

FDA Seattle District Division of Human and Animal Foods Welcome and Updates

Alaska Food Protection Task Force Educational Workshop

April 27, 2021

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Program Division Director/Seattle District Director

Office of Human and Animal Food Operations – Division 6 West

U.S. Food & Drug Administration



Objectives

- Provide Updates/Overview of FDA/District Programs
- Better Together – Collaboration, Coordination, Continuous Improvement for the best public health outcomes



Overview of FDA Office of Regulatory Affairs Seattle District Office (SEA-DO)

The Seattle District Office (SEA-DO) is located in Bothell, Washington and encompasses Alaska, Idaho, Montana, Oregon and Washington.

Maintain longstanding relationships with state and local public health agencies, academia, and regulated industry to protect and promote public health in the region.

Who We Are

SEA-DO District Director and Program Division Director OHAFO Division VI West:

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Who We Are

Additional Key Contacts

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Recall Coordinator, OHAFO Division VI West:

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Who We Are:

FDA staff work in a range of program areas and locations geographically dispersed across the Five State Area

- Total locations: 13
- Resident Posts: **12** + **1** District Office
- Laboratories: **1**

- Approximately 250 Employees

Where We Are

Alaska Anchorage Resident Post (RP)

Idaho Boise RP, Eastport RP*

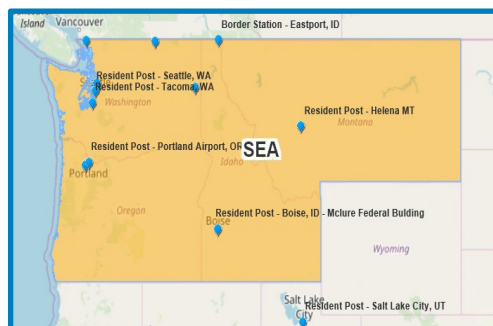
Montana Helena RP and Sweetgrass RP*

Oregon Portland RP(Beaverton) and Rose City RP (Portland)

Washington Blaine RP*, Oroville RP*, Spokane RP, Tacoma RP, Puget Sound RP (Seattle)

