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

Alaska Food Protection Task Force Educational Workshop

April 12, 2022

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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

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS-WEST

# Objectives

- Provide Updates/Overview of FDA/District Programs
- Inspections and common violations (this is a popular industry
- Recall Readiness
- Better Together – Collaboration, Coordination, Continuous Improvement for the best public health outcomes

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# 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.

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# Who We Are

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

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**Director, Pacific Northwest Laboratory, Office of Regulatory Science:**

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# Who We Are

## Additional Key Contacts

**Health Communications Specialist:**
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**Emergency Response Coordinator:**
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**Recall Coordinator, OHAFO Division VI West:**
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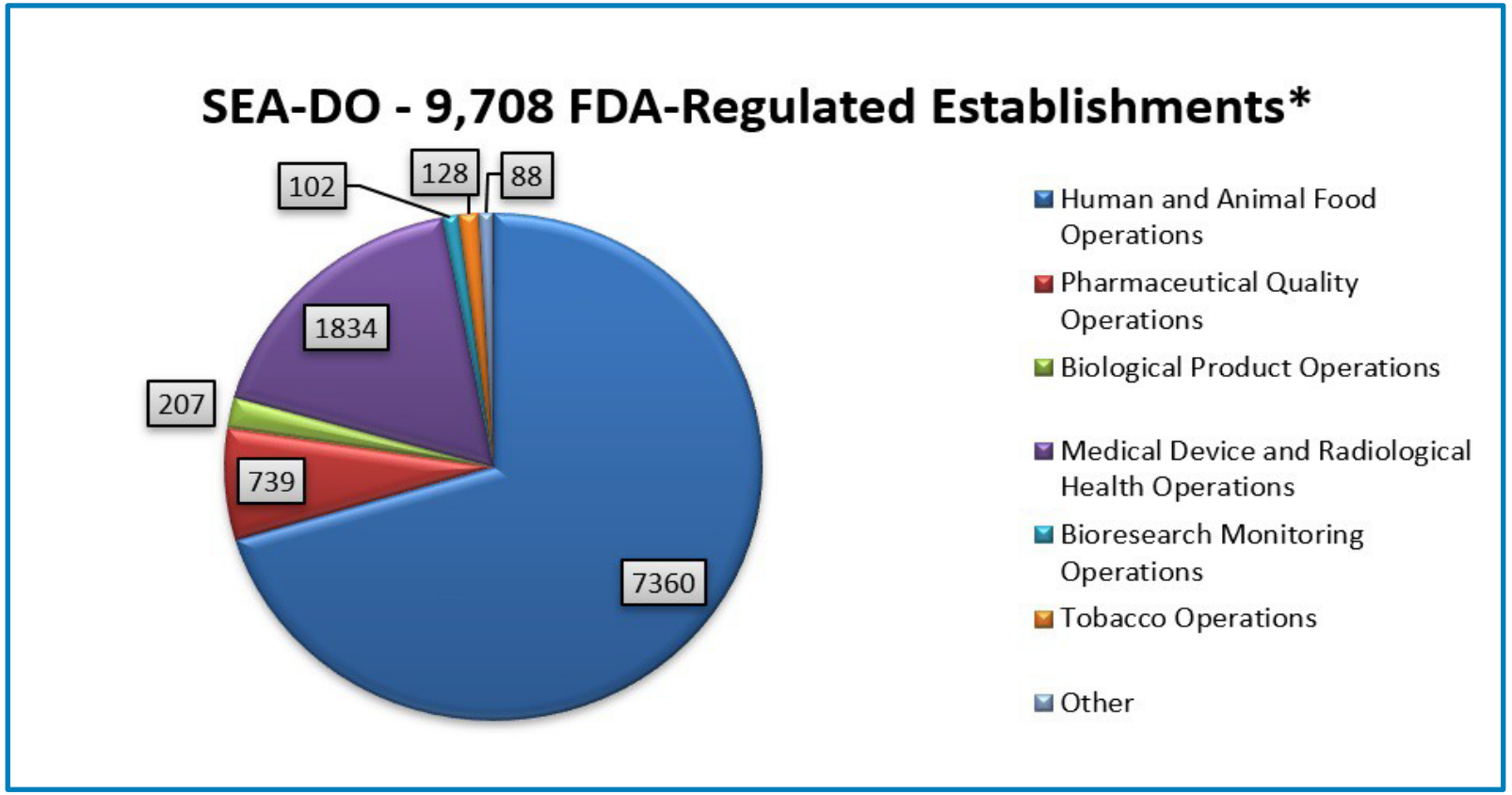
# Who We Are:

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 all Programs
- Human and Animal Food Division West 6

# What We Do


SEA-DO - 9,708 FDA-Regulated Establishments*
102
128
88
1834
207
739
7360
Human and Animal Food Operations
Pharmaceutical Quality Operations
Biological Product Operations
Medical Device and Radiological Health Operations
Bioresearch Monitoring Operations
Tobacco Operations
Other

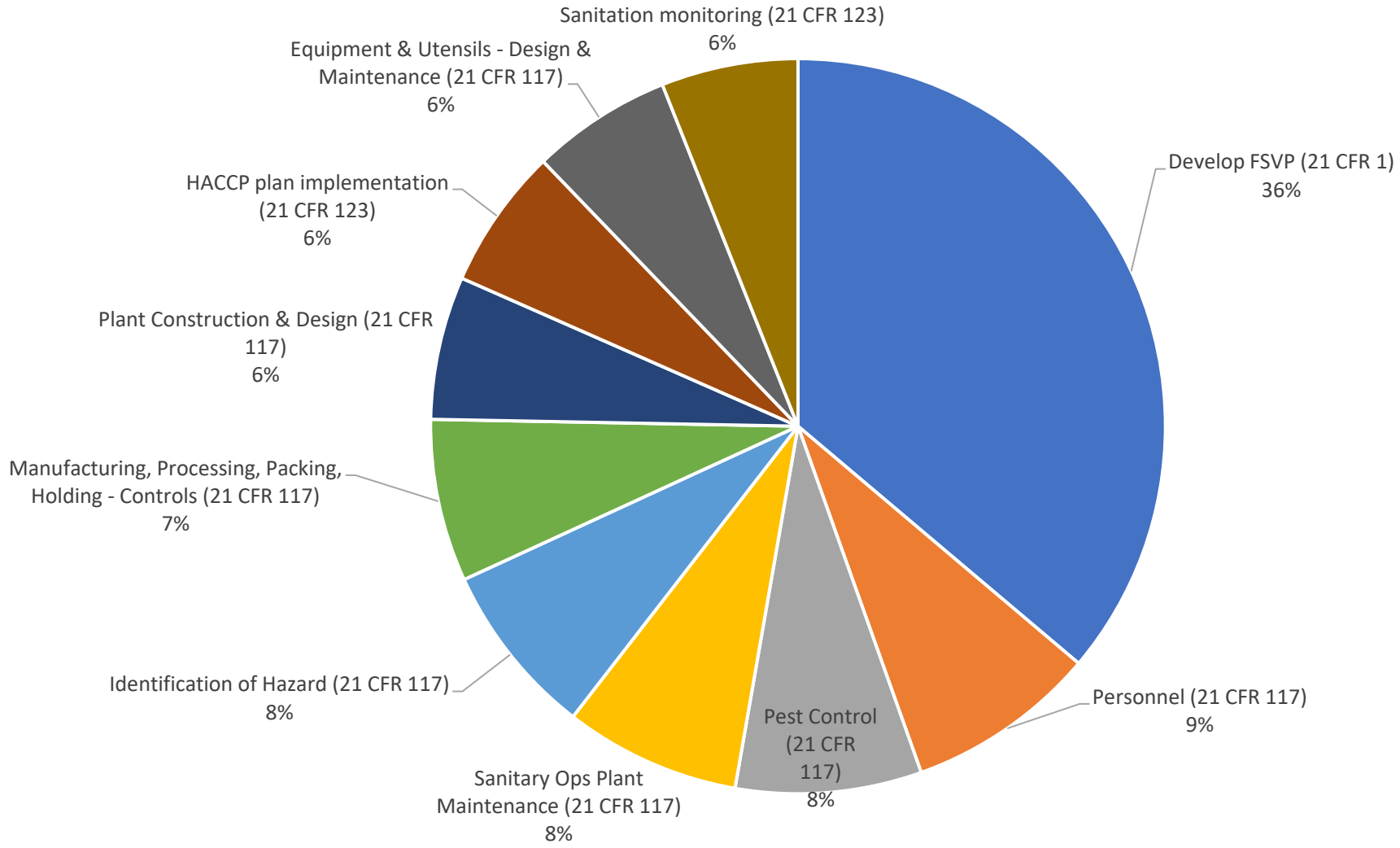
# Where We Are

| | |
|---|---|
| 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

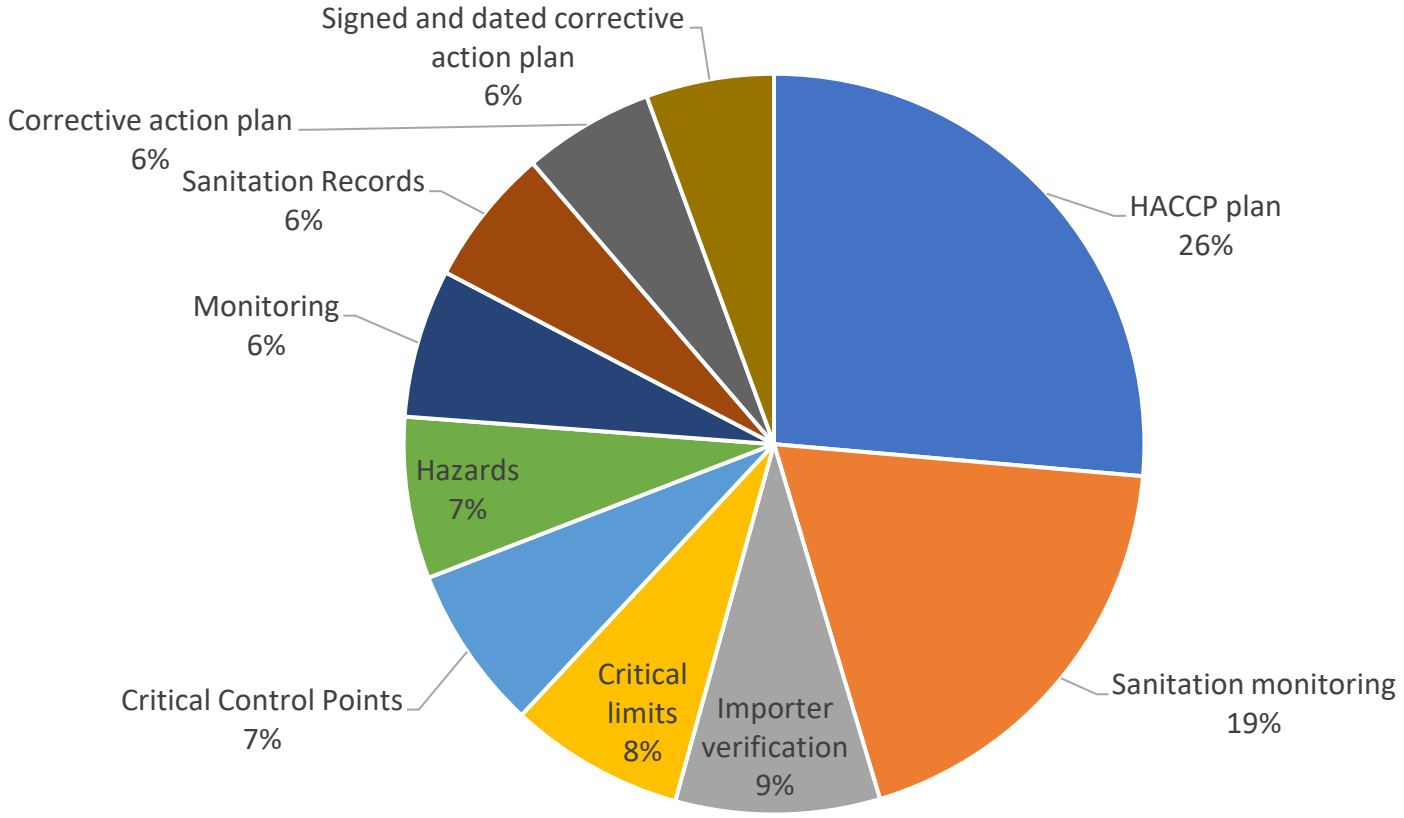
FDA Pacific Northwest Lab - Bothell, WA


# Top 10 General Observations (FY19 – FY22)



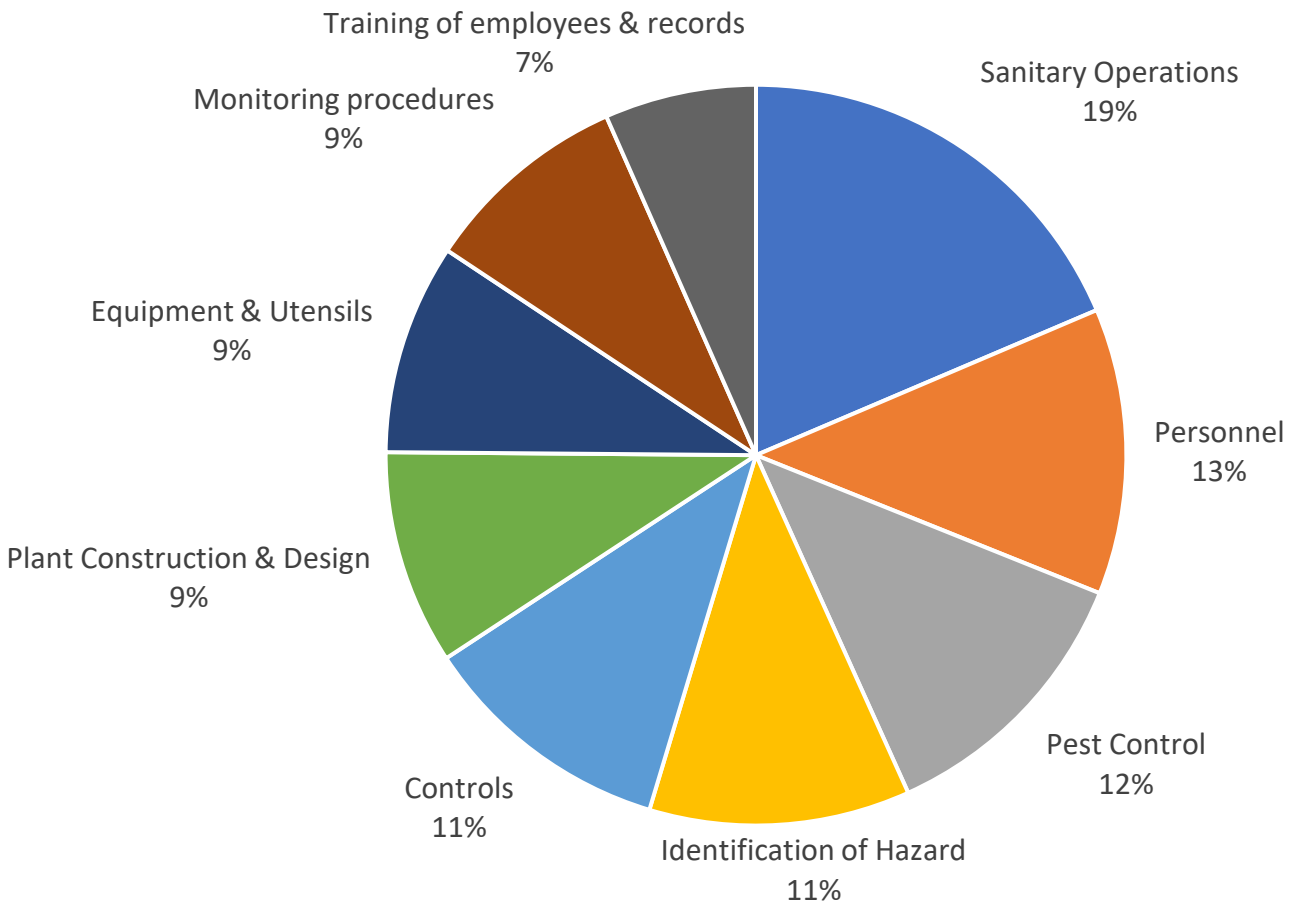

Data Source: FDA Data Dashboard, FY19-FY22

# Top 10 Seafood Observations, 21 CFR 123




Data Source: FDA Data Dashboard, FY19-FY22

