

Oregon Department of Agriculture Produce Safety Program

Susanna Pearlstein, Ph.D. and Casey Prentiss

Board of Agriculture

May 5, 2022



**OREGON
DEPARTMENT OF
AGRICULTURE**

Today's Talk

- Food Safety Modernization Act Produce Safety Rule Updates
- ODA's Current Program, "Path A"
- FDA-led Inspections
- Other States and Inspections
- If Oregon Took On Inspections "Path B"



Food Safety Modernization Act

- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
- Foreign Supplier Verification Programs
- Sanitary Transport of Human and Animal Food
- Mitigation Strategies to Protect Food Against Intentional Adulteration



OREGON
DEPARTMENT OF
AGRICULTURE

FSMA Produce Safety Rule

- Sets mandatory standards for growing, harvesting, packing, and holding produce for human consumption
- Worker health & hygiene
- Wildlife & domesticated animals
- Agricultural water
- Post harvest handling and sanitation
- Biological soil amendments of animal origin



**OREGON
DEPARTMENT OF
AGRICULTURE**

Farm Coverage Under the Rule

- What is being grown?
- How much is sold?
- Where it's going?



Produce Safety Rule – Updates

- Agricultural Water (Subpart E) is still on hold
 - Proposed Rule published in Federal Register December 6, 2021
 - Docket FDA-2021-N-0471
 - Enforcement discretion will occur during FDA-led inspections

- Rarely Consumed Raw list



**OREGON
DEPARTMENT OF
AGRICULTURE**

Produce Safety Program at ODA

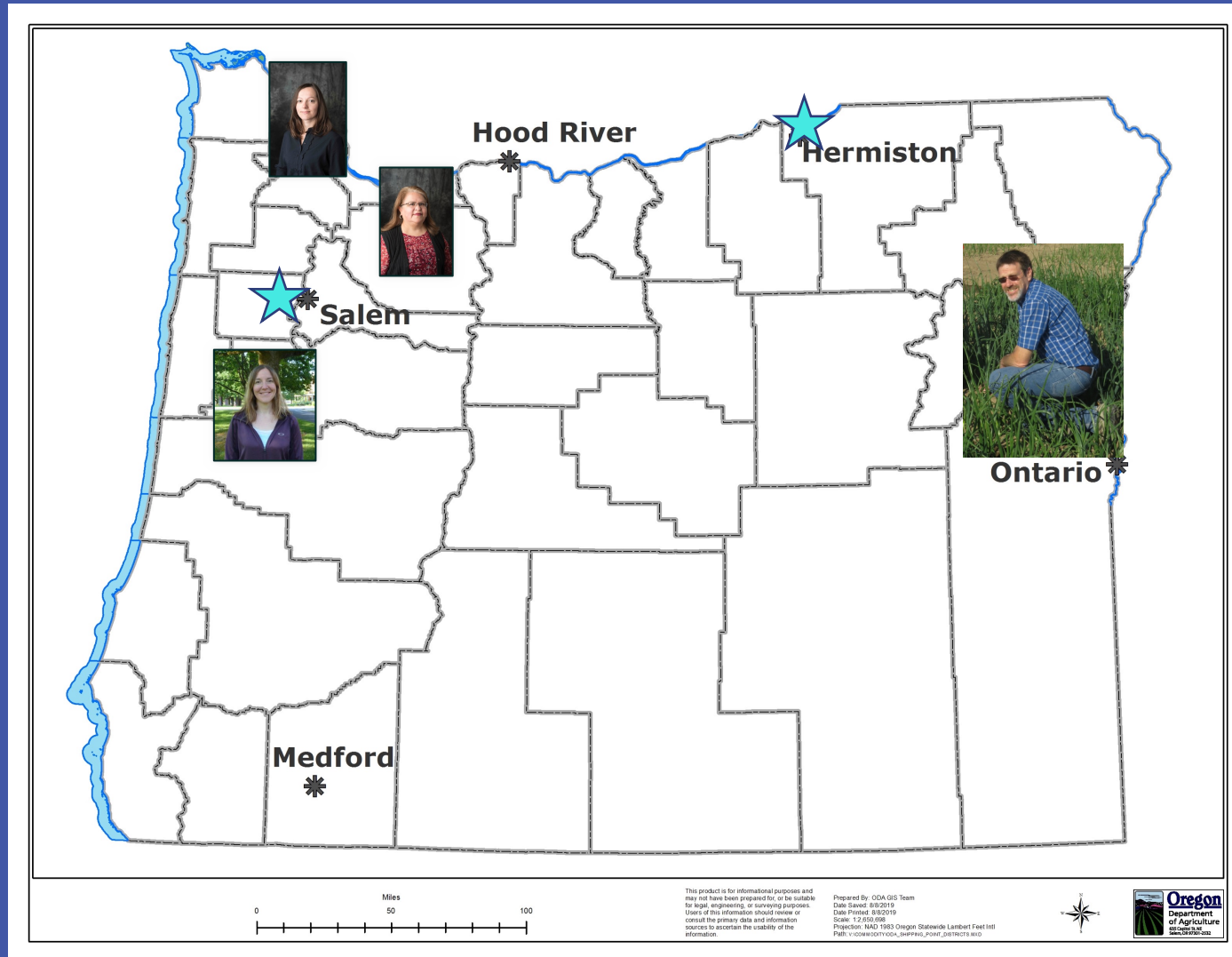
- Non-regulatory program funded by grant from the Food and Drug Administration
- FDA conducts Produce Safety Rule inspections in Oregon
- Partnership with Oregon State University
- 4 program staff
- Current budget: \$630,000