FDA Seattle District Office – Bothell, WA

FDA Pacific Northwest Lab - Bothell, WA



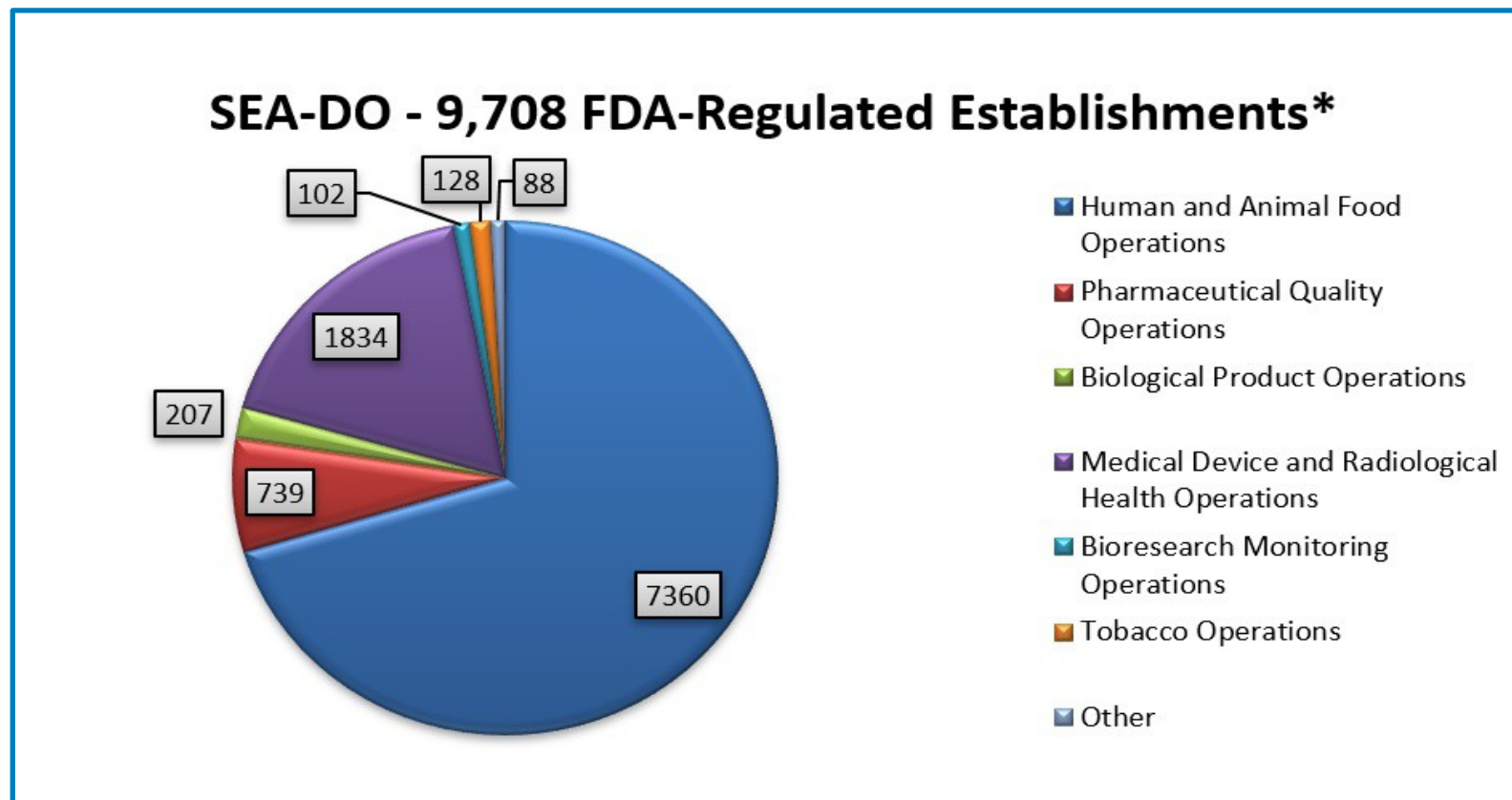


What We Do

SEA-DO includes the following ORA Program Divisions	
OFFICE OF BIOLOGICAL PRODUCTS OPERATIONS DIVISION 2	OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS DIVISION 6 WEST
OFFICE OF BIORESEARCH MONITORING OPERATIONS DIVISION 2	OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS DIVISION OF SOUTHEAST IMPORTS (Alaska)
OFFICE OF MEDICAL DEVICE AND RADIOLOGICAL HEALTH OPERATIONS DIVISION 3	OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS DIVISION OF NORTHERN BORDER IMPORTS (Washington -Partial, Montana, Idaho)
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS DIVISION 4	OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS DIVISION OF WEST COAST IMPORTS (Washington - Partial, Oregon)

