What's New in the World of FSMA?

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Industry Manager for Food & Beverage, GaMEP

NJAFP Webcast • April 14, 2022

WHAT'S NEW WITH FDA & FSMA?

Food Safety Modernization Act Celebrates its 10th Birthday!!

10 YEARS
120 MONTHS
3652 DAYS
87660 HOURS
5259600 MINUTES
315576000 SECONDS
OF BEING AWESOME

FSMA Recap

FDA Authority

- More Inspections
- Mandatory Recall
- Expanded Record Access
- Expanded Administrative Detention
- Suspension of Registration
- Enhanced Product Tracing
- Third Party Lab Testing

Seven Rules of FSMA

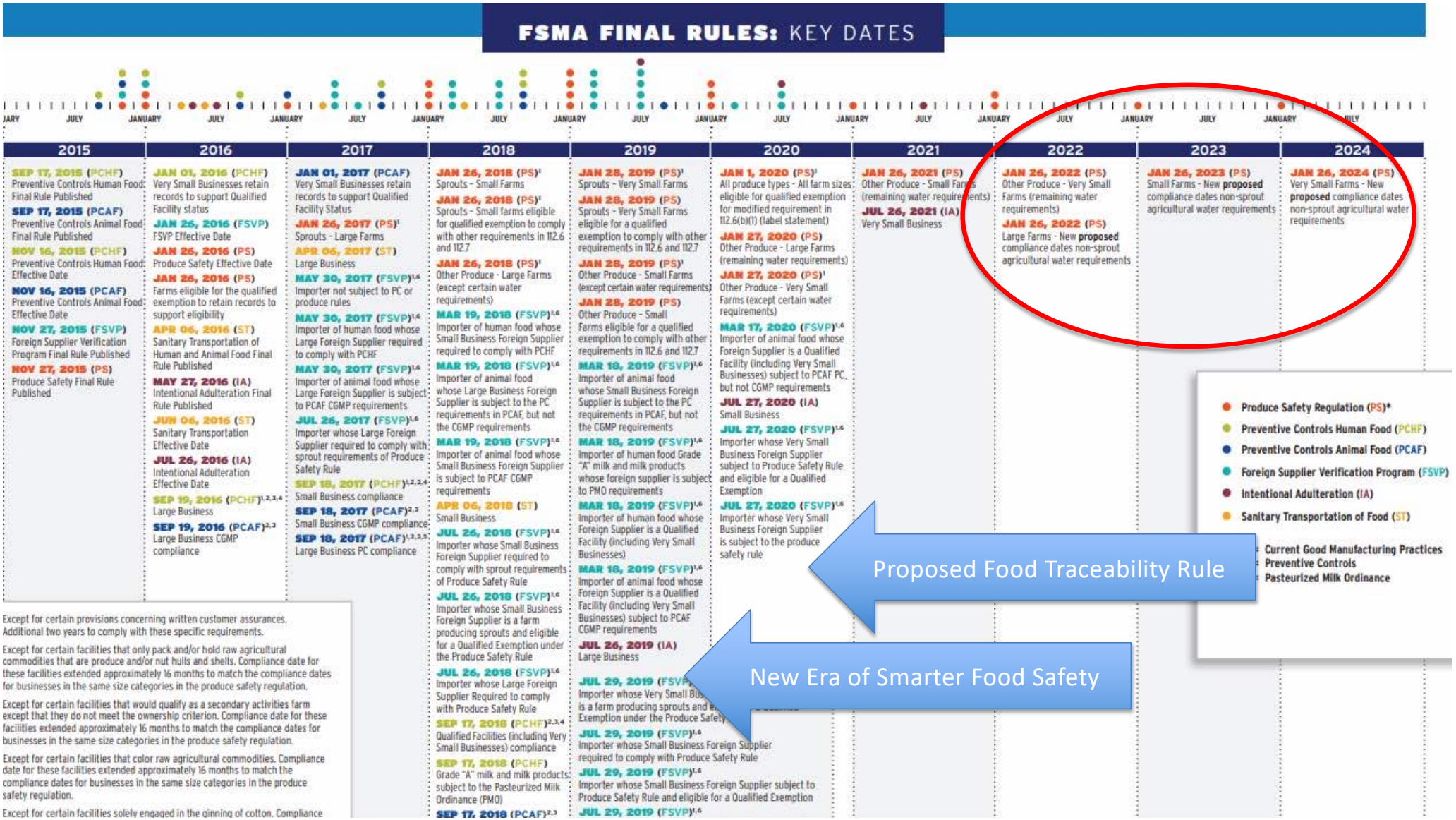
FDA FOOD SAFETY MODERNIZATION ACT

1. Produce Safety
2. Preventive Controls for Human Food
3. Preventive Controls for Animal Food
4. Foreign Supplier Verification Programs
5. Accredited Third Party Certification
6. Sanitary Transport
7. Intentional Adulteration