oda.direct/producesafety



Current Staffing – Non-Regulatory Path A	
Position	Number of people
Program Manager	1
Outreach Specialists	3

Oregon State University Partnership



Education & Outreach



- Attendance at a recognized training is a requirement for covered farms
- Free, online during COVID-19

Technical Assistance



- Voluntary, free, confidential and non-regulatory
- Assess specifics of your farm with the Produce Safety Rule
- 125 completed

Farm Inventory

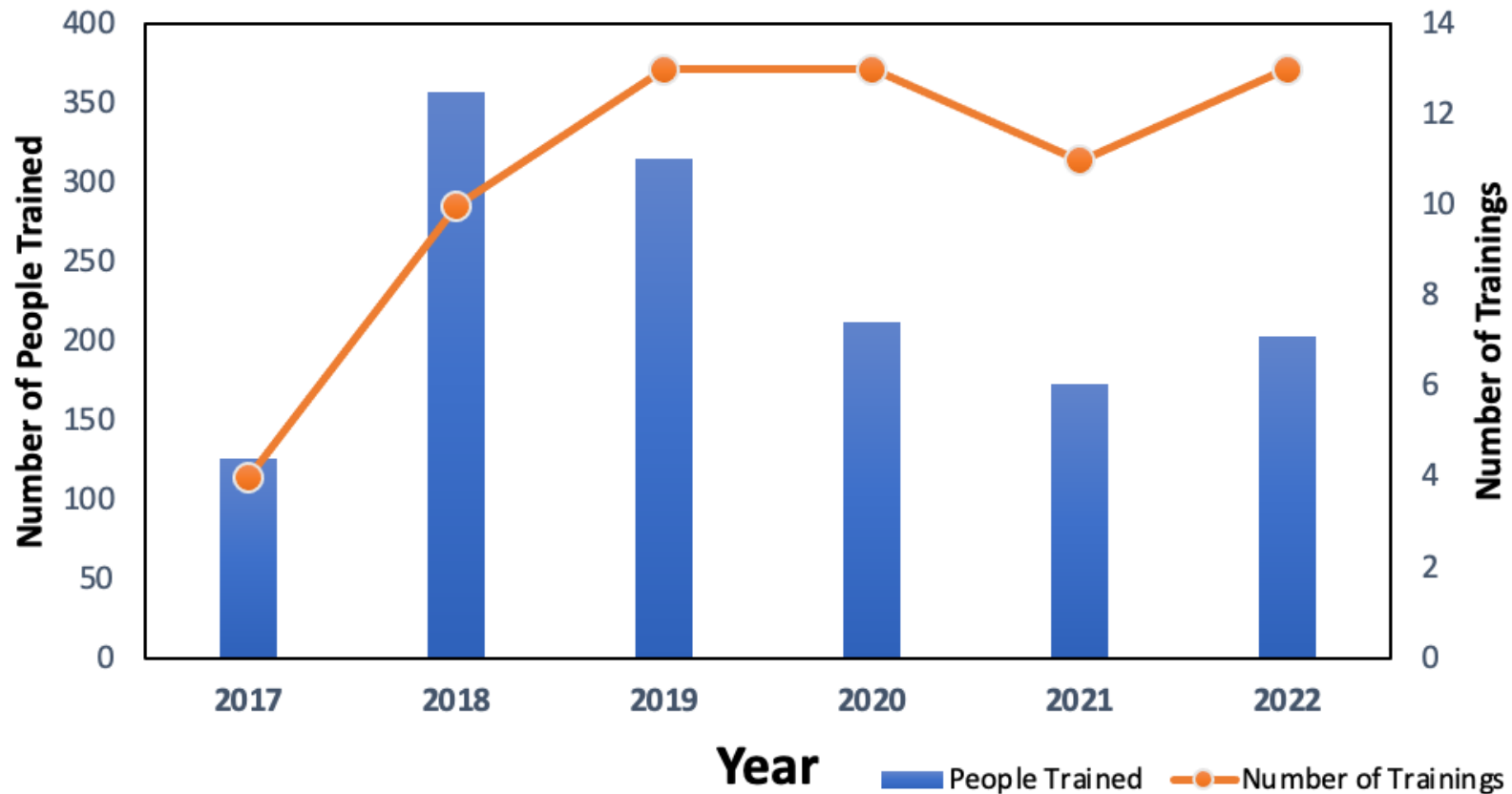


- Identify farms subject to the rule
- Provided to FDA for inspection planning

oda.direct/producesafety

Produce Safety Alliance Trainings

Grower Training Classes



**OREGON
DEPARTMENT OF
AGRICULTURE**

Timeline – *First Five Years*

- Oregon takes on non-regulatory funding to form a Produce Safety Program

2016

2017

- Senate Bill 18 passed, not adopted into reference
- Water portion put on hold

- Program hiring

2018

2019