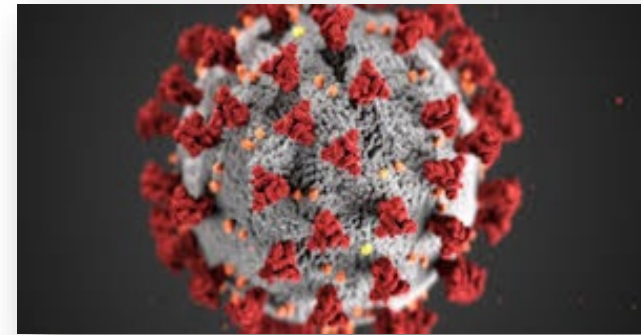


What We Do

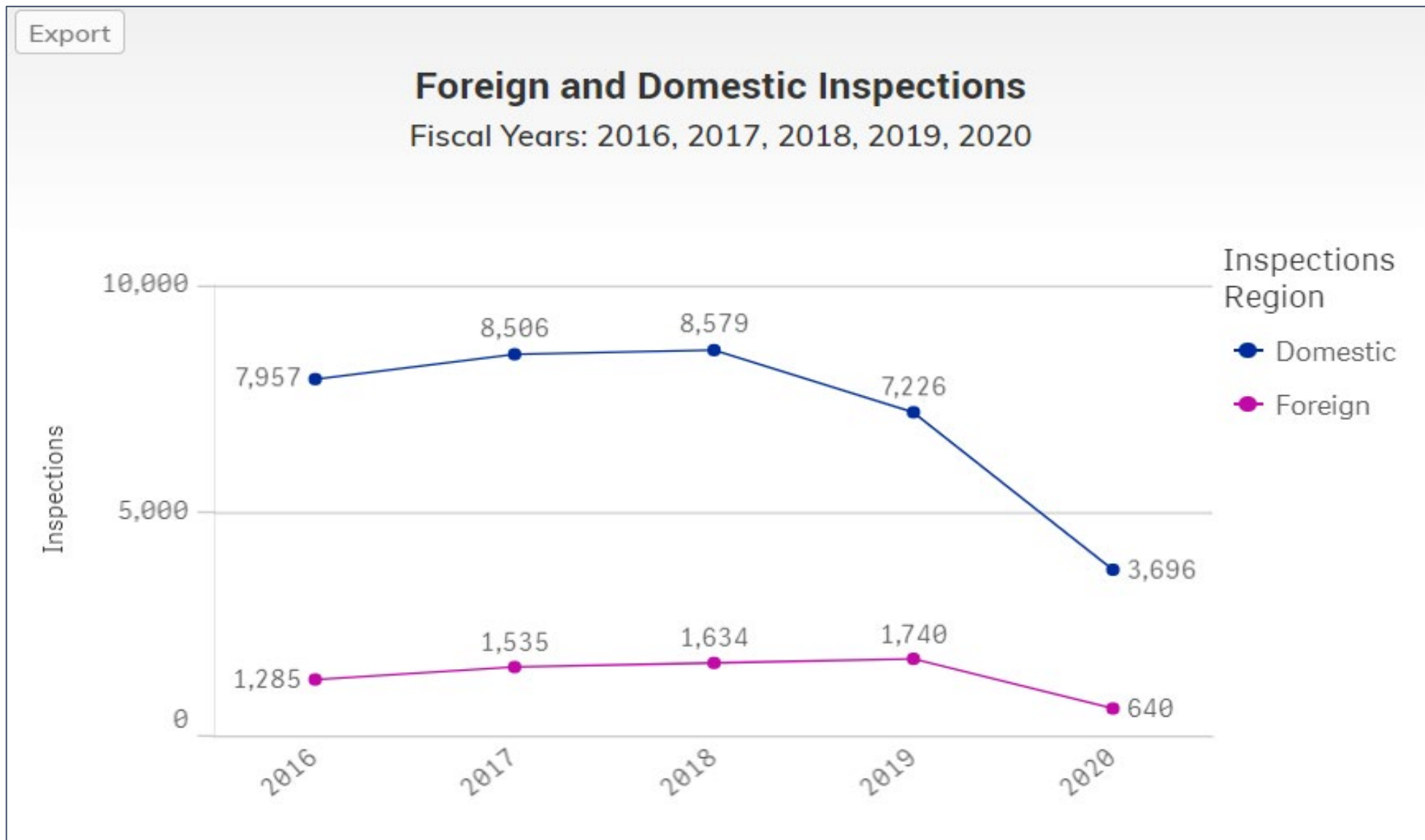




Thank You to All Workers! Communications and Support Critical During 2020 & 2021



- We are all in this together! Workers at all levels of the food supply chain, state and federal workers.
- FDA's webpage [Food Safety and the Coronavirus Disease 2019](#)
- Some inspections are temporarily on hold, but the food industry is still required to meet food safety requirements – this has not changed.



