



# FSMA Enforcement Actions Begin: Trends and Unanswered Questions

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# FSMA Enforcement Actions Begin: Trends and Unanswered Questions

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# Agenda

- Food Safety Plan Compliance
- Food Safety Plan Components
  - Hazard Analysis
  - Identification of Preventive Controls
  - Process Controls
  - Allergen Controls
  - Sanitation Controls
- Supply Chain
- Compliance & Enforcement Data
- Top 10 CFR Part 117 Citations
- Animal Food PC
- FSVP Citations (Top 5)

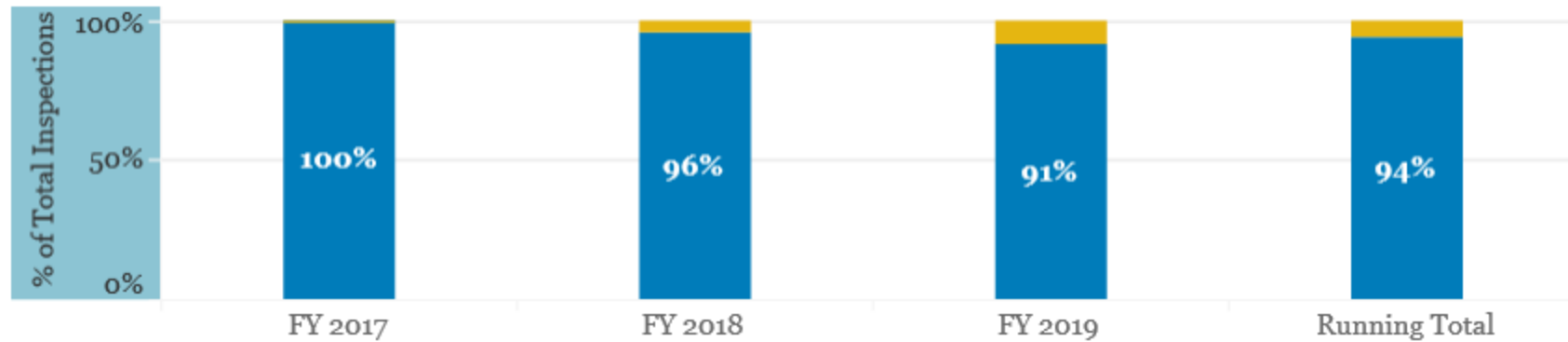
# Food Safety Plans

## Food Safety Plan

Percent of inspections in which facilities have a written food safety plan when required

*Note: Due to staggered compliance dates, FY 2017 only represents inspections of large businesses. FY 2018 includes large and small businesses.*

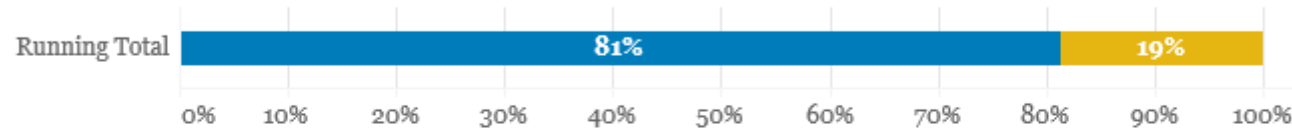
■ Not Compliant  
■ Compliant



# Food Safety Plan Components

## Hazard Analysis

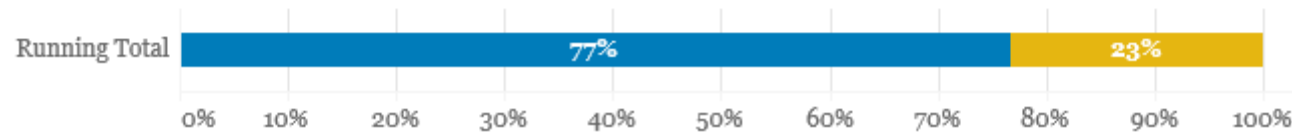
Of inspections in which facilities have a food safety plan when required, percent of inspections in which facilities are determined by an FDA investigator to have a written hazard analysis identifying appropriate known or reasonably foreseeable hazards that require a preventive control.