Unprecedented Approach to New Regulation

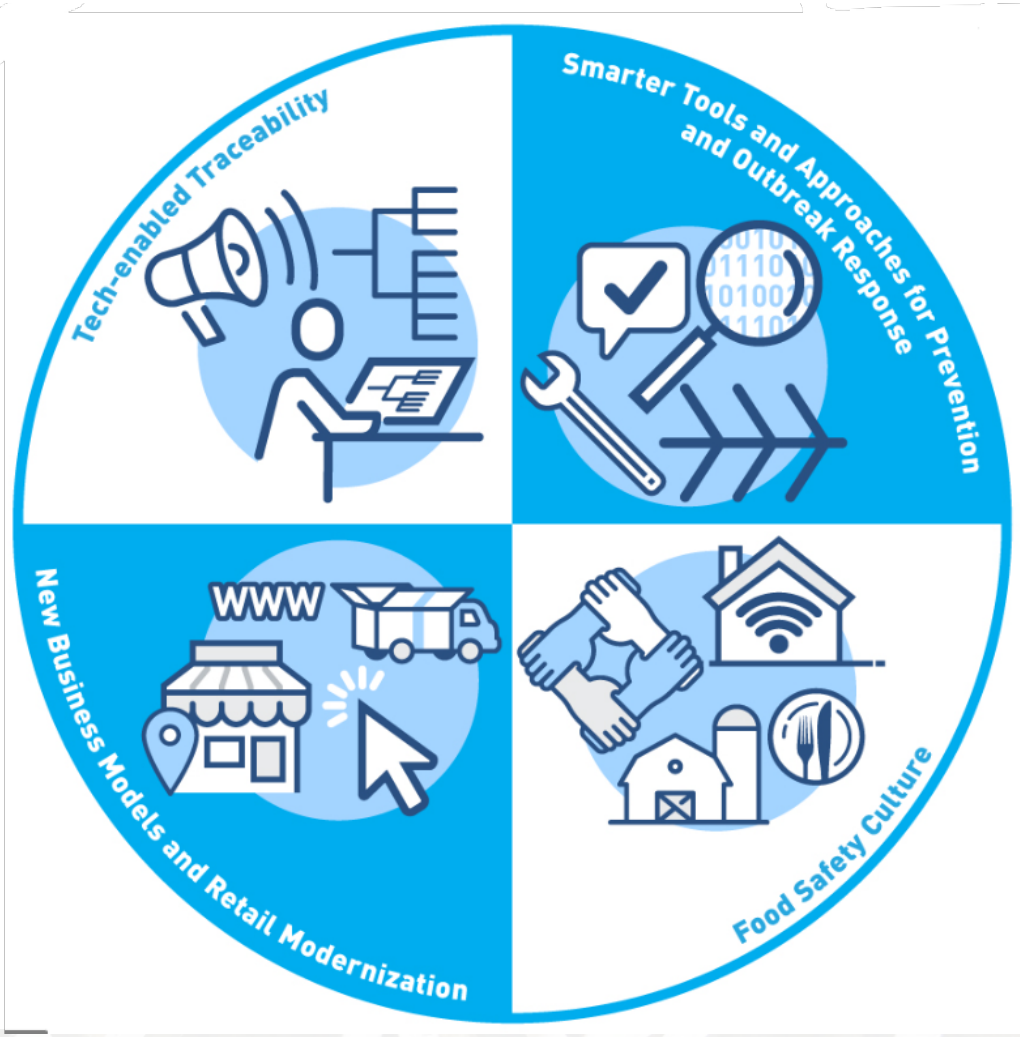
- Public Meetings
- Extensive Comment Periods
- Industry Consulting
- Long Compliance Deadlines
- Huge Focus on FDA Staff Training
- IFPTI – Training Curriculum Development

Educate While You Regulate


FSMA FINAL RULES: KEY DATES
2015
SEP 17, 2015 (PCHF) Preventive Controls Human Food: Final Rule Published
SEP 17, 2015 (PCAF) Preventive Controls Animal Food: Final Rule Published
NOV 16, 2015 (PCHF) Preventive Controls Human Food: Effective Date
NOV 16, 2015 (PCAF) Preventive Controls Animal Food: Effective Date
NOV 27, 2015 (FSVP) Foreign Supplier Verification Program Final Rule Published
NOV 27, 2015 (PS) Produce Safety Final Rule Published
2016
JAN 01, 2016 (PCHF) Very Small Businesses retain records to support Qualified Facility status
JAN 26, 2016 (FSVP) FSVP Effective Date
JAN 26, 2016 (PS) Produce Safety Effective Date
JAN 26, 2016 (PS) Farms eligible for the qualified exemption to retain records to support eligibility
APR 06, 2016 (ST) Sanitary Transportation of Human and Animal Food Final Rule Published
MAY 27, 2016 (IA) Intentional Adulteration Final Rule Published
JUN 06, 2016 (ST) Sanitary Transportation Effective Date
JUL 26, 2016 (IA) Intentional Adulteration Effective Date
SEP 19, 2016 (PCHF)1,2,3,4 Large Business
SEP 19, 2016 (PCAF)2,3 Large Business CGMP compliance
2017
JAN 01, 2017 (PCAF) Very Small Businesses retain records to support Qualified Facility Status
JAN 26, 2017 (PS)1 Sprouts - Large Farms
APR 06, 2017 (ST) Large Business
MAY 30, 2017 (FSVP)1,6 Importer not subject to PC or produce rules
MAY 30, 2017 (FSVP)1,6 Importer of human food whose Large Foreign Supplier required to comply with PCHF
MAY 30, 2017 (FSVP)1,6 Importer of animal food whose Large Foreign Supplier is subject to PCAF CGMP requirements
JUL 26, 2017 (FSVP)1,6 Importer whose Large Foreign Supplier required to comply with sprout requirements of Produce Safety Rule
SEP 18, 2017 (PCHF)1,2,3,4 Small Business compliance
SEP 18, 2017 (PCAF)2,3 Small Business CGMP compliance
SEP 18, 2017 (PCAF)1,2,3,5 Large Business PC compliance
2018
JAN 26, 2018 (PS)1 Sprouts - Small Farms
JAN 26, 2018 (PS)1 Sprouts - Small farms eligible for qualified exemption to comply with other requirements in 112.6 and 112.7
JAN 26, 2018 (PS)1 Other Produce - Large Farms (except certain water requirements)
MAR 19, 2018 (FSVP)1,6 Importer of human food whose Small Business Foreign Supplier required to comply with PCHF
MAR 19, 2018 (FSVP)1,6 Importer of animal food whose Large Business Foreign Supplier is subject to the PC requirements in PCAF, but not the CGMP requirements
MAR 19, 2018 (FSVP)1,6 Importer of animal food whose Small Business Foreign Supplier is subject to PCAF CGMP requirements
APR 06, 2018 (ST) Small Business
JUL 26, 2018 (FSVP)1,6 Importer whose Small Business Foreign Supplier required to comply with sprout requirements of Produce Safety Rule
JUL 26, 2018 (FSVP)1,6 Importer whose Small Business Foreign Supplier is a farm producing sprouts and eligible for a Qualified Exemption under the Produce Safety Rule
JUL 26, 2018 (FSVP)1,6 Importer whose Large Foreign Supplier Required to comply with Produce Safety Rule
SEP 17, 2018 (PCHF)2,3,4 Qualified Facilities (including Very Small Businesses) compliance
SEP 17, 2018 (PCHF) Grade "A" milk and milk products subject to the Pasteurized Milk Ordinance (PMO)
SEP 17, 2018 (PCAF)2,3
2019
JAN 28, 2019 (PS)1 Sprouts - Very Small Farms
JAN 28, 2019 (PS) Sprouts - Very Small Farms eligible for a qualified exemption to comply with other requirements in 112.6 and 112.7
JAN 28, 2019 (PS)1 Other Produce - Small Farms (except certain water requirements)
JAN 28, 2019 (PS) Other Produce - Small Farms eligible for a qualified exemption to comply with other requirements in 112.6 and 112.7