- Water compliance dates finalized
- Large Farm inspections start nationwide
- Enforcement discretion issued

- COVID-19 postponed regulatory inspections
- Transition to remote classes and technical assistance
- Listening sessions postponed

2020

2021

- Cycle 2 funding application submitted and awarded
- Water portion of the rule still on hold

Current Cooperative Agreement

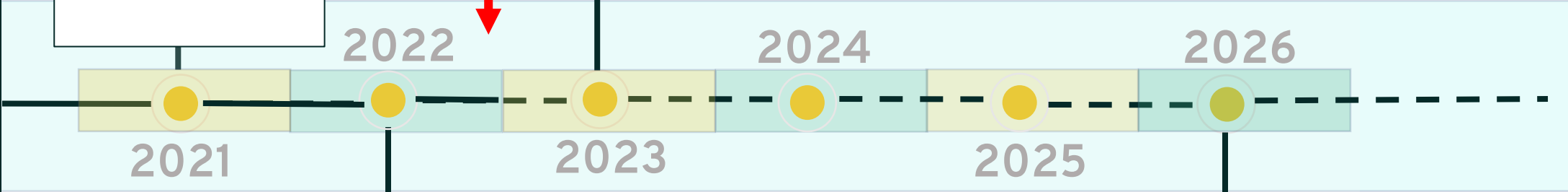
ODA will continue to work with local, regional and national partners to implement the Produce Safety Rule in Oregon

2016 - 2021 (Cycle 1)
Non-regulatory Produce Safety Program doing education, outreach and technical assistance

- Applied for and were awarded Cycle 2 non-regulatory funding
- Proposed Agricultural Water Subpart released

You are here

- Commodity specific outreach



- Hiring
- OFRR's
- Commodity Specific Outreach & Listening Sessions
- Taught 10 Produce Safety Classes

- 100% of farm inventory to be verified

Why Is ODA Not Doing Inspections?

