

# FDA Inspection Updates

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Southern Region Integrated Produce Safety Conference

Presented by:

Leah Tapley, Office of Regulatory Affairs

Investigator, Domestic Produce Safety Branch I, Produce Safety Network (PSN)

## Overview

- FDA's Inspection Findings
- Observation Examples
- ORA PSN Program Updates

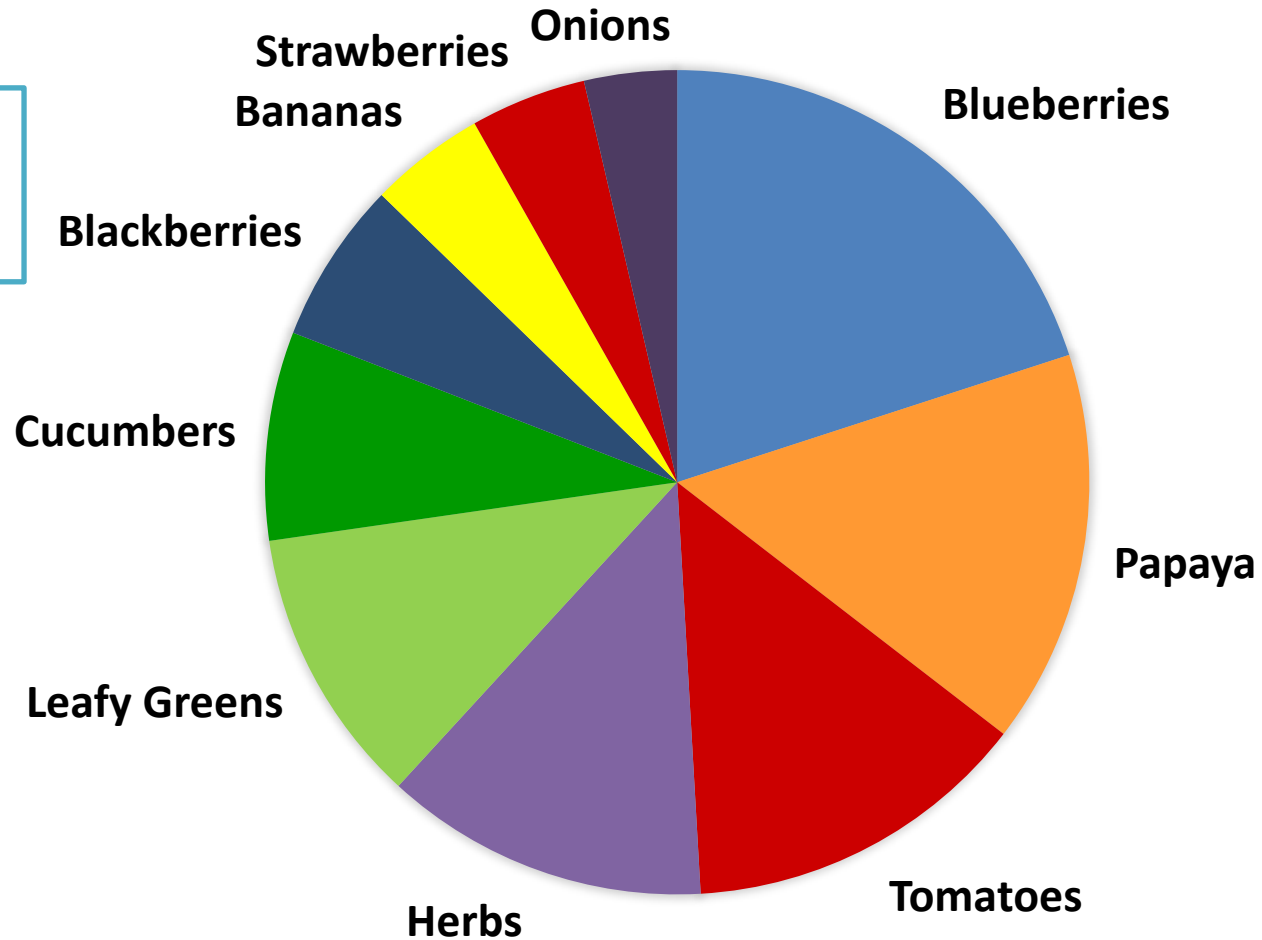




# Top Ten Commodities By Number of Inspections



286 inspections in FY23  
229 domestic inspections  
57 foreign inspections



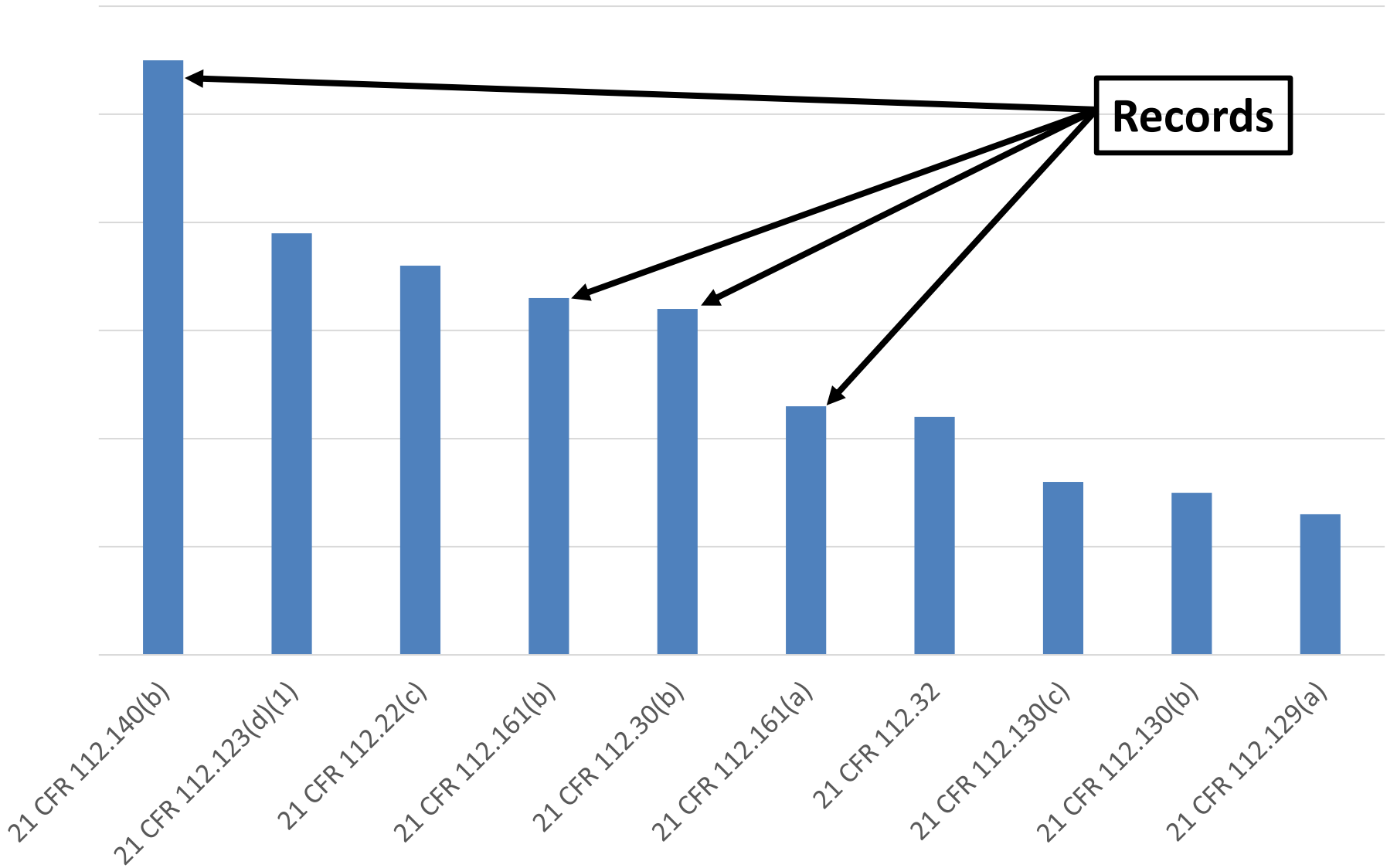
# Inspection Observations and General Discussion with Management

There are two categories of observations\* which may be documented during an inspection:

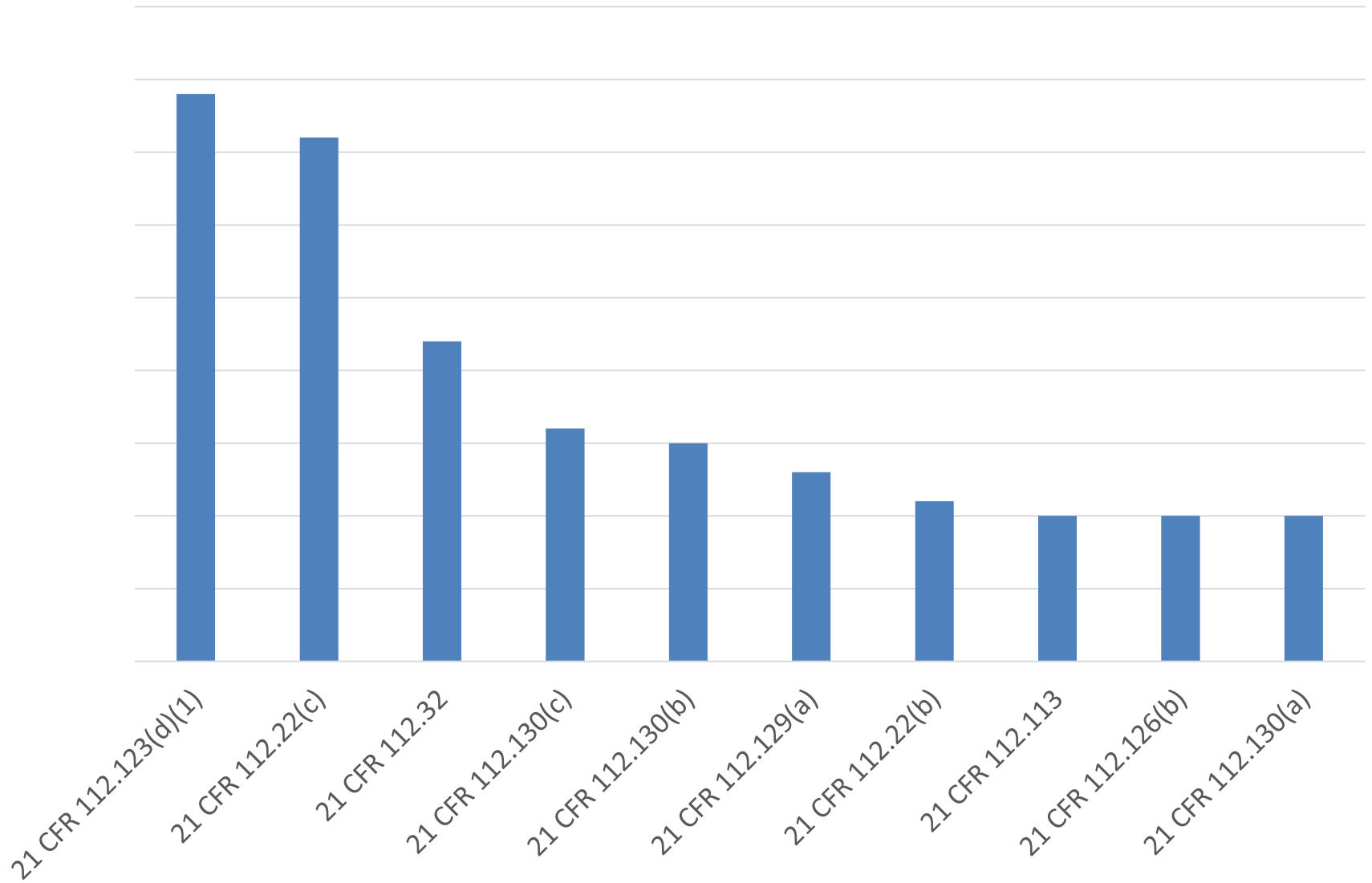
- 1) Inspection Observations: These items are documented on the Form FDA 4056, Produce Farm Inspection Observations.
- 2) General Discussion Items: These are verbally discussed with farm management at the time of the inspection and included in the Produce Farm Inspection Report (PFIR) under the section titled, “General Discussion with Management.”

\*For the purposes of analysis/discussion

# Top Ten Cites Used During FDA-led Inspections



# Top Ten Cites Used During FDA-led Inspections (Records-related cites removed)



## 21 CFR 112.123(d)(1): Examples

- Lack of cleaning of food contact surfaces
- Use of visibly unclean harvest containers in contact with covered produce
- Lack of cleaning prior to use of a sanitizer
- Wet cleaning without the use of a soap, detergent, or other cleaning agent



## 21 CFR 112.22: Examples

- 112.22(c) – Supervisor training
  - No Produce Safety Alliance grower training or equivalent
  - 20% of domestic and foreign combined
  
- 112.22(b) – Harvest employee training
  - Not including harvest-specific elements in training
  - Mechanically harvested product

## 21 CFR 112.32: Examples

- Not washing hands after –
  - Using toilet facilities
  - Touching non-food-contact surfaces
  
- Lack of glove management practices
  - Not replacing as needed when damaged
  - Not maintaining in sanitary condition

# 21 CFR 112.130 (hand-washing facilities) and 21 CFR 129 (toilet facilities): Examples

- 112.130(c)
  - Hand-washing gray water not captured
  - Hand-washing gray water leaking from catch basin
  
- 112.130(b)
  - Lack of soap and drying devices
  
- 112.130(a)
  - No hand-washing facilities provided near harvest activities
  - Hand-washing facilities located away from harvesting
  
- 112.129(a)
  - No toilet facilities provided within reasonable walking distance
  - Employees permitted to use areas adjacent to growing/harvesting

## 21 CFR 112.113: Examples

- Nesting/stacking containers with harvested produce
- Placing harvested produce in perforated containers on ground/floor
- Picking up harvested produce that has fallen

## 21 CFR 112.126(b): Examples

- Product stored under condensers in coolers with dripping
- Leaking roofs dripping onto product
- Strip curtains with condensate in contact with product
- Use of pressure-washers to remove organic matter and creating splash/aerosol from floors/walls

- Two new Branch Chiefs
  - Cullen Wilson, Branch 1
  - Kate Allen, Branch 3
  
- Calibration Program
  - Three ORA PSN Investigators have gone through process
  
- Outbreak response and sampling activities
  
- Ag Water reporting updates

# Questions?

# Thank you!

Leah Tapley

Investigator, Domestic Produce Safety Branch I, Produce Safety Network (PSN)

Cell: (240) 328-5983

[Leah.Tapley@fda.hhs.gov](mailto:Leah.Tapley@fda.hhs.gov)