MAR 18, 2019 (FSVP)1,6 Importer of animal food whose Small Business Foreign Supplier is subject to the PC requirements in PCAF, but not the CGMP requirements
MAR 18, 2019 (FSVP)1,6 Importer of human food Grade "A" milk and milk products whose foreign supplier is subject to PMO requirements
MAR 18, 2019 (FSVP)1,6 Importer of human food whose Foreign Supplier is a Qualified Facility (including Very Small Businesses)
MAR 18, 2019 (FSVP)1,6 Importer of animal food whose Foreign Supplier is a Qualified Facility (including Very Small Businesses) subject to PCAF CGMP requirements
JUL 26, 2019 (IA) Large Business
JUL 29, 2019 (FSVP) Importer whose Very Small Bus... is a farm producing sprouts and e... Exemption under the Produce Safet...
JUL 29, 2019 (FSVP)1,6 Importer whose Small Business Foreign Supplier required to comply with Produce Safety Rule
JUL 29, 2019 (FSVP)1,6 Importer whose Small Business Foreign Supplier subject to Produce Safety Rule and eligible for a Qualified Exemption
JUL 29, 2019 (FSVP)1,6
2020
JAN 1, 2020 (PS)1 All produce types - All farm sizes eligible for qualified exemption for modified requirement in 112.6(b)(1) (label statement)
JAN 27, 2020 (PS) Other Produce - Large Farms (remaining water requirements)
JAN 27, 2020 (PS)1 Other Produce - Very Small Farms (except certain water requirements)
MAR 17, 2020 (FSVP)1,6 Importer of animal food whose Foreign Supplier is a Qualified Facility (including Very Small Businesses) subject to PCAF PC, but not CGMP requirements
JUL 27, 2020 (IA) Small Business
JUL 27, 2020 (FSVP)1,6 Importer whose Very Small Business Foreign Supplier subject to Produce Safety Rule and eligible for a Qualified Exemption
JUL 27, 2020 (FSVP)1,6 Importer whose Very Small Business Foreign Supplier is subject to the produce safety rule
2021
JAN 26, 2021 (PS) Other Produce - Small Farms (remaining water requirements)
JUL 26, 2021 (IA) Very Small Business
2022
JAN 26, 2022 (PS) Other Produce - Very Small Farms (remaining water requirements)
JAN 26, 2022 (PS) Large Farms - New proposed compliance dates non-sprout agricultural water requirements
2023
JAN 26, 2023 (PS) Small Farms - New proposed compliance dates non-sprout agricultural water requirements
2024
JAN 26, 2024 (PS) Very Small Farms - New proposed compliance dates non-sprout agricultural water requirements
Except for certain provisions concerning written customer assurances. Additional two years to comply with these specific requirements.
Except for certain facilities that only pack and/or hold raw agricultural commodities that are produce and/or nut hulls and shells. Compliance date for these facilities extended approximately 16 months to match the compliance dates for businesses in the same size categories in the produce safety regulation.
Except for certain facilities that would qualify as a secondary activities farm except that they do not meet the ownership criterion. Compliance date for these facilities extended approximately 16 months to match the compliance dates for businesses in the same size categories in the produce safety regulation.
Except for certain facilities that color raw agricultural commodities. Compliance date for these facilities extended approximately 16 months to match the compliance dates for businesses in the same size categories in the produce safety regulation.
Except for certain facilities solely engaged in the ginning of cotton. Compliance
Produce Safety Regulation (PS)*
Preventive Controls Human Food (PCHF)
Preventive Controls Animal Food (PCAF)
Foreign Supplier Verification Program (FSVP)
Intentional Adulteration (IA)
Sanitary Transportation of Food (ST)
Current Good Manufacturing Practices
Preventive Controls
Pasteurized Milk Ordinance
Proposed Food Traceability Rule
New Era of Smarter Food Safety