- Unclear at the time who the monetary burden would fall to if FDA funding went away
 - When states were first approached to take on funding, Cooperative Agreement with FDA was for five years (2016 – 2021). Currently in second five year funding cycle
- Majority of industry had not been in favor of ODA taking on this role
- Parts of the rule were put on hold soon after it came out and have not been finalized



Inspection Related Industry Outreach

Location	Date	Commodity
Private farm Lebanon, Willamette Valley	April 25, 2022	Blueberries
Mid-Columbia Agricultural Research and Extension Center Hood River	June 8, 2022	Tree Fruit
Southern Oregon University Medford	June 21, 2022	Mixed Vegetables
Malheur Experiment Station Ontario / Treasure Valley	August 24, 2022	Onions



Additional session is being planned for Hermiston

FDA-led Produce Safety Rule Inspections

- Began nationwide in 2019
- FDA is calling farms for 2022 inspections
- Inspections are generally pre-announced
- 25 FDA Produce Safety Network investigators for 2022
- FDA requesting 2 days for inspections



**OREGON
DEPARTMENT OF
AGRICULTURE**

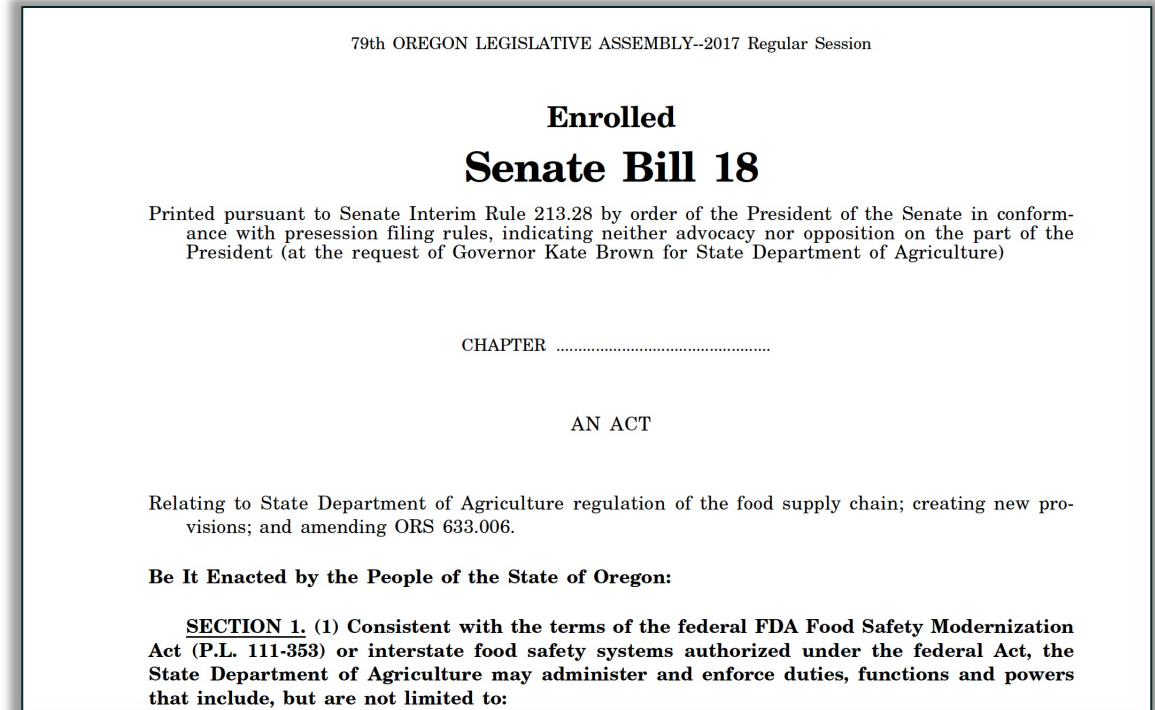
Other States and Inspections

State	Number of Inspections (Since 2019)	Number of Inspectors	Authority
Oregon	150	25 FDA Investigators	
Washington	139	3 Full time inspectors	FDA Authority
Idaho	~105	2 Part time inspectors	State Authority