## Identification of Preventive Controls

Of inspections in which facilities have a food safety plan when required, percent of inspections in which facilities are determined by an FDA investigator to have appropriate hazards *and* preventive controls identified.

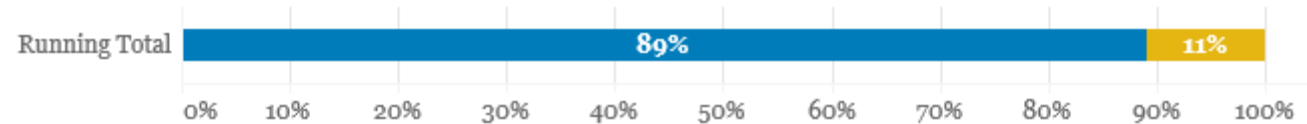
*Note: This measure excludes inspections in which facilities are not required to implement preventive controls under certain circumstances specified in 21 CFR 117.136.*



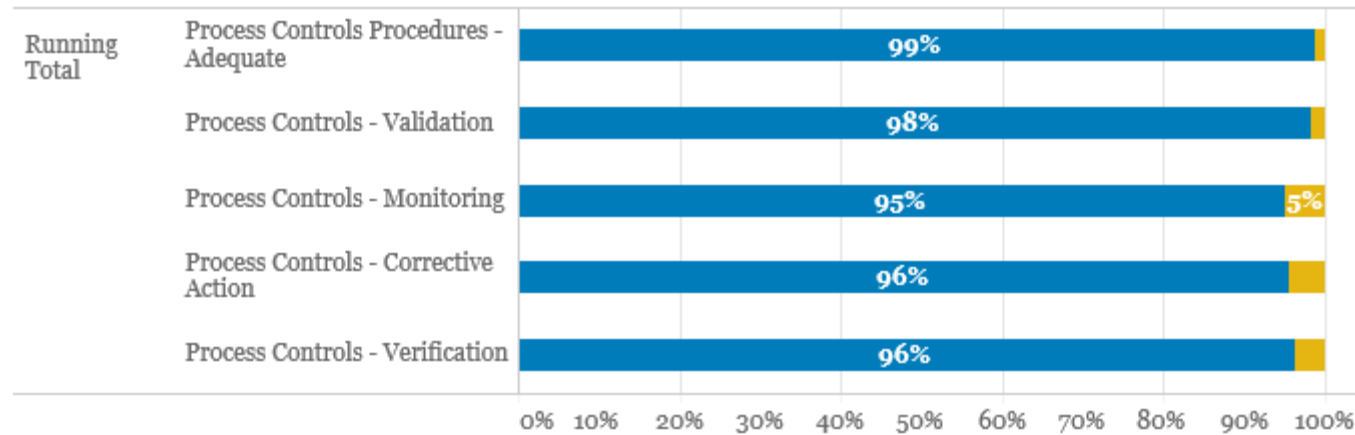
# Components Cont.

## Process Controls

Of inspections in which facilities have identified process controls for hazards requiring them, percent of inspections in which facilities are compliant with all applicable process controls requirements covered associated with: Adequate Procedures, Monitoring, Corrective Action, Validation, and Verification.



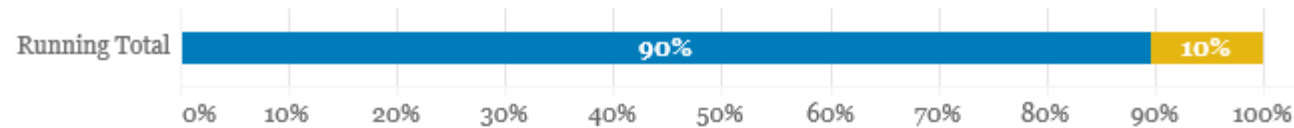
**Process Controls Detail:** Here is a detailed breakdown of requirements comprising the measure.