FDA's New Era of Smarter Food Safety

1. Tech-Enabled Traceability
2. Smarter Tools and Approaches for Prevention & outbreak Response
3. New Business Models & Retail Modernization
4. Food Safety Culture



FDA's Proposed Rule on Food Traceability

- **Applicable to those high-risk foods** on the "Food Traceability List"
- Traceability Capabilities:
  - Keep records on Key Data Elements (KDE)
  - Critical Tracking Events (CTE)
- Records:
  - List of your FTL foods
  - KDA & CTE records (receiving, batch sheets, etc.)
  - Lot Code definitions
- Very Small Exempt: ≤ 10 Full-time Employee
- Compliance: 2 years after final publication (Publish in Q4 = 2024/5 ???)

Food Traceability List (FTL)

- Cheese (>39% moisture)
- Shell Eggs
- Nut Butters
- Cucumber (fresh)
- Herbs (fresh)
- Leafy greens (fresh & cut)
- Melons (fresh)
- Peppers (fresh)
- Sprouts (fresh)
- Tomatoes (fresh)
- Tropical Tree Fruits (fresh)
- Fruits & Vegetables (fresh cut)
  - Rarely consumed raw are exempt
- Finfish (including smoked)
- Crustaceans
- Mollusks
- RTE Deli Salads

FDA Free/Cheap Traceability Challenge Winners (P1)

- atma.io provides item-level traceability to each participant in the food supply chain, from source to store and from farm to fork, using Avery Dennison systems and proprietary blockchain technology using Mastercard Provenance.
- FarmTabs is free, downloadable software run on Microsoft Excel that helps small and mid-size farmers manage records for traceability and other farm-related metrics.
- Freshly is traceability and batch-tracking software designed for small businesses, including retailers, manufacturers, and distributors.
- HeavyConnect provides cloud-based digital traceability and compliance documentation solutions, including an intuitive mobile app that allows producers to capture traceability data in the field and seamlessly share it across the supply chain.
- Kezzler uses self-service portals to generate item-level identifiers and associate homogenized datasets at the grower level through simple mobile applications.
- Mojix uses industry standards to link traceability events for each individual item and/or lot throughout the food supply chain to enable a low-cost and collaborative open data network.

