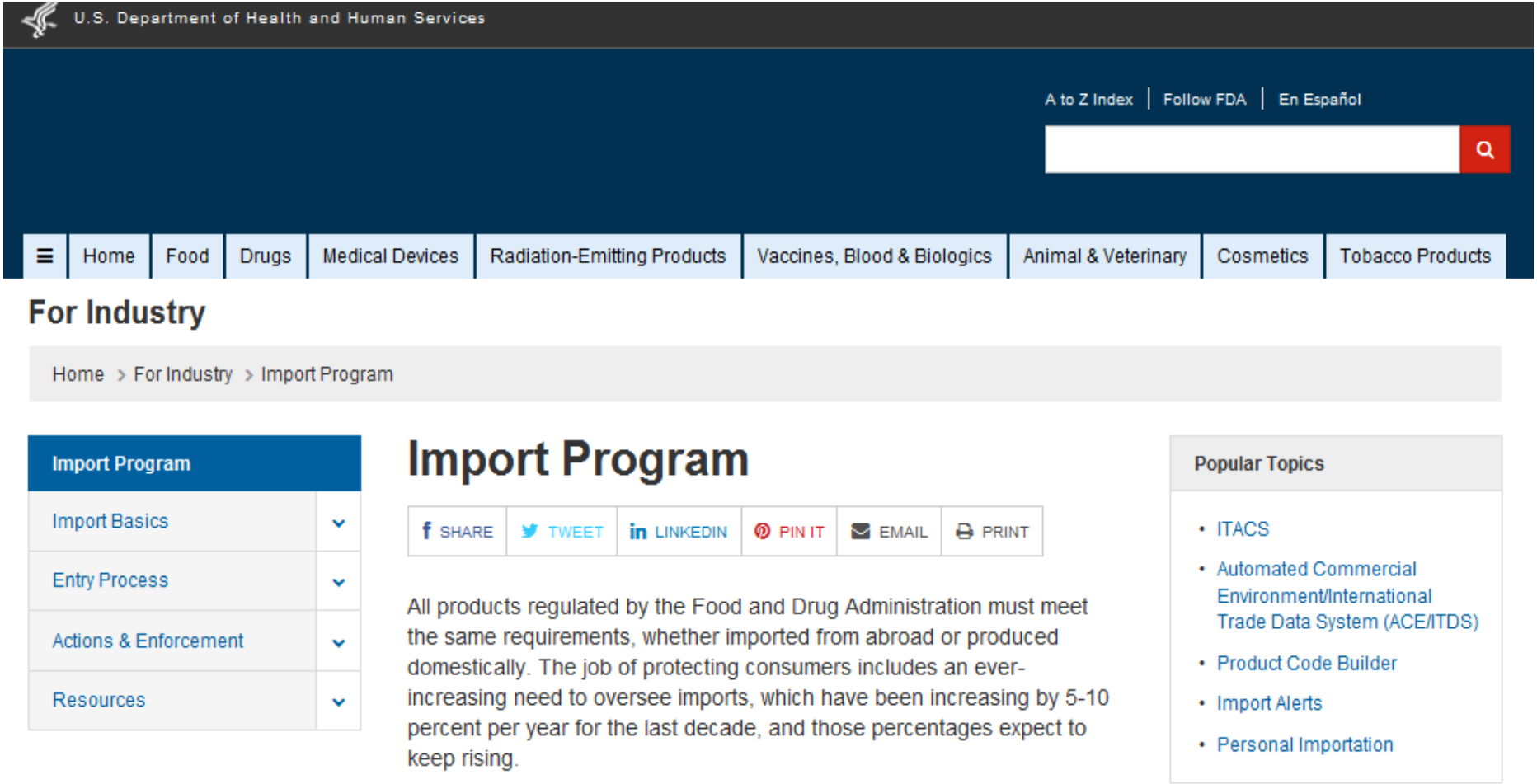
# FDA Import Program



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*Thank You*