2018 MFRP Alliance Meeting

_workplanning - a nationally coordinated effort_

Clint Priestley
on behalf of Ellen Buchanan

[Email]

FDA/ORA/OHAFO/Audit Staff
Background

• Evolution of state contracts
  – 10K contract inspections
• Partnership Inspections
  – Inspection data for resources
• OIG Reports
  – 2000 and 2011
  – Findings
  – FDA Response
Contributing Factors

- Frequency mandates
  - State vs FDA
- Inventory
  - Valid?
  - Numbers?
  - Aligned?
- Contract requirements
  - Training
- IT Issues
  - eSAF, data exchange, secure access
Moving Forward...
while looking back

• Work Planning is an evolving process
  - FSMA, ER/RRT, priorities, emerging issues

• State and FDA are working collaboratively to improve the process.

• Projects
  - Data exchange
  - National Work Planning
  - National Sampling

• Identify areas for expansion
Mutual Reliance Work planning

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Wisconsin Department of Agriculture, Trade and Consumer Protection

Albuquerque, NM January 2018
Mutual Reliance Premise and Goals

• By meeting program standards, state and federal regulatory programs can rely on each to more effectively and efficiently achieve compliance outcomes and protect public health.

• “One program, one mission”
Mutual Reliance Work planning

- Avoid duplicating inspectional work between agencies
  - Part of an Integrated Food Safety System (IFSS)
- Exchange work product to increase inspectional coverage
Metrics of Success

Slide from Joel Hustedt: Number of Firms With Independent Routine Inspections by both WDATCP and FDA in Same FY/CY

µ = 2,258 total inspections for FY
µ = 2,261 total inspections per CY
Why do we need Mutual Reliance Work planning?

– WI does not meet our targeted frequency, due to lack of trained staff and position authority to hire more staff

– Inventory of Manufactured Food Establishments
  ~3,500
    • DATCP MF Inspections per year (2015-2017): 1,200-1,949
    • 46% Overdue-Haven’t been inspected since 2016 or before: we need the FDA to help us catch up
Mutual Reliance Work planning

• Prerequisites:
  – Access to un-redacted FDA reports
  – System to protect FDA reports from public requests for information
  – Best practices and quality assurance
Mutual Reliance in WI

• Ongoing practices formalized in a Mutual Reliance Pilot Project in FFY 2016
• Mutual Reliance Pilot activities are now formalized in a three-year MOU with FDA
• MRP now means “Mutual Reliance Practices”
MRP Work Planning

• Wisconsin DATCP counts FDA inspections of our shared inventory as its own.
• DATCP conducts 20 or so extra “MRP” unbilled contract inspections, which FDA counts as its own.
  – Initial inspection in a FSMA risk cycle
How Wisconsin Counts FDA inspections

- FDA Annual Work plan (~100 inspections) assigned to “FDA Inspector” each year.
  - Additional ad hoc inspections (100+) throughout the year.
  - WI Flexible, Risk-Based Work Planning
  - One month ahead of time
Mutual Reliance Challenges

• Majority of firms on HAF 1 Work plan for Wisconsin are not eligible for assignment to the FDA
  – Out of Business
  – Not required to be licensed by WI
  – Grade A Mandated

• Adjusting to ad hoc inspections not always possible; nor does it reduce duplication
Mutual Reliance Challenges

- FFY 2016: 92 of 569 inspections assigned to FDA
- FFY 2017: 179 of 536 inspections assigned to FDA
- FFY 2018: 98 of 338 inspections assigned to FDA
Challenges and Successes

• To increase inspectional coverage, it is necessary to agree that firms only need 1 regulatory inspection/year.

• Would mean that both agencies could focus on establishments that have not been inspected by either agency in more than 1 year.
Last inspection date?

• Half (49 of 101) FDA-assigned/planned inspections in FFY 2018 have not been inspected since 2016 or before (success!)
• Half (51 of 101) have been inspected by WDATCP in 2017, as recently as November 2017
Overdue establishments 30% more likely to need re-inspection

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Future MRP

- Improvements will come from agreement about when the establishment was last inspected; this will entail more “counting” of WI inspections
- MRP bring sustainable benefits, to both agencies and to the public
- Most tangible benefit to meeting MFRPS for inspection staff
Thank you!

Contact Information

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FDA Work Planning

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Albuquerque, NM January 31, 2018
FDA Work Planning

- Food Strategic Plans
- Resources
- Center Priorities
- ORA Field
FDA Field Activities

Inspections
  • Domestic
  • International

Sampling
  • Product
  • Environmental Sample
  • FDA Laboratory Analysis

Unplanned
  • Consumer Complaints
  • Referrals from state and other federal agencies
  • Foodborne Outbreaks

Miscellaneous Activities
  • New Hire Training
  • Programmatic Training
FDA Field Activities

Let’s Focus on Inspections:

- **FSMA Inspection Resources**
  - Mandated to inspect domestic **high-risk** facilities not less often than once every three years.
  - Mandated to inspect domestic **non-high-risk** facilities not less often than once every five years.

- **NEW** FSMA Rules: Preventive Controls- Human and Animal (CGMP), FSVP, Sprout Inspections

- **Center assignments**
  - Emerging issues
  - Compliance follow-up
  - Congressional requests
FDA Registered Firms (Domestic) by Facility Risk Category

n = 78,304

- FFHR 70%
- FFHR 30%
- FFNR 70%
FSMA Inspection Resources

Are we allocating resources – FDA and state - to meet inspection frequency mandate?

Data Source: FY2018 ORA – Field Activities Budget – FY16 Actuals, Unique Counts
FY2017 FSMA Inspection Frequency Mandates

- FDA: 87%
- State: 13%
Quotes from the report:

We recommend that FDA improve how it handles attempted inspections to ensure better use of resources.....

Shortened timeframes pose challenges for future non-high-risk cycles.
Room for Improvement

• Fragmented and outdated IT systems; data quality.
• Communicating FDA’s national work plan for domestic operations.
• Minimizing duplication of work with states and other federal agencies.
• Coordination with state contracts to meet FSMA inspection frequency mandate, particularly for NHR facilities.
Take Home Message

- Efficiency
- Accountability
- Timeliness
- Interactive
- Dynamic
- SkillSets
- Preventive Controls
- Inspection
- Frequency
- Mandate

Work Planning Is Complicated
Work Plan Before
Work Plan Success!

Work Plan 101 Meeting
References

• **FSMA Domestic Facility Risk Categorization (FY 2012)**

• **FY2018 ORA – Field Activities** Budget – FY16 Actuals, Unique Counts

• **OIG Challenges Remain in FDA’s Inspections of Domestic Food Facilities**, September 2017

• **Field Management Directive 50** – State Correspondence, 5/2/2011
Contact Information

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