FDA Free/Cheap Traceability Challenge Winners (P2)

- OpsSmart provides an industry-proven, cloud-based traceability software solution to meet food safety, recall management, and traceability needs of a complex supply chain.
- Precise's Traceability Suite delivers efficient end-to-end supply chain tracking to all segments of the food market by utilizing geospatial, machine learning, and Internet of Things (IoT) technologies.
- Roambee/GSM/Wiliot's solution uses low-cost IoT sensor tags in combination with shipment visibility and verification technologies to provide end-to-end traceability from farm to plate.
- Rfider is software-as-a-service that simplifies capturing, securing, and sharing critical event data along supply chains all the way to consumers.
- TagOne uses a role-based data capture framework that updates an open source blockchain platform, leverages industry standards to ensure interoperability, and ensures ease of use and data security.
- Wholechain is a supply chain traceability system that utilizes blockchain technology, in collaboration with Mastercard, to trace products back to their original source.

Traceability Rule Exemptions

- Small Establishments (< 10 Full-time, farms exempt from PSA, < $25k annual sales)
- Farms
  - Direct to consumer sales
  - Packaged on farm

- Processed with 5-log Reduction Kill Step
- Produce that's not Consumed Raw (asparagus, beans)
- Personal Consumption
- Transporters, Non-Profit, Temp-Holding Warehouse (not distribution)

Proposed Agricultural Water Rule

- Part of the Produce Safety Rule
- Why?
  - Many produce outbreaks traced to contaminated irrigation water & nearby ponds/streams
- Initial mandatory micro limits proposed were challenged by industry

Proposed Agricultural Water Rule

- Revised Subpart E of the FSMA Produce Safety Rule.
- Comment Period closed this week.
- FDA is exercising enforcement discretion.
- Replace mandatory micro limits with ag water assessments.

https://agwaterassessment.fda.gov/?utm_medium=email&utm_source=govdelivery

Exceptions

- Harvest & Post-Harvest Water
- Public Water System
- Meets Standards in Produce Safety Rule
- Sprout Water isn't Applicable

Factors that Covered Farms Would be Required to Assess

Factor	Description

Agricultural water system(s)	• The location and nature of the water source (including whether it is ground water or surface water)
	• The type of water distribution system (such as whether it is open or closed to the environment)
	• The degree to which the system is protected from possible sources of contamination, including:
	  ◦ other users of the water system
	  ◦ animal impacts (such as from grazing animals, working animals, and animal intrusion)
	  ◦ adjacent and nearby land uses related to animal activity, the application of biological soil amendments of animal origin, or the presence of untreated or improperly treated human waste

Agricultural water practices	• The type of application method (such as overhead sprinkler or spray; drip, furrow, flood, and seepage irrigation) • The time interval between the last direct application of agricultural water and harvest of the covered produce (other than sprouts)
Crop characteristics	• Susceptibility of the produce to surface adhesion or internalization of hazards
Environmental conditions	• Frequency of heavy rain or extreme weather events that may impact the agricultural water system – such as by stirring sediments that may contain human pathogens - or that may impact or damage produce. Damage can increase the susceptibility of produce to contamination. • Air temperatures • Sun (UV) exposure
Other relevant factors	• Including, if applicable, results of testing that could inform the assessment

Possible Actions Required

If you determine	Then you must
that your agricultural water is not safe or is not of adequate sanitary quality for intended use(s)	• Immediately discontinue use (s) ***And*** • Take corrective measures before resuming use of the water for pre-harvest activities
there is one or more known or reasonably foreseeable hazards related to animal activity, BSAAOs, or untreated or improperly treated human waste for which mitigation is reasonably necessary	• Implement mitigation measures promptly, and no later than the same growing season
there is one or more known or reasonably foreseeable hazards not related to animal activity, BSAAOs, or untreated or improperly treated human waste, for which mitigation is reasonably necessary	• Implement mitigation measures as soon as practicable and no later than the following year ***Or*** • Test water as part of the assessment and implement measures, as needed, based on the outcome of the assessment
that there are no known or reasonably foreseeable hazards for which mitigation is reasonably necessary	• Inspect and adequately maintain the water system(s) regularly, and at least once each year

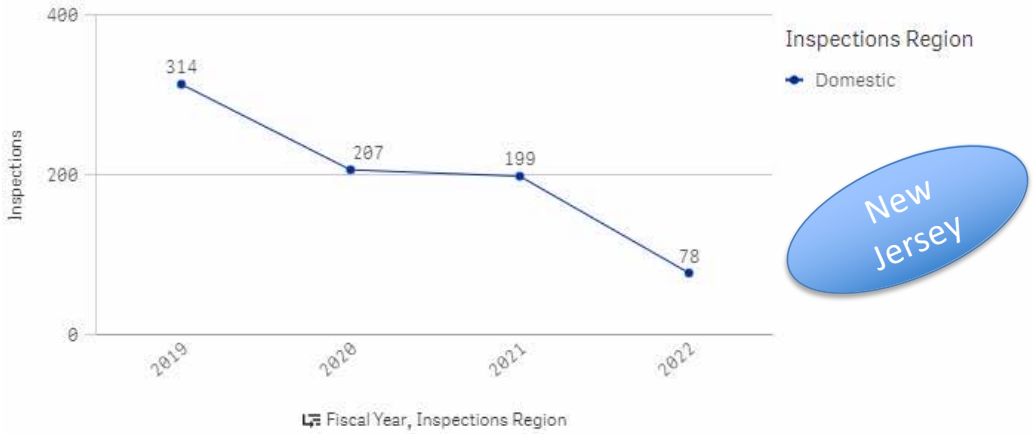
2019 – 2022 FDA Inspection Analysis

Georgia Tech | Georgia Manufacturing Extension Partnership
A unit of the Enterprise Innovation Institute

Advancing Georgia Manufacturing
www.gamep.org

Foreign and Domestic Inspections

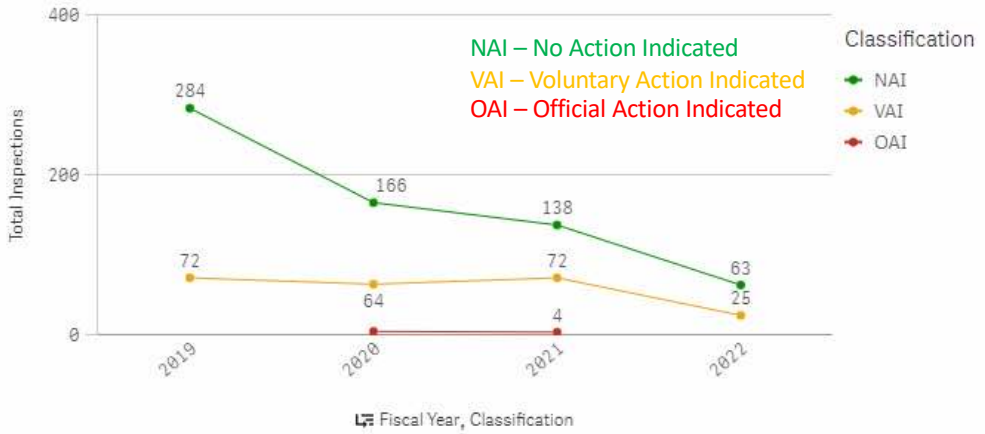
Fiscal Years: 2019, 2020, 2021, 2022



New Jersey

Inspections Classification by Fiscal Year

Fiscal Years: 2019, 2020, 2021, 2022



NAI – No Action Indicated
VAI – Voluntary Action Indicated
OAI – Official Action Indicated