If ODA took on a regulatory program, we would be under FDA Authority

If ODA Took On A Regulatory Program – Legislative Authority

- Passed in 2017
- ODA has legislative ability to do Produce Safety Rule inspections under FDA authority
- ODA has not adopted this ability into reference



Budget

- Program funding has been reduced nationwide

Past Funding *FSMA Cycle 1*

Year	Award Amount
Year 5 (2020 – 2021)	\$773,002

Current Funding *FSMA Cycle 2*

Year	Award Amount
Year 1 (2021-2022)	\$630,000

Budget

- 5 year funding cycle (2021 – 2026)
- Non-regulatory (Path A)
 - Total Award: \$630,000
 - Assessment & Planning, Program Administration, Farm Inventory, Outreach & Education, Technical Assistance
- Regulatory (Path B), under FDA authority
 - Total Award: \$1,130,000 (+\$500,000)
 - Same duties as Path A
 - Inspection Program



**OREGON
DEPARTMENT OF
AGRICULTURE**

Process to Add Regulatory Program

1. Apply for Path B funding from FDA
 1. Times to apply: any time before March 2023
 2. Last date to apply: March 2023
2. Application must undergo FDA review and Objective Review Board
3. Estimate 1 year of overlap with FDA
 1. Limited additional funding
 2. FDA conducts inspections in Oregon during this time
4. ODA would not conduct inspections until late 2023 or 2024 at the earliest



If ODA Took On A Regulatory Program

- Conduct inspections under FDA Authority (Senate Bill 18)
- Required to inspect 165 operations / year
 - FDA requires states to inspect 20% of farms in inventory
- ODA would not conduct inspections until late 2023 or 2024, overlap with FDA

Inspectors	3
Annual Required Inspection Number	165
Number of Inspections / Inspector	55



**OREGON
DEPARTMENT OF
AGRICULTURE**

ODA Produce Safety Staffing

Path B, full time staff would be added
 + Four NRS3,
 + One NRS 2 and
 + One AS1

Current Staffing – Non-Regulatory Path A		Anticipated Staffing – Regulatory Path B	
Position	Number of people	Position	Number of people
Principle Executive Manager D	1	Principle Executive Manager D	1
NRS1	3	NRS3 (New)	3
		NRS 2 (New)	1
		NRS1	2
		AS1 (New)	1