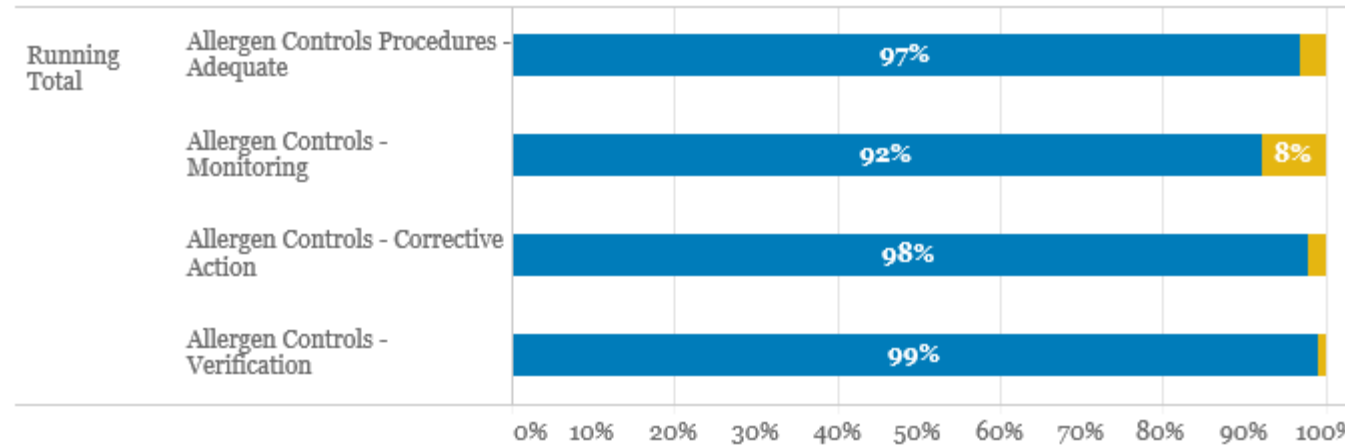
# Components Cont.

## Allergen Controls

Of inspections in which facilities have identified allergen controls for hazards requiring them, percent of inspections in which facilities are compliant with all applicable allergen controls requirements covered associated with: Adequate Procedures, Monitoring, Corrective Action, and Verification.



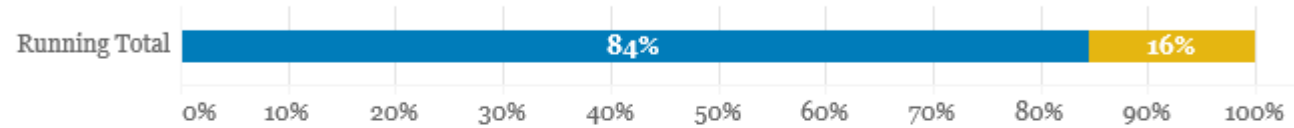
**Allergen Controls Detail:** Here is a detailed breakdown of requirements comprising the measure.



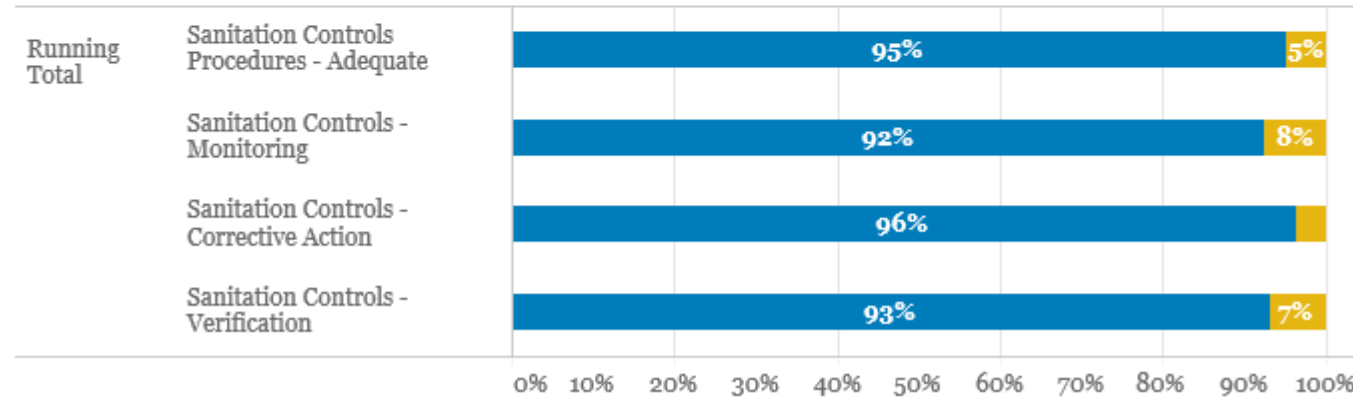
# Components Cont.