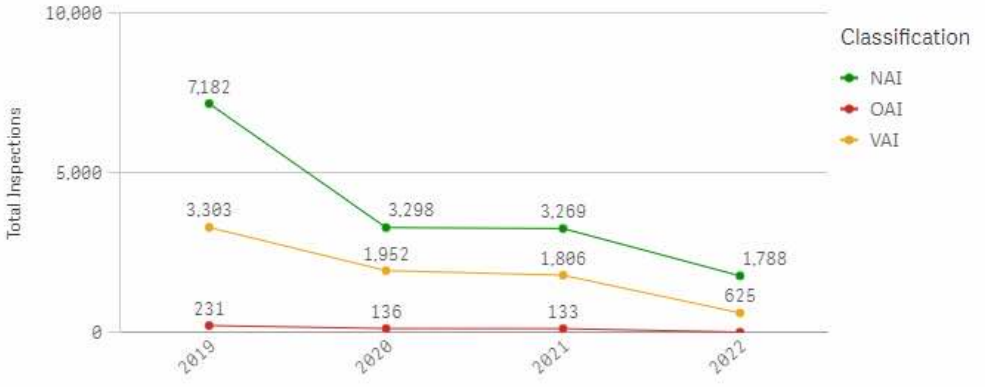
Foreign and Domestic Inspections

Fiscal Years: 2019, 2020, 2021, 2022

All Inspections

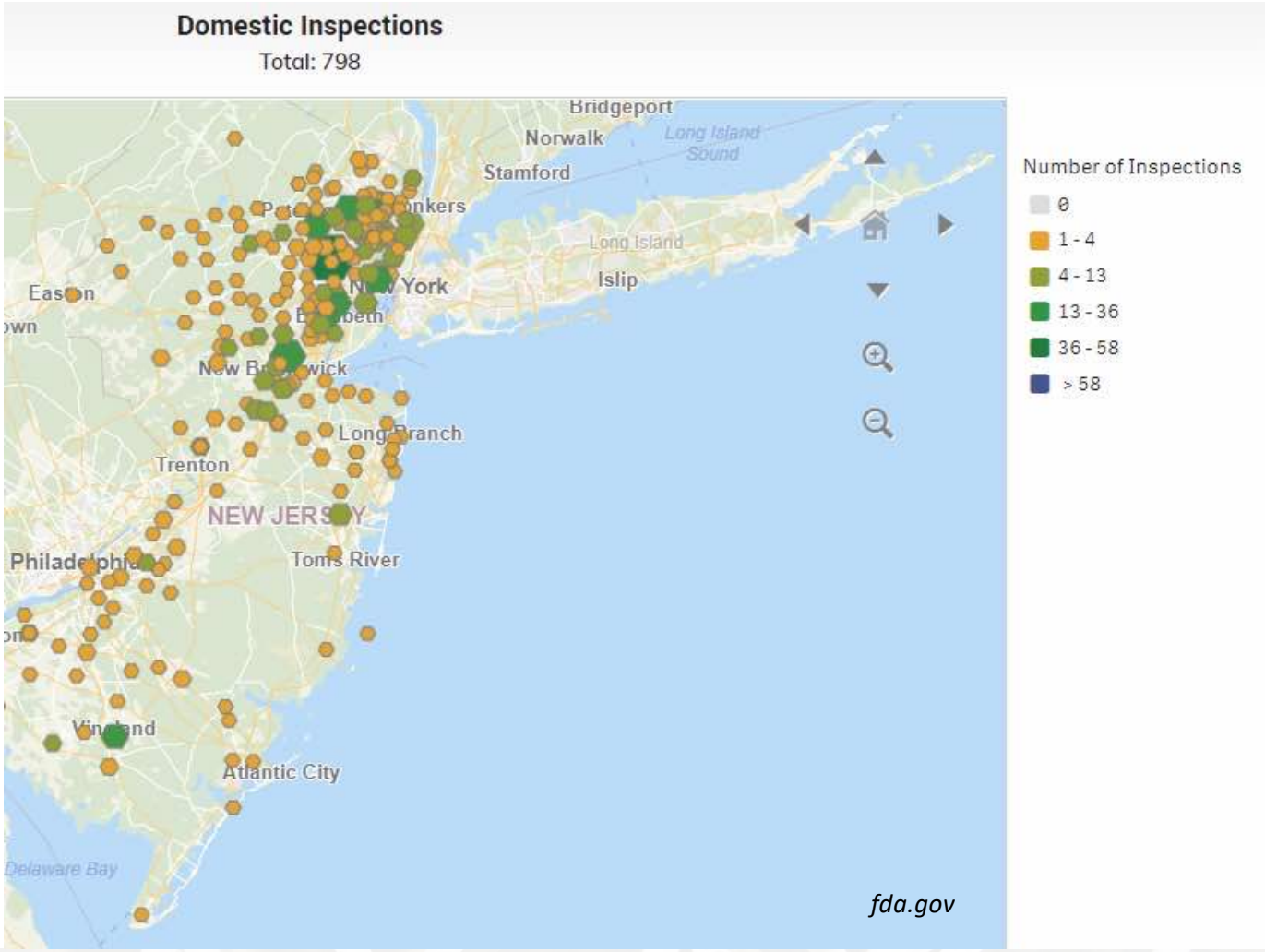
Inspections Classification by Fiscal Year