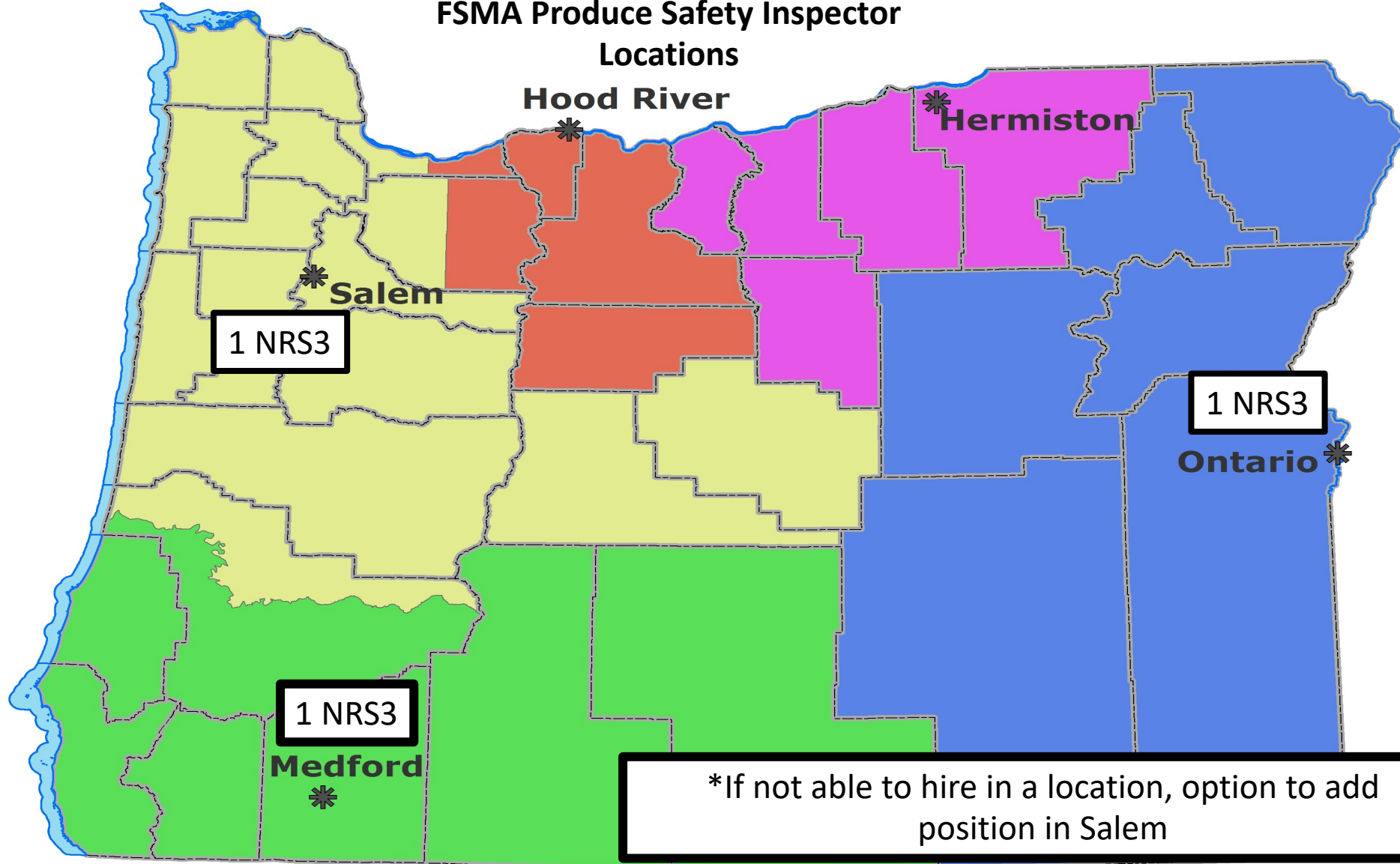
Salary July – June: \$433,722

68% of total budget (\$630,000)

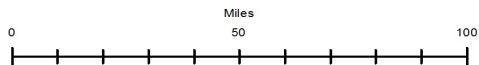
Estimated salary July – June: \$746,316

66% of total budget (\$1,130,000)