## Sanitation Controls

Of inspections in which facilities have identified sanitation controls for hazards requiring them, percent of inspections in which facilities are compliant with all applicable sanitation controls requirements covered associated with: Adequate Procedures, Monitoring, Corrective Action, and Verification.



**Sanitation Controls Detail:** Here is a detailed breakdown of requirements comprising the measure.

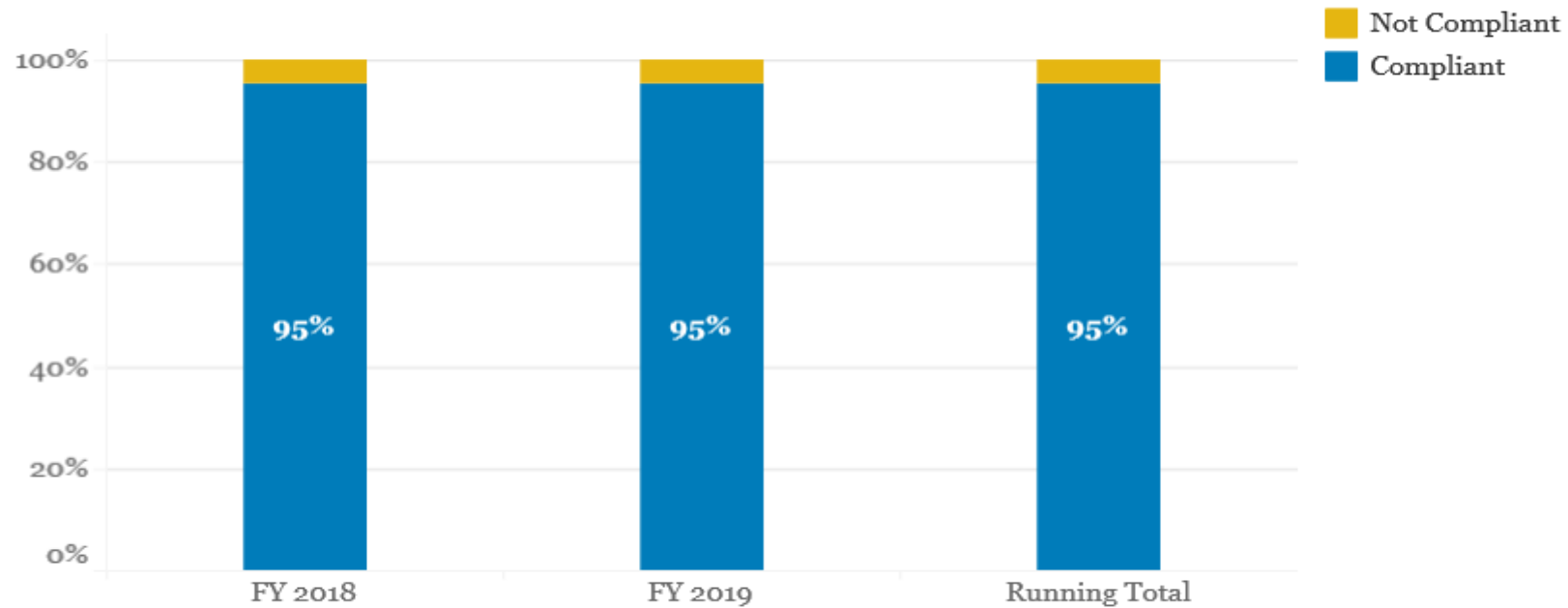




# Supply-Chain

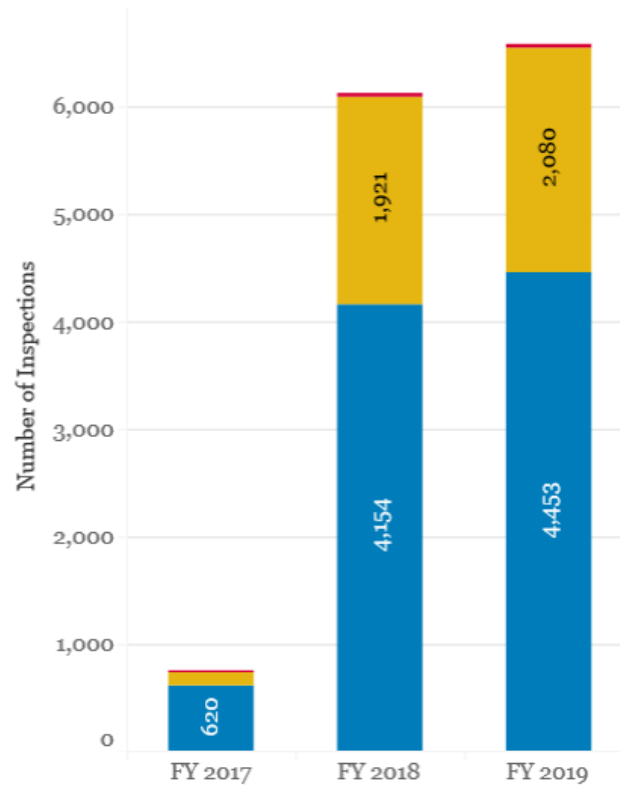