Fiscal Years: 2019, 2020, 2021, 2022



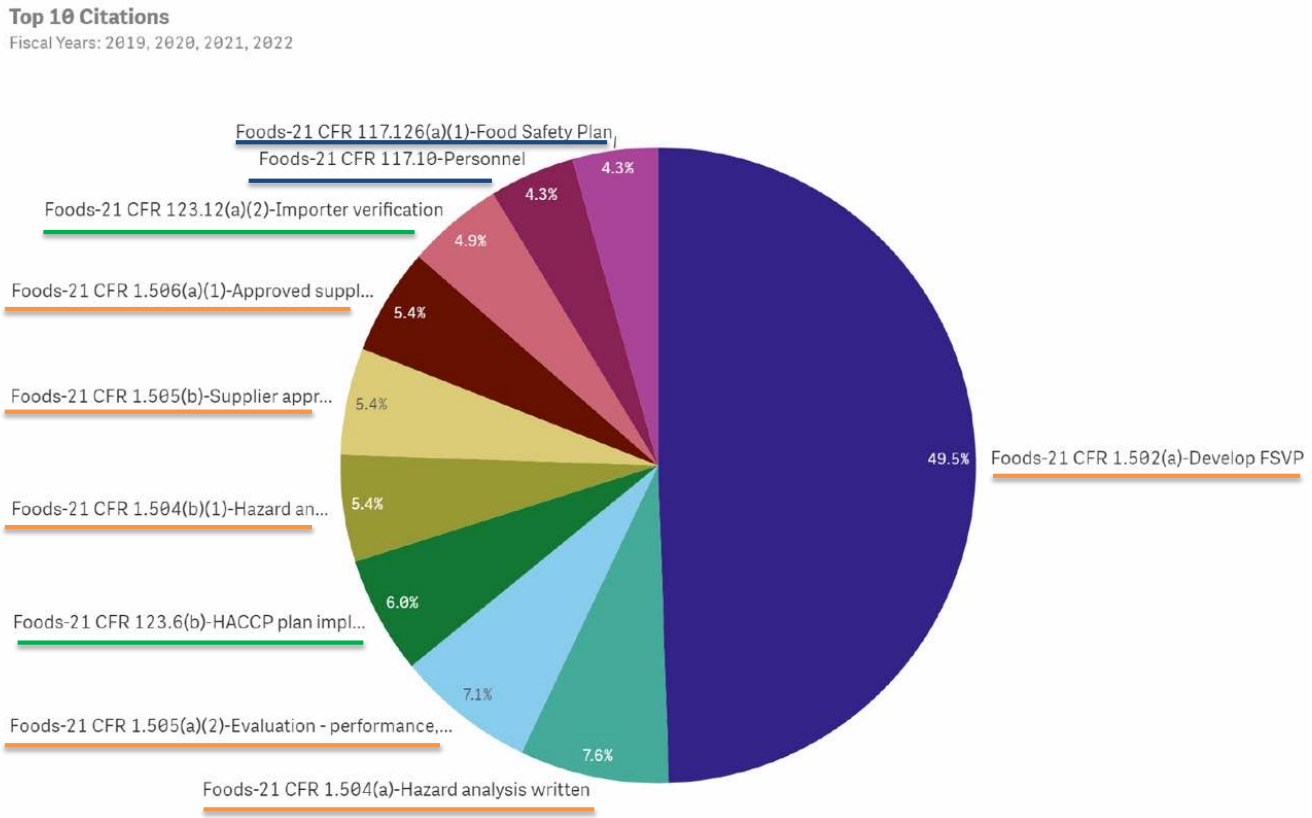
fda.gov

Distribution of FDA Inspections in New Jersey



New Jersey's Top 10 FDA Citations ('19-'22)

- General Enforcement Regulations 21 CFR 1
  - 50% Failure to develop a Foreign Supplier Verification Program for imported foods.
  - 7.5% Not having Hazard Analysis written
  - 7% No documented Foreign Supplier evaluation
  - 5% Failing to identify hazards in HA
  - 5% No Approved Supplier List
  - 5% No Approved Supplier Procedures
- Fish & Fishery Products 21 CFR 123
  - 6% No implemented HACCP Plan
  - 5% No written verification procedures for foreign suppliers
- Preventive Controls for Human Foods 21 CFR 117
  - 4% Personal Hygiene cGMP violations
  - 4% Failure to have a written Food Safety Plan



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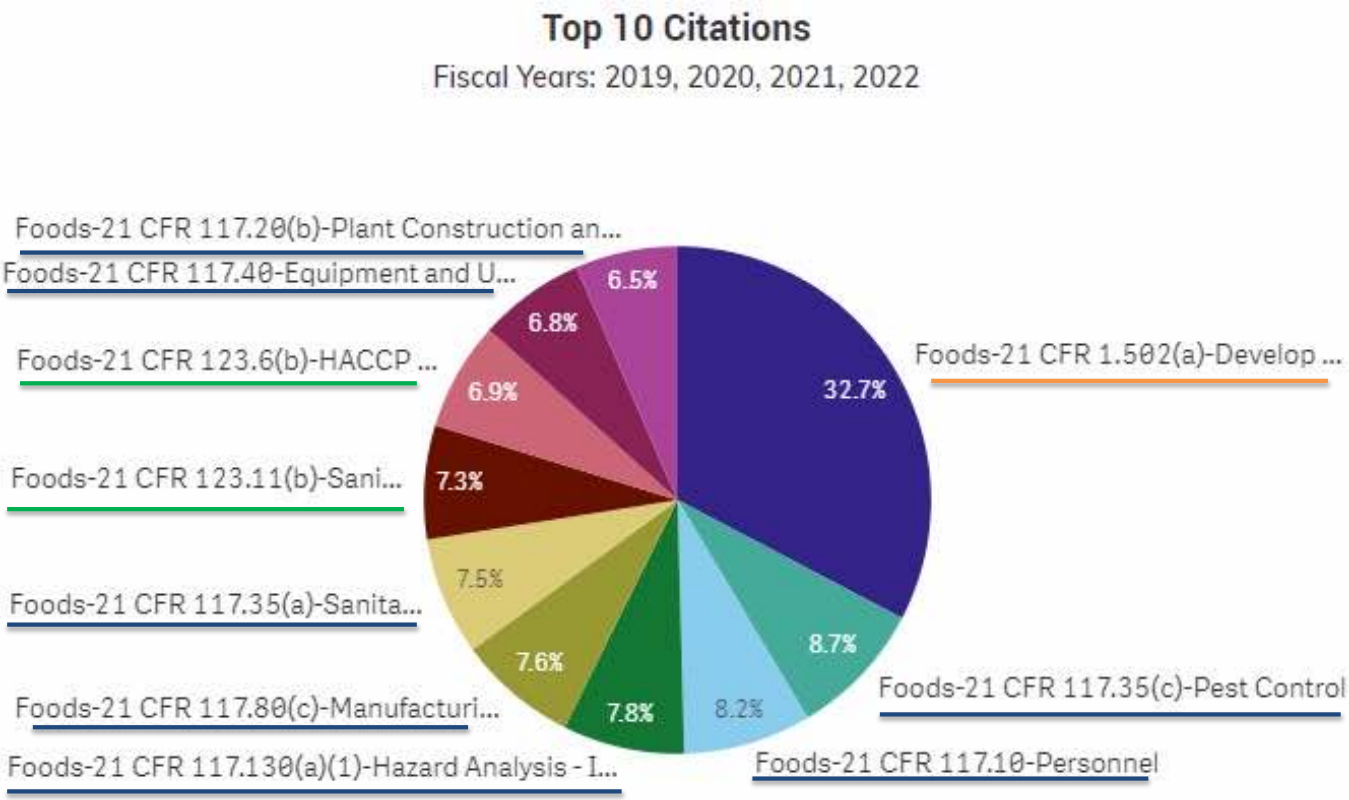
How Citations Compares with USA (‘19-’22)