FSMA Produce Safety Inspector Locations



*If not able to hire in a location, option to add position in Salem

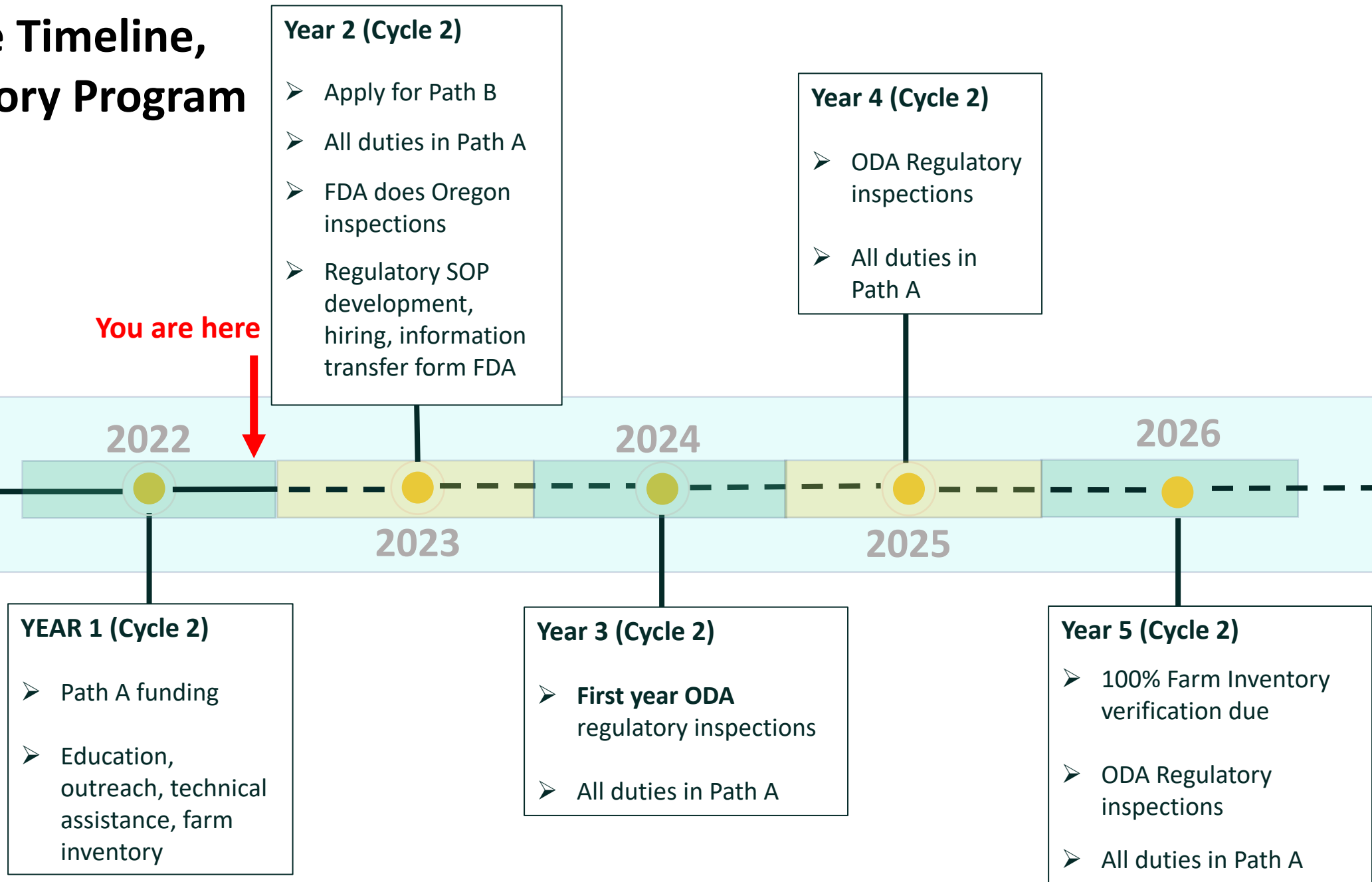


This product is for informational purposes and may not have been prepared for, or be suitable for legal, engineering, or surveying purposes. Users of this information should review or consult the primary data and information sources to ascertain the usability of the information.

Prepared By: ODA GIS Team
Date Saved: 8/8/2019
Date Printed: 8/8/2019
Scale: 1:2,650,000
Projection: NAD 1983 Oregon Statewide Lambert Feet Intl
Path: V:\COMMODITY\ODA_SHIPPING_POINT_DISTRICTS.MXD



Possible Timeline, Regulatory Program



If ODA Took On A Regulatory Program

- Conduct inspections under FDA Authority (Senate Bill 18)
- Required to inspect 165 operations / year
 - FDA requires states to inspect 20% of farms in inventory
- ODA would not conduct inspections until late 2023 or 2024, overlap with FDA

Inspectors	3
Annual Required Inspection Number	165
Number of Inspections / Inspector	55



**OREGON
DEPARTMENT OF
AGRICULTURE**



Thank You

Susanna Pearlstein

spearlstein@oda.oregon.gov

971-283-4749

Casey Prentiss

cprentiss@oda.oregon.gov

541-212-3361



**OREGON
DEPARTMENT OF
AGRICULTURE**