Mission Critical

(e.g. outbreaks of foodborne illness, Class 1 Recalls)

Outbreak Investigations by Year

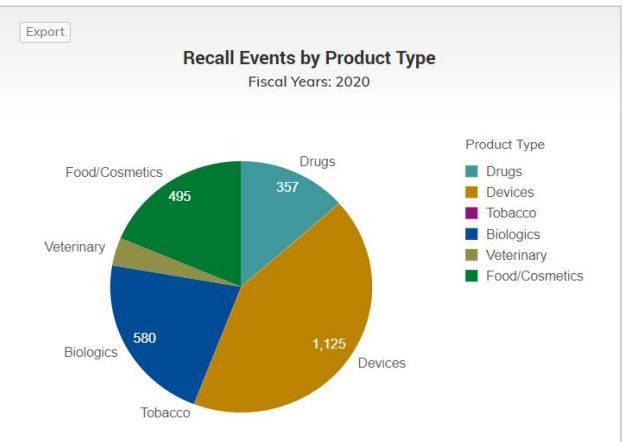
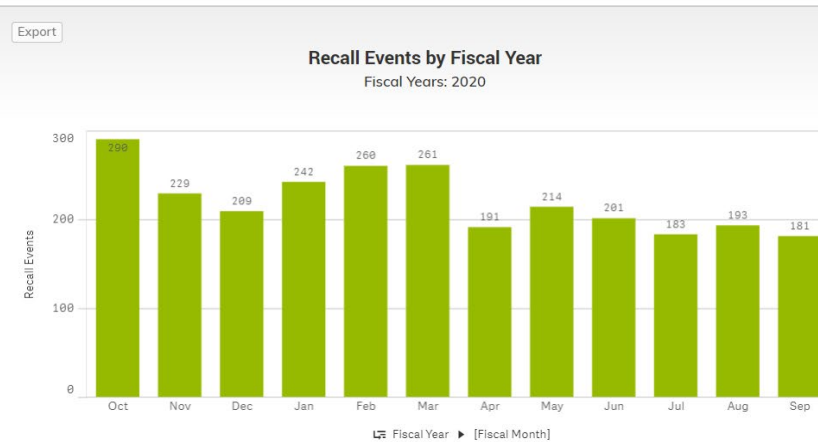
2020

- *Salmonella*: Wood Ear Mushrooms - Dried Fungus (September 2020)
- *Salmonella*: Peaches (August 2020)
- *Cyclospora*: Bagged Salad (June 2020)
- *Salmonella*: Red Onions (July 2020)
- *Listeria monocytogenes*: Enoki Mushrooms (March 2020)
- *E. coli*: Clover Sprouts (February 2020)



FDA Activities

Recall Events





FDA Inspection Timeline

March 10, 2020

- FDA postponed *foreign* inspections

March 18, 2020

- FDA postponed *domestic* inspections

July 10, 2020

- Resumption of inspections using risk assessment system (COVID-19 Advisory Tool)



FDA Activities

- Resuming inspections using an **Advisory Rating System**
- **Pre-announcing** inspections using standardized field script with assessment questions
- Enhanced official establishment inventory improvement activities
 - Domestic Food Inventory ~ 72,000
 - Domestic Animal Food/Feed Inventory ~23,000
 - Foreign Food Inventory ~10,000



FDA Activities

- Resumed inspections using an **Advisory Rating System**

Three step process to plan Field Activities: inspections, investigations, sample collections, consumer complaint follow-up