# Top 10 Preventive Controls Observations, 21 CFR 117




Data Source: FDA Data Dashboard, FY19-FY22

# Recall Ready

## ‘Recall Ready’ to Protect Public Health as Part of Final Guidance for Voluntary Recalls – March 3, 2022

- **Topic-specific:**
- Recommendations for contingency planning for voluntary recalls and prompt recall initiation when appropriate
- Provide industry policy and process recommendations to better, more quickly protect the American public when products need to be recalled
- Guidance is part of a larger effort FDA has undertaken, provides additional guidance to industry and FDA staff regarding the execution and oversight of voluntary recalls - 21 CFR part 7, Subpart C

FDA Urges Companies to be ’Recall Ready’ to Protect Public Health as Part of Final Guidance for Voluntary Recalls

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# Recall Ready

- Focus to help expedite industry action of a voluntary recall by taking key steps to be “Recall Ready”

- Recommends adequate product coding, maintain distribution records to facilitate faster, more accurate recall actions

- Encourages recalling companies to use electronic communications to quickly identify and provide certain product information when alerting consignees and the public about a voluntary recall.

# Recall Ready

## Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C

- Encourages firms to maintain contingency plans and to prepare for a recall before one is needed
- Promotes quick action to minimize the exposure to potentially dangerous or violative products
- Highlights requirements for certain regulated products, such as reporting and product coding
- Provides FDA resources available, including access to FDA recall coordinators
