ORA Produce Safety Rule Inspection Update

February 12, 2020
## PSR Implementation: Entity with responsibility for inventory development & inspections by location

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

* 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