## Supply-chain Program

Of inspections in which facilities established a written supply-chain program when required, percent of inspections in which facilities are in compliance with all supply-chain program requirements covered

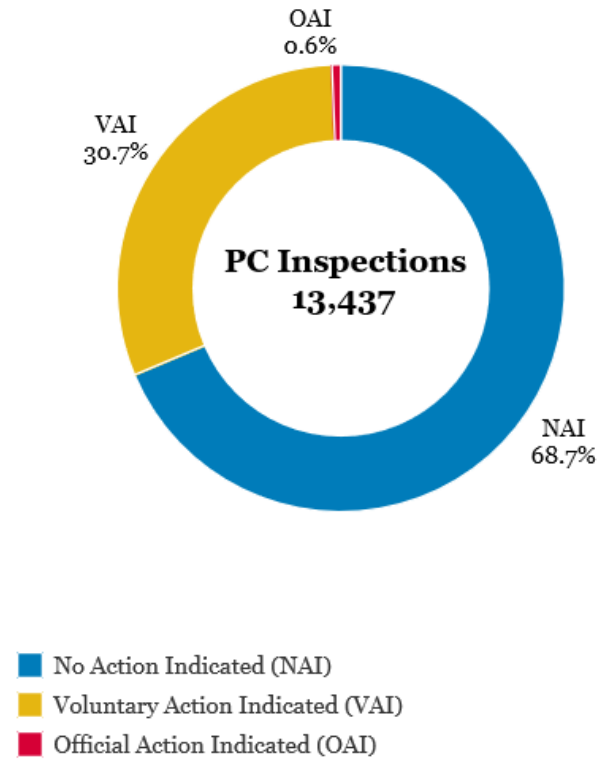


# Domestic Preventive Controls NAI/VAI/OAI

Number of Inspections by Classification



Percent of Inspections by Classification



# CFSAN and CVM Warning and Untitled Letters

		2017	2018	2019	SUM
<b>CFSAN</b>	<b>Untitled Letter</b>	1	9	40	<b>50</b>
	<b>Warning Letter</b>	2	23	35	<b>60</b>
<b>CVM</b>	<b>Untitled Letter</b>	1	3	2	<b>6</b>
	<b>Warning Letter</b>		3	3	<b>6</b>
<b>SUM</b>		<b>4</b>	<b>38</b>	<b>80</b>	<b>122</b>