- Templates and related recall guidance
- Provides FDA policy for when it will recommend a firm initiate a voluntary recall

# Recall Ready

Recent years FDA has made proactive and systemic improvements to recall processes,

Issued guidance on:

- Public availability of lists of retail consignees to effectuate certain human and animal food recalls
- Mandatory recalls for human and animal foods
- Public warnings and notifications for all FDA-regulated products
- Post new recalls to the FDA's weekly Enforcement Reports,

# Recall Ready

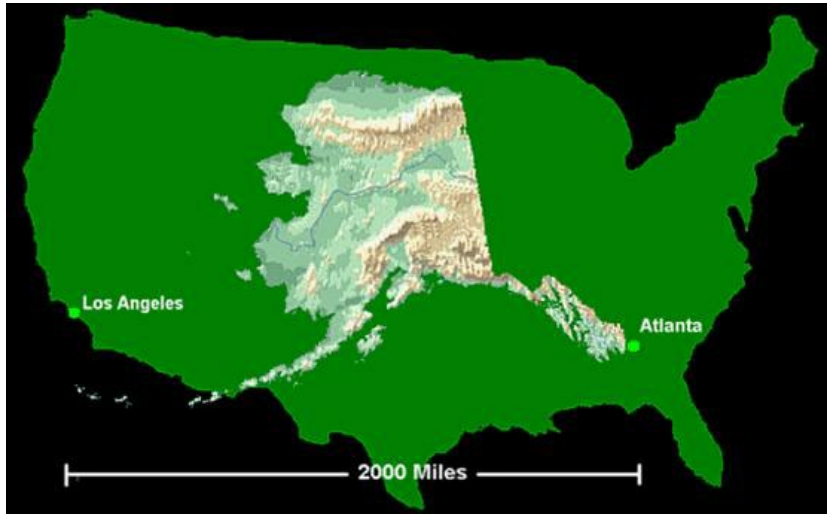
- Related References

- Recalls, Market Withdrawals & Safety Alerts
- Industry Guidance for Recalls
- Foodborne Outbreak Response Improvement Plan

# Working Together

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

**We will get there TOGETHER**
**#strongertogether**



# Questions?