- Selection
- Pre-announce
- Day of inspection

Verifying the agency's Official Establishment Inventory

Assist FDA Produce staff and Medical Product Programs with work

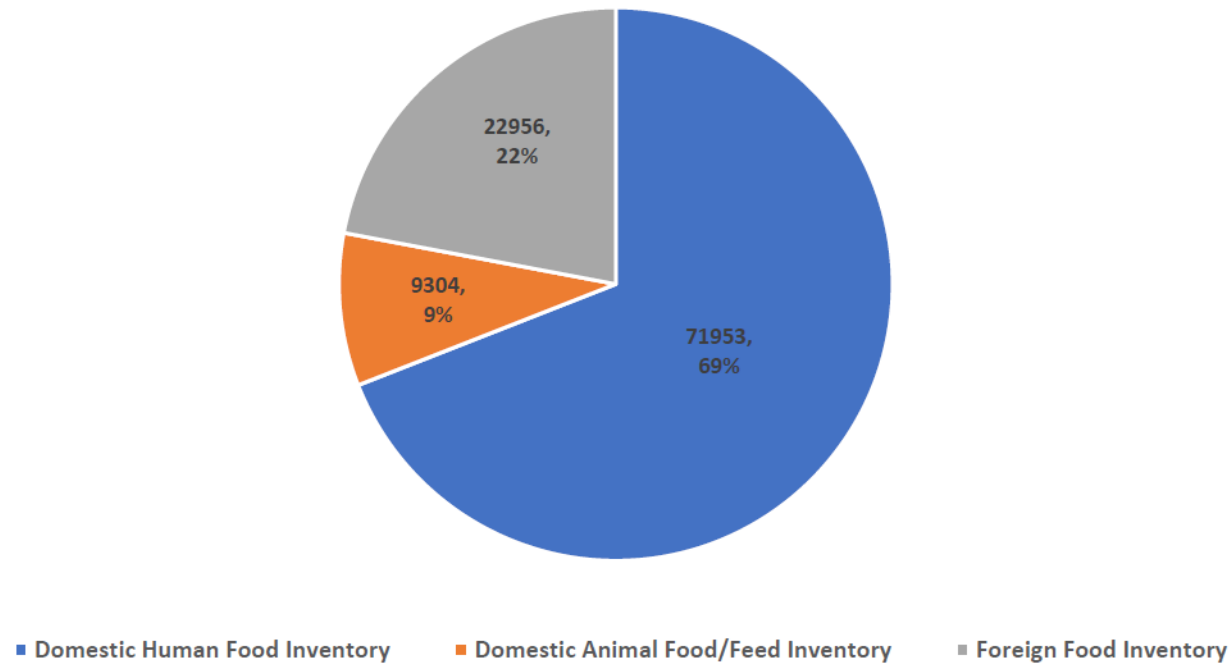
FDA Activities

- FDA held a webinar with partners at OSHA and CDC to provide a COVID-19 update for food operations stakeholders.
- The agencies developed a resource document (checklist) for Food Operators: [Employee Health and Food Safety Checklist for Human Food Operations During the COVID-19 Pandemic.](#)
- The webinar was held on Tuesday, September 1, 2020. During the webinar FDA and OSHA discussed the checklist and CDC provided additional information.