## FY 17: 10/01/2016 - 09/30/2017

21 CFR 117.40	Equipment and Utensils Design and Maintenance
21 CFR 117.80(c)	Manufacturing, Processing, Packing, Holding – Controls
21 CFR 117.35(a)	Sanitary Operations – Plant Maintenance
21 CFR 117.10	Personnel
21 CFR 117.20(b)	Plant Construction and Design
21 CFR 117.31	Sanitary Facilities and Control
21 CFR 117.35(a)	Sanitary Operations – Plant Sanitation
21 CFR 117.35(c)	Pest Control
21 CFR 117.93	Storage and Transportation
21 CFR 117.35(d)	Sanitation of food contact surfaces - frequency

## FY18: FY 10/01/2017 - 09/30/2018

21 CFR 117.35(c)	Pest Control
21 CFR 117.80(c)	Manufacturing, Processing, Packing, Holding – Controls
21 CFR 117.35(a)	Sanitary Operations - Plant Maintenance
21 CFR 117.10	Personnel
21 CFR 117.40	Equipment and Utensils - Design and Maintenance
21 CFR 117.37	Sanitary Facilities and Control
21 CFR 117.20(b)	Plant Construction and Design
21 CFR 117.35(d)	Sanitation of food contact surfaces – frequency
21 CFR 117.35(a)	Sanitary Operations - Plant Sanitation
21 CFR 117.93	Storage and Transportation

## FY19: FY 10/01/2018 - 09/30/2019

21 CFR 117.10	Personnel
21 CFR 117.35(c)	Pest Control
21 CFR 117.35(a)	Sanitary Operations - Plant Maintenance
21 CFR 117.20(b)	Plant Construction and Design
21 CFR 117.80(c)	Manufacturing, Processing, Packing, Holding – Controls
21 CFR 117.40	Equipment and Utensils - Design and Maintenance
21 CFR 117.130(a)(1)	Hazard Analysis – Identification of Hazard
21 CFR 117.37	Sanitary Facilities and Control
21 CFR 117.35(a)	Sanitary Operations - Plant Sanitation
21 CFR 117.35(d)	Sanitation of food contact surfaces – frequency

# FY19 PCAF Common Citations

- Common inspection citations:
  - Failure to identify/implement a preventive control
  - Hazard analysis
  - No written food safety plan
  - Food safety plan not done/overseen by PCQI
  - Failure to establish/implement corrective action procedures
  - Failure to validate preventive control
  - Failure to conduct reanalysis

# FY19 PCAF Inspection Experiences

- Perspectives:
  - Hazard analysis
  - Pre-requisite programs
  - HACCP
  - Corporate plans vs. facility specific plans
  - Decisions made in a vacuum
  - Training



# FY19 PCAF Inspection Experiences

- Perspectives from Industry:
  - Concerns about requests for complaint files
  - Supply-chain applied controls vs. supply-chain pre-requisite programs

# FSVP Citations

- 21 CFR 1.502(a) Develop FSVP- You did not develop an FSVP
- 21 CFR 1.504(a) Hazard analysis written - You did not have a written hazard analysis to identify and evaluate known or reasonably foreseeable hazards [to determine whether there are any hazards requiring a control].
- 21 CFR 1.506(b) Supplier verification - establish written procedures - You did not establish [adequate] written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to a food you import.
- 21 CFR 1.505(b) Supplier approval documentation - You did not document your approval of your foreign supplier.
- 21 CFR 1.504(b)(1) Hazard analysis biological, chemical, physical - Your hazard analysis did not include a known or reasonably foreseeable [biological] [chemical] [physical] hazard that requires a control.



