

ORA Produce Safety Rule Inspection Update

FDA FOOD SAFETY
MODERNIZATION ACT

THE FUTURE IS NOW

February 12, 2020

PSR Implementation: Entity with responsibility for inventory development & inspections by location



Location	Inventory Development	Inspections
States with PS Cooperative Agreement Program (CAP) Competition A/B (44 States)	States	States*
States with PS CAP Competition A (OR, IA, ND)	States	FDA
Non- grantee States (IL, SD, WY)	FDA	FDA
U.S. Territories & Washington D.C.	FDA	FDA
Foreign Countries (exporting to U.S.)	FDA	FDA
Tribal Nations	FDA	FDA

* 16 states conducting inspection under FDA authority

PSR Implementation: Standardized Approach to Inspection & Compliance Activities



- Documents outlining standardized approach
 - Standardized Approach to Farm Inspections
 - Compliance and Enforcement Action Plan
 - Compliance and Enforcement Decision Tree
 - Farm Inspection Prioritization Decision Analysis Tool (PDAT)
- Inspection Documents (for farms)
 - “What to Expect” during a regulatory inspection handout
 - FDA 4056 – Produce Farm Inspection Observations (state equivalent)
 - Inspection Report Summary
- FDA Large Farm Inspection Assignment
 - FDA in ~ 6 states and foreign countries
 - States (16) conducting inspections under FDA authority

PSR Target Numbers: Inspection Year 1

- Year 1 of inspections: Spring 2019-Spring 2020
- Targets:
 - States with the number of large farms (**produce sales >\$500K**) less than or equal to 10% of their total inventory of covered farms: inspection of all large farms
 - States with the number of large farms greater than 10% of their total inventory of covered farms: inspection of the number of large farms equal to 10% of total inventory, prioritized based on PDAT
- Numbers based on total inventory. If inventory is not fully verified, states can use NASS numbers to estimate the baseline of covered farms.

PSR Inspections and Investigation Numbers (approximate) (2019 – current)



- 150 FDA Domestic inspections
Locations: OR, HI, IL, IA, ND, KY
Potential Additional locations in 2020: SD, WY, DC, Puerto Rico
- 42 FDA Foreign Inspections
Locations: Mexico, Peru, Chile, Ecuador, Netherlands, & Spain
- 14 Farm Investigations (both FDA & state-led work included)
- 990 PS Comp A/B States inspections (through October 2019)

PSR Implementation Challenges



- Consistent interpretation of the PSR
- Inspection Infrastructure is still under development
- Identification of inspectional location in relation to the farm definition
- Resources and Travel
- Ensuring that outreach, training, and technical assistance needs are identified and followed up on
- Coordination of coverage on farms subject to multiple regulations (e.g., PC, HACCP, FSVP)

2020 Inspections

- Continue with Large (produce sales >\$500K) and start Small Farms (produce sales \$250K-\$500K)
- Utilize the same inspection and enforcement approach and documents as used in 2019
- FDA Assignment – largely the same