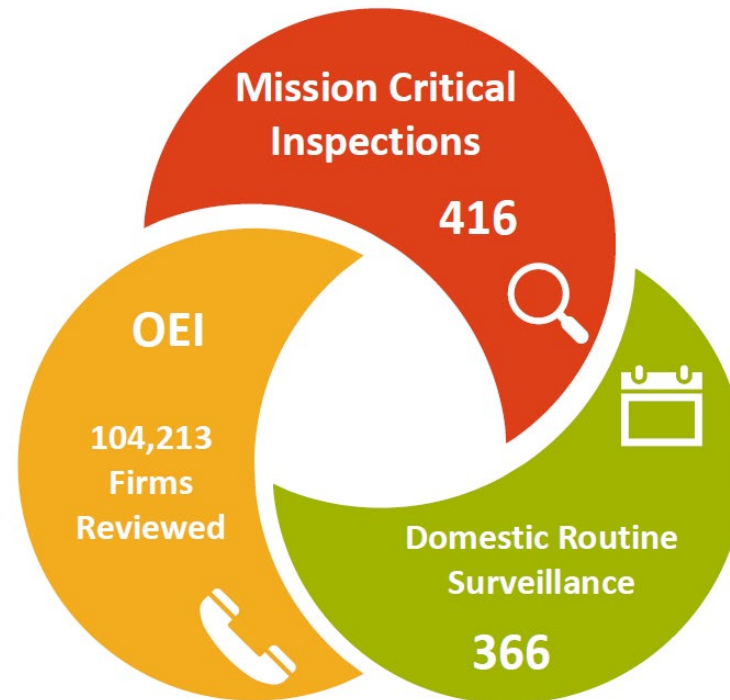
OHAFO Activities During the Pandemic

Enhanced Official Establishment Inventory Improvement Activities



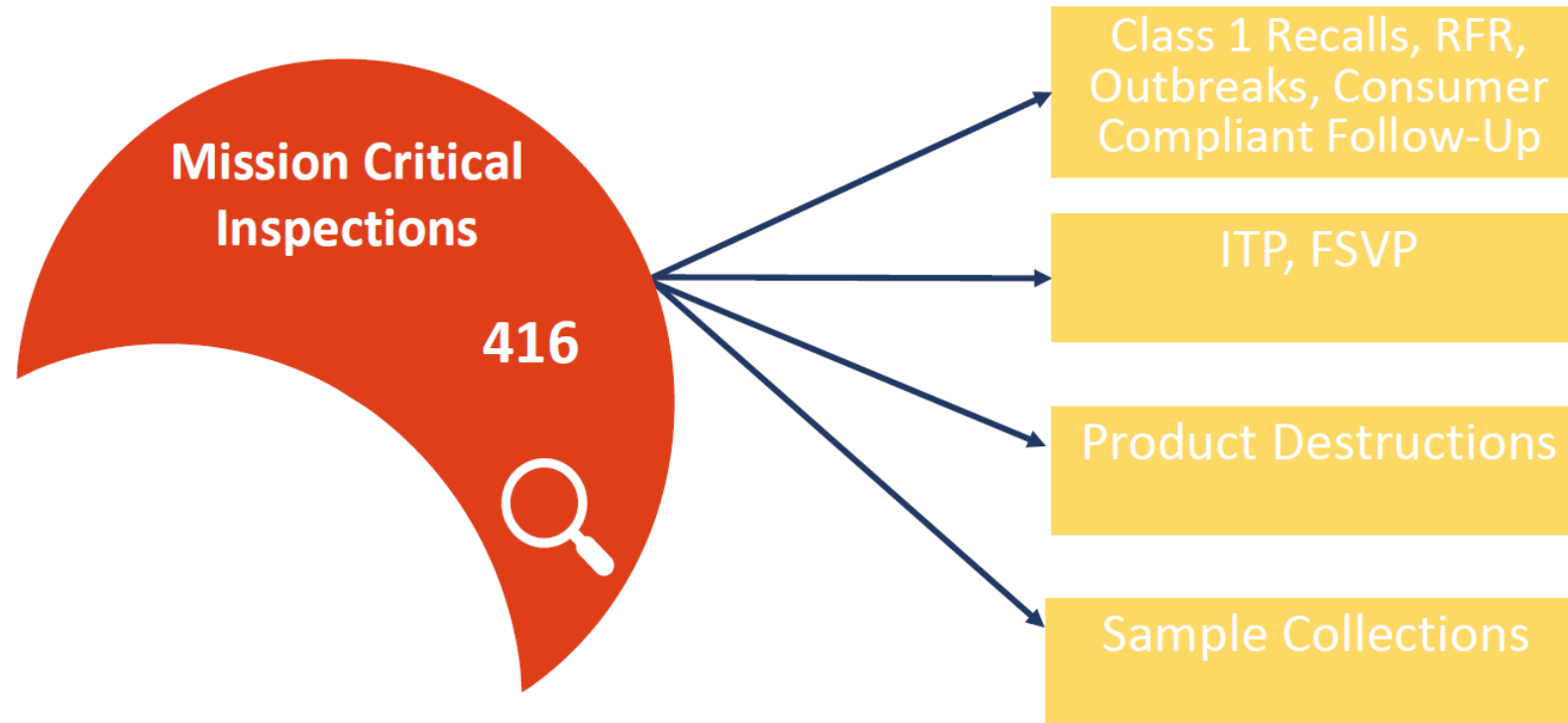
OHAFO Activities During the Pandemic

March 2020 – April 2021



OHAFO Activities During the Pandemic

Inspections and Investigations March 2020 – April 2021



FDA Challenges

- Challenges due to COVID-19:

- Impact on FSMA 201- Inspection frequency **MANDATE**
- As conditions on the ground change and the impact of COVID-19 changes, we continue to revise the field instructions to meet the present conditions;
- Travel takes longer
- Wildfires and Social unrest- unpredictable but must be considered when providing the final Go or No Go for the inspection
- Learning Curve for new procedures and precautions
- Impact on staff and their families
- Staff PHS Officers Deployed for National COVID Response



What's Next

- Reassess situation frequently – What have we learned?
- Discuss innovative ways to meet the mission to have the best public health outcomes
- Continue to protect health, safety and well-being of the public and our workforce

FDA Resources

- FDA's webpage: [Food Safety and the Coronavirus Disease 2019 \(COVID-19\)](#)
- Have a Food Safety Modernization (FSMA) Question? Technical Assistance Network
- [Employee Health and Food Safety Checklist for Human Food Operations During the COVID-19 Pandemic \(recorded session\)](#)
- Questions may be submitted for food products to: [Food and Cosmetics Information Center](#)

FDA Resources

- [New Era Smarter Food Safety](#), webpage updated 9/3/20.
- [FDA and OSHA Team Up to Publish Checklist to Assist Food Industry](#) During COVID-19, 8/19/20.
- [Industry FAQs: Animal Food Safety and the Coronavirus Disease 2019](#), updated 7/29/2020.
- [Getting Smarter about Food Safety: The Pandemic and Lessons Learned](#), Consumer Update, 6/23/2020.
- [FDA's Perspective on Food Safety and Availability During and Beyond COVID-19](#), 4/16/20.
- [FDA Offers Assurance About Food Safety and Supply for People and Animals](#), Frank Yiannas, 4/20/20.
- [Food Safety and Availability During the Coronavirus Pandemic](#), Consumer Updates, 4/1/2020.
- [FDA Briefing for Foods Stakeholders](#) on Coronavirus Disease 2019, 3/17/20.
- [Update: Foreign Inspections](#), 3/10/2020.



Celebrating Accomplishments

Food Safety Modernization Act (FSMA)