**U.S. FOOD & DRUG**  
ADMINISTRATION



# **FSMA Enforcement Actions Begin: Trends and Unanswered Questions**

**Hilary Thesmar**, Chief Food & Product Safety  
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Programs, Food Marketing Institute



**FDLI ENFORCEMENT, LITIGATION, AND  
COMPLIANCE CONFERENCE –  
DECEMBER 11-12, 2019**

**FSMA ENFORCEMENT ACTIONS BEGIN:  
TRENDS AND UNANSWERED QUESTIONS**

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# FSVP Compliance

- Publication November 27, 2015; Effective date January 26, 2016.
  - <https://www.federalregister.gov/documents/2015/11/27/2015-28158/foreign-supplier-verification-programs-for-importers-of-food-for-humans-and-animals>

# FSVP Compliance

- Compliance dates begin 18 months after publication of final rule:
  - May 30, 2017.
  - March 19, 2018.
    - Others depending on food product and size of business up to July 27, 2020.
    - <https://www.fda.gov/food/food-safety-modernization-act-fsma/compliance-dates-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and>

# FSVP Compliance

- [21 C.F.R. § 1.514](#)
- What are some consequences of failing to comply with the requirements of this subpart?
- (a) *Refusal of admission.* An article of food is subject to refusal of admission under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act if it appears that the importer of that food fails to comply with this subpart with respect to that food. If there is no U.S. owner or consignee of an article of food at the time the food is offered for entry into the United States, the article of food may not be imported into the United States unless the foreign owner or consignee has appropriately designated a U.S. agent or representative as the importer in accordance with § 1.500.



# FSVP Compliance

- **(b) *Prohibited act.*** The importation or offering for importation into the United States of an article of food without the importer having an FSVP that meets the requirements of section 805 of the Federal Food, Drug, and Cosmetic Act, including the requirements of this subpart, is prohibited under section 301(zz) of the Federal Food, Drug, and Cosmetic Act.

# “Educate While Regulate”

- FDA stated policy:
  - “educate before and while we regulate, ....”
    - Discussed at length during rulemaking.
    - Discussed after rulemaking. E.g., statement of FDA CFSAN Division of Enforcement Supervisory Consumer Safety Officer Priya Rathnam—4/2017
    - 483s not the preferred method of addressing observations unless “really significant findings.”

# Observational Trends—The 483

- FDA cited failure to develop an FSVP 108 times in 2017. (21 CFR 1.502(a)). *FY 2017 Inspection Observation Data.*
- FDA cited failure to develop an FSVP 278 times in 2018. *FY 2018 Inspection Observation Data.*
- FDA cited failure to develop an FSVP 298 times so far in 2019. *FY 2019 Inspection Observation Data.*

# Import Alert 99-41

- [https://www.accessdata.fda.gov/cms\\_ia/importalert\\_1160.html](https://www.accessdata.fda.gov/cms_ia/importalert_1160.html)-- July 31, 2019
  - "Detention Without Physical Examination of Human and Animal Foods Imported from Foreign Suppliers by Importers Who Are Not in Compliance with the Requirements of the Foreign Supplier Verification Program (FSVP) Regulation"
    - Applicable Center makes recommendation for addition to the list.
    - An importer may be added to the Red List if it **"appears that"** the importer is not in compliance with FSVP requirements for one or more foods.
    - "The importer should submit **information** to adequately demonstrate that the importer has resolved the conditions that gave rise to the appearance of the FSVP violation."
    - "The purpose of this is to provide FDA with assurance that the importer is meeting the requirements of FSVP for **future entries** of the food from the foreign supplier. As appropriate, FDA may conduct a follow-up inspection of the importer to determine whether **the appearance of the FSVP violation** has been removed."

# Warning Letter

- Brodt Zenatti Holdings LLC
  - July 30, 2019
    - FSVP inspection.
    - Initiated as part of Salmonella Concord multi-state outbreak investigation.
    - Form FDA 483 issued.
    - Did not develop FSVP that covered imported sesame paste tahini.

# Warning Letter

- Conducted voluntary recall of tahini product but did not respond to 483 regarding failure to have FSVP.
- “Our inspection revealed that **you were not familiar with FSVP requirements**....If you do not promptly correct the above violations, we may place food that you import on Detention Without Physical Examination (DWPE)....”

# The Red List

- October 18, 2019--Brodt Zenatti identified as first firm on Red List for noncompliance with FSVP requirements.



# Questions?

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