- General Enforcement Regulations 21 CFR 1
  - 33% Failure to develop a Foreign Supplier Verification Program for imported foods.
- Fish & Fishery Products 21 CFR 123
  - 7% No implemented HACCP Plan
  - 7% Insufficient Sanitation Monitoring
- Preventive Controls for Human Foods 21 CFR 117
  - 9% Pest Control failures
  - 8% Personal Hygiene cGMP violations
  - 8% Not having Hazard Analysis written
  - 8% Manufacturing Violations/Contamination
  - 8% Unsanitary Conditions
  - 7% Equipment & Utensil violations
  - 7% Inadequate Plant Design or Issues with Grounds

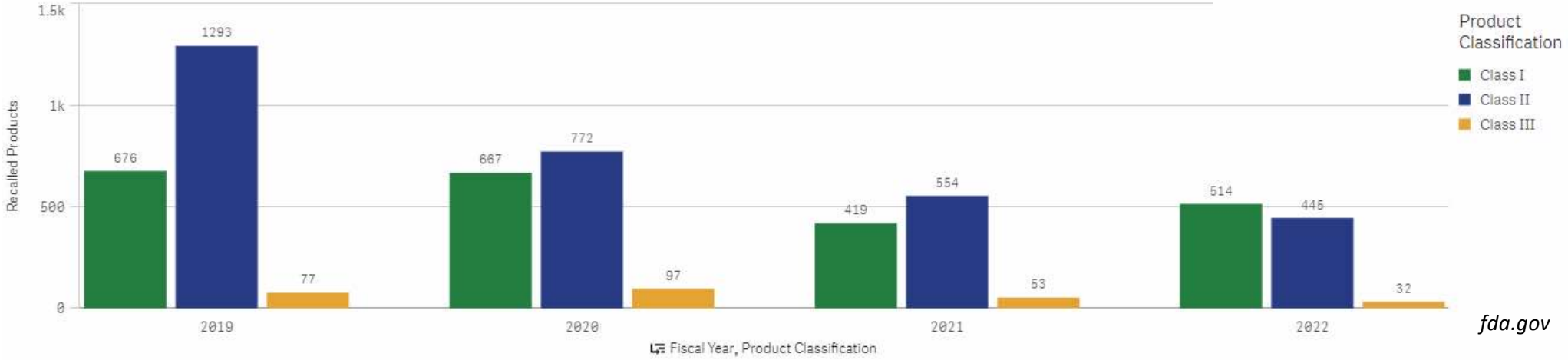


fda.gov

2019-2022 FDA Recalls

Recall Events by Status
Fiscal Years: 2019, 2020, 2021, 2022

Recalled Products by Classification
Fiscal Years: 2019, 2020, 2021, 2022



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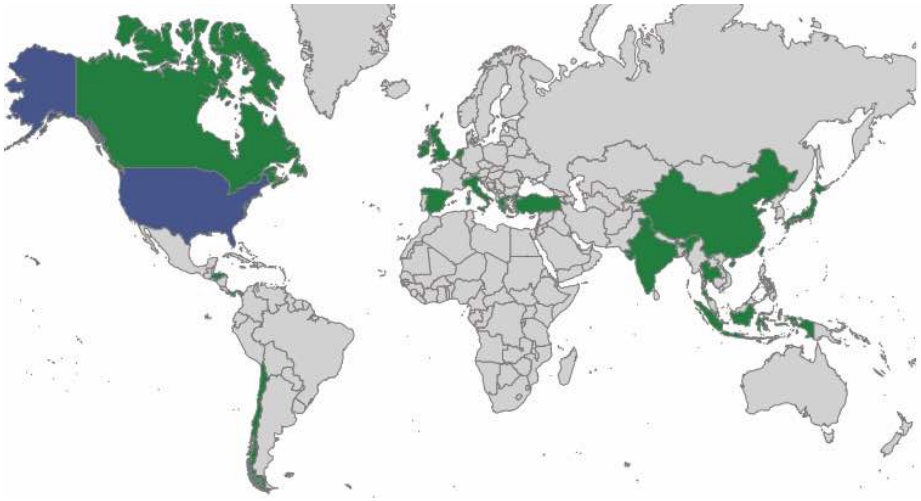
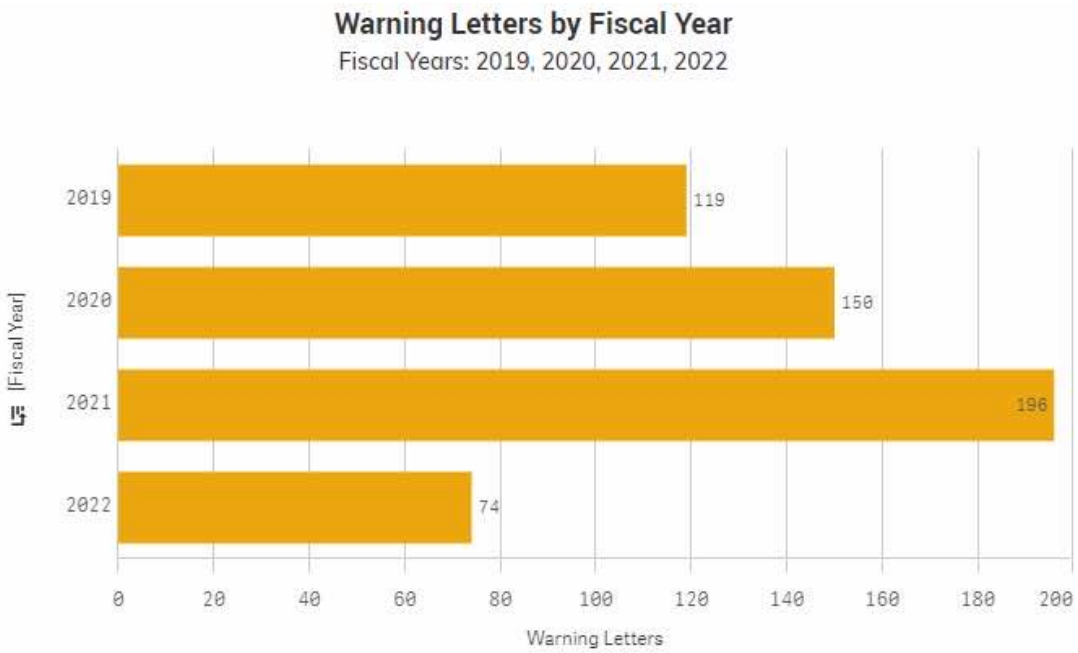
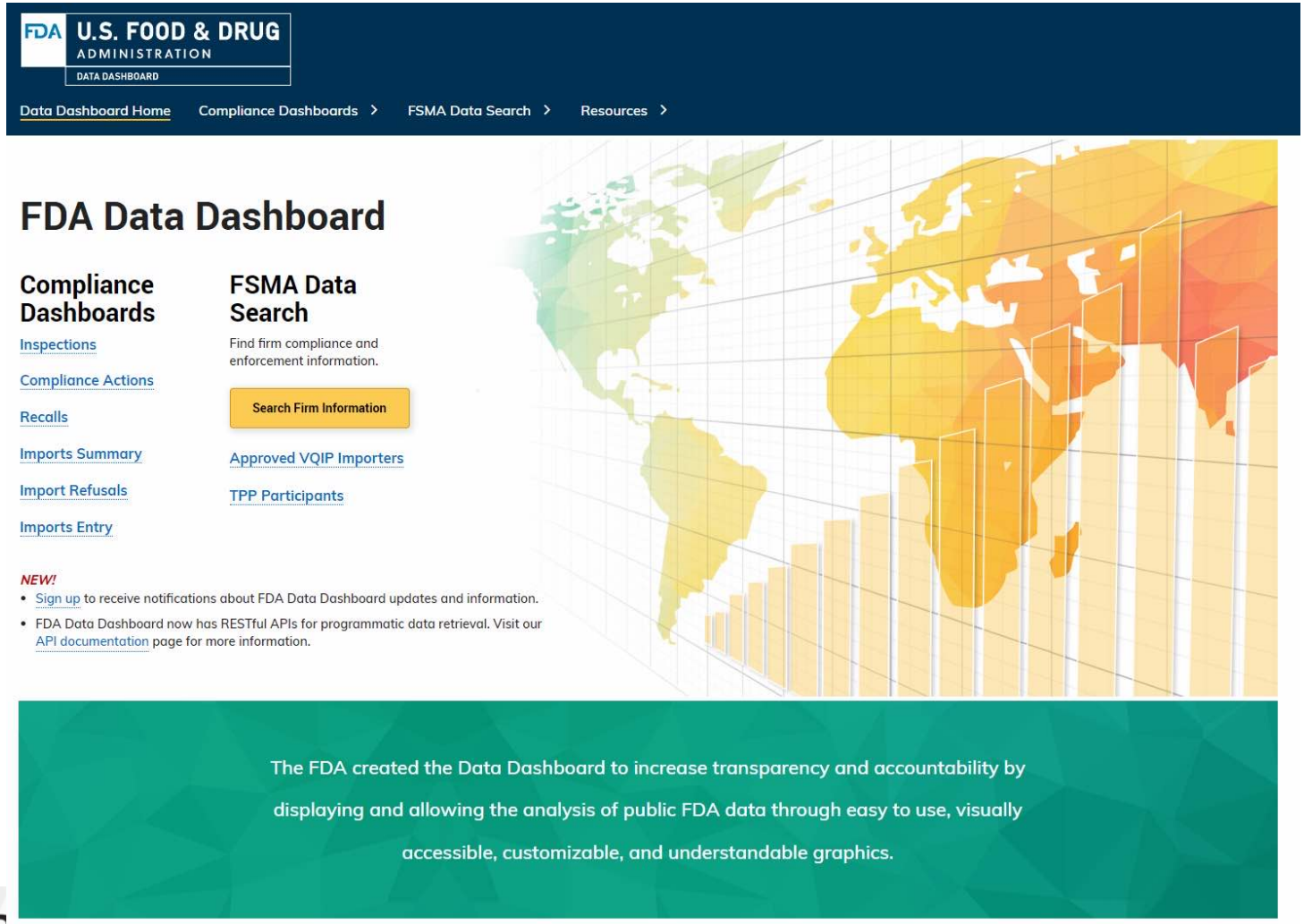



Warning Letters by Fiscal Year
Fiscal Years: 2019, 2020, 2021, 2022
[Fiscal Year]
2019
2020
2021
2022
119
150
196
74
0
20
40
60
80
100
120
140
160
180
200
Warning Letters

fda.gov

https://datadashboard.fda.gov/ora/index.htm



Other Recent Items

- **21 Forward** – Data analysis tool, using CDC data to track COVID-19 occurrences and determine where there might be interruptions in the food supply.
- **Import Screening** – Enhanced Food Traceability Predictive Analytics to predict import issues
- **Remote Inspections** – Already doing this with Foreign Suppliers.
- **User Fees:**
  - Reinspection (~$300/hour to travel, prepare, and conduct inspections)
  - Third-Party Certification Program (TPP) - $45k
  - Voluntary Qualified Importer Program (VQIP) - $16k

Job Opportunities in the FAS Foreign Service, beginning this May.

IMAGINE YOUR FUTURE...

- Living and working overseas
- Learning new languages and cultures
- Being part of a diverse team
- Solving problems to help tackle trade barriers, food insecurity, and climate change
- Having pride in your work and making a difference in service to U.S. agriculture

...as a Foreign Service officer with the USDA Foreign Agricultural Service (FAS)

Virtual Info Sessions:

April 5, 8:30-10:00 a.m. EDT
May 3, 1:00-2:30 p.m. EDT

www.fas.usda.gov
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Questions?

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Additional Resources:

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