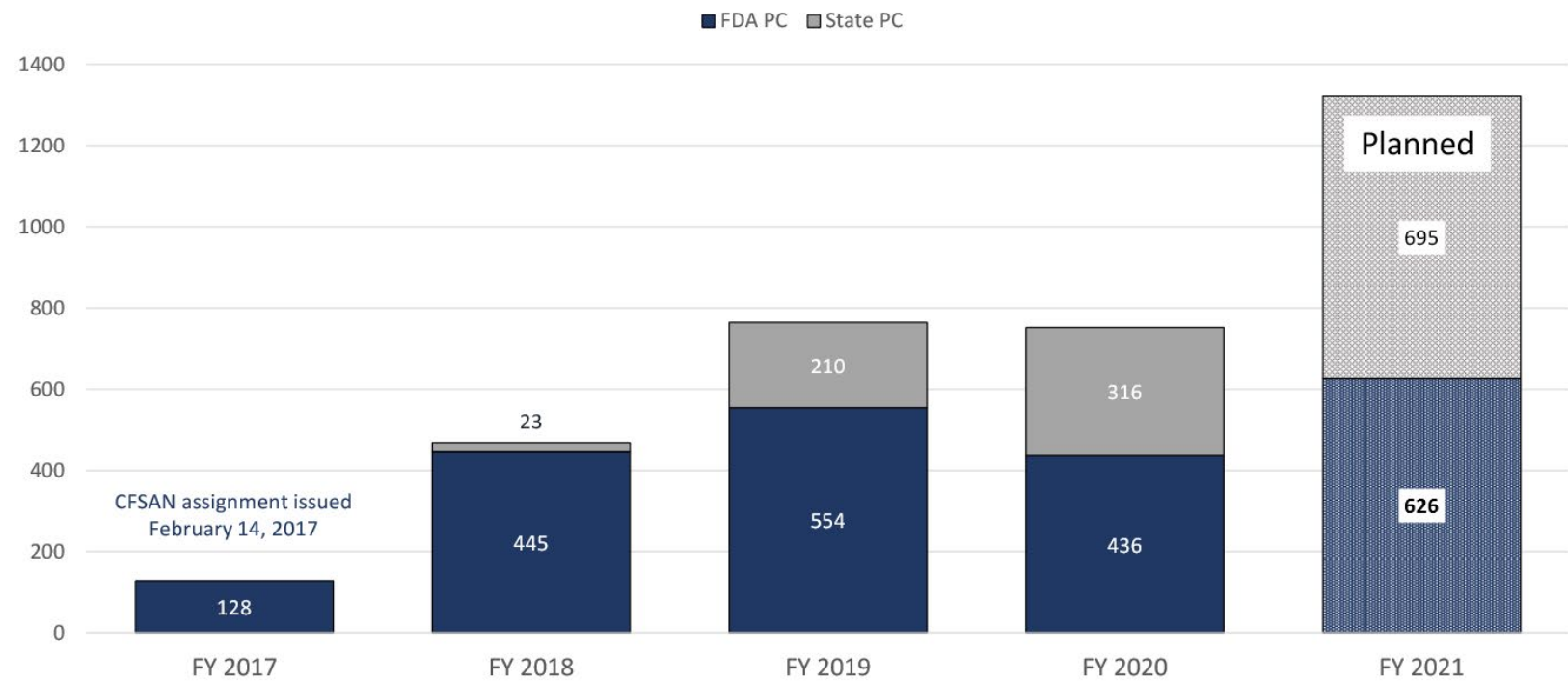
10
Years

7
Rules



Domestic Inspections FY 2017-2021

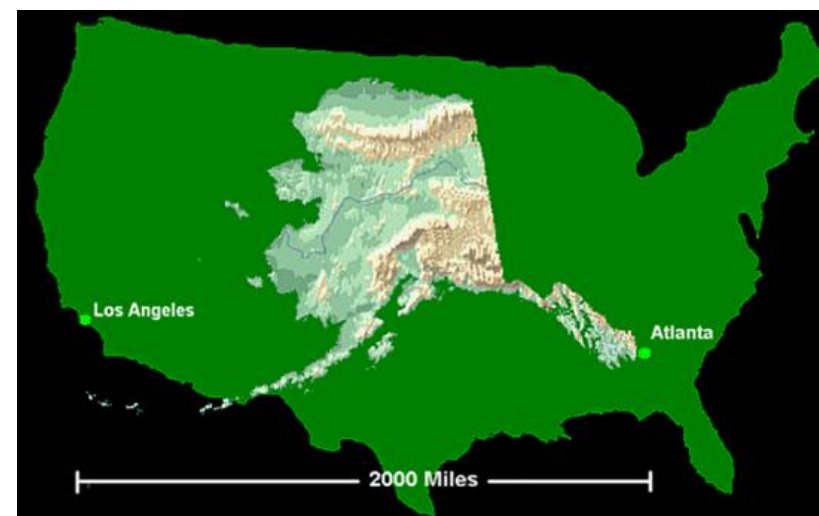
Domestic Inspections, FY 2017 – FY 2021 Preventive Controls for Human Food





Working Together

- **Collaboration**
Working together
- **Coordination**
Let's get this done
- **Continuous improvement**
Let's improve and learn



We will get there **TOGETHER**, stronger and more resilient than ever

#strongertogether

Questions?

