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FOOD PROTECTION
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IFPTI Fellowship Cohort VI: Research Presentation

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Corrections after FDA and Wisconsin Manufactured Food Inspections Show Comparable Compliance Rates

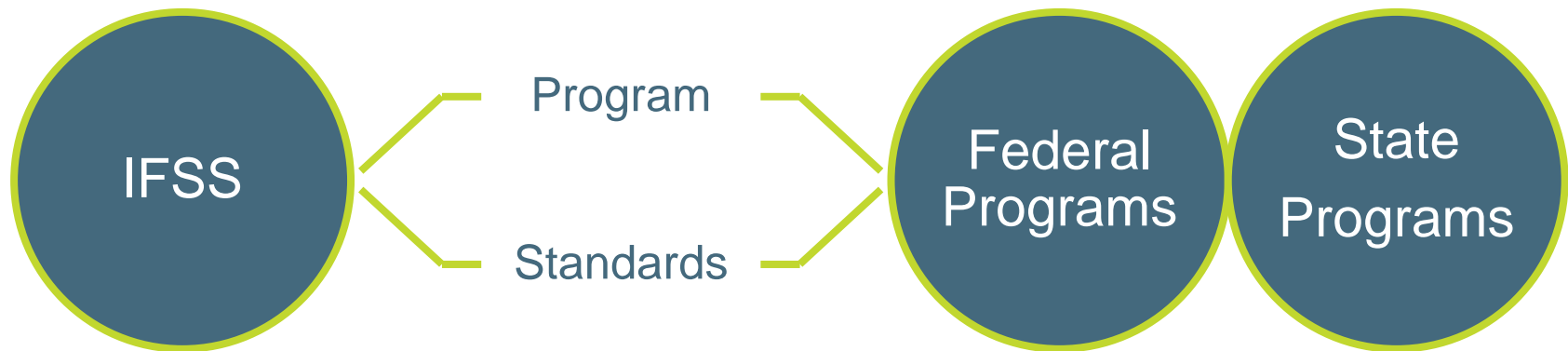
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Consumer Protection, Wisconsin*

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- The Integrated Food Safety System (IFSS) concept asserts that by meeting program standards, state and federal regulatory programs can rely on each other to more effectively and efficiently achieve compliance outcomes and protect public health.



Wisconsin Department of Agriculture, Trade and Consumer Protection (WDATCP) was found in full conformance with the Manufactured Food Regulatory Standards in 2014



WDATCP began counting FDA inspections toward its workload in 2014, and currently work planning together



Images source: Courtesy of WDATCP

- Inspection key similarities:
 - Verbally communicate findings and expectation that firm corrects all violations
 - Written reports and follow-up on previous inspection findings
- Inspection key differences:
 - Inspection duration
 - Terminology for violations
 - Provision of written inspectional observations to firm
 - Timeframe for firm receipt of inspection report
 - Reinspections

The effect of a regulatory inspection on a firm's future compliance with the law may be different depending on whether FDA or WDATCP does the inspection.



Image source: Courtesy of WDATCP

1. Do FDA and WDATCP regulatory inspections achieve the same degree of compliance at manufactured food firms in Wisconsin?



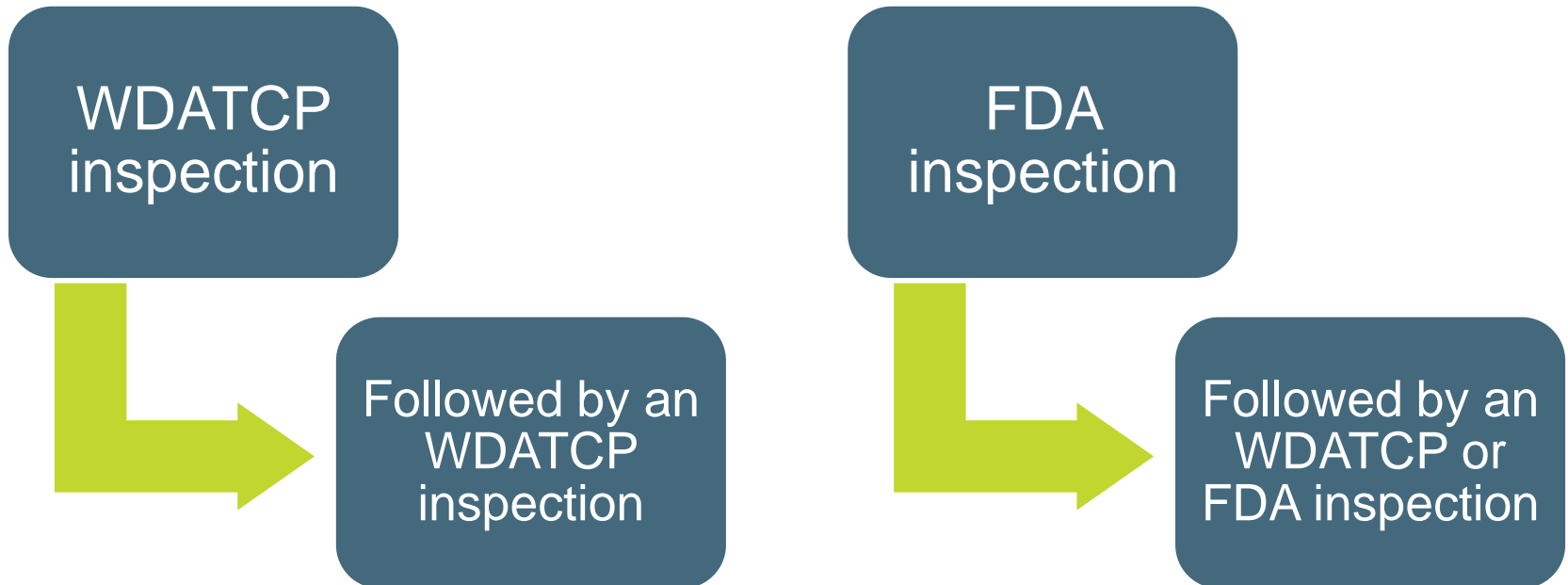
Image source: Courtesy of WDATCP



Image source: FDA/flickr

- Analyze inspection reports written by both agencies, where at least one violation of commonly-enforced regulations is noted.
- Measure degree of compliance as % violations corrected between inspections.
- Estimate average degree of compliance achieved between inspections:
 - WDATCP followed by WDATCP
 - FDA followed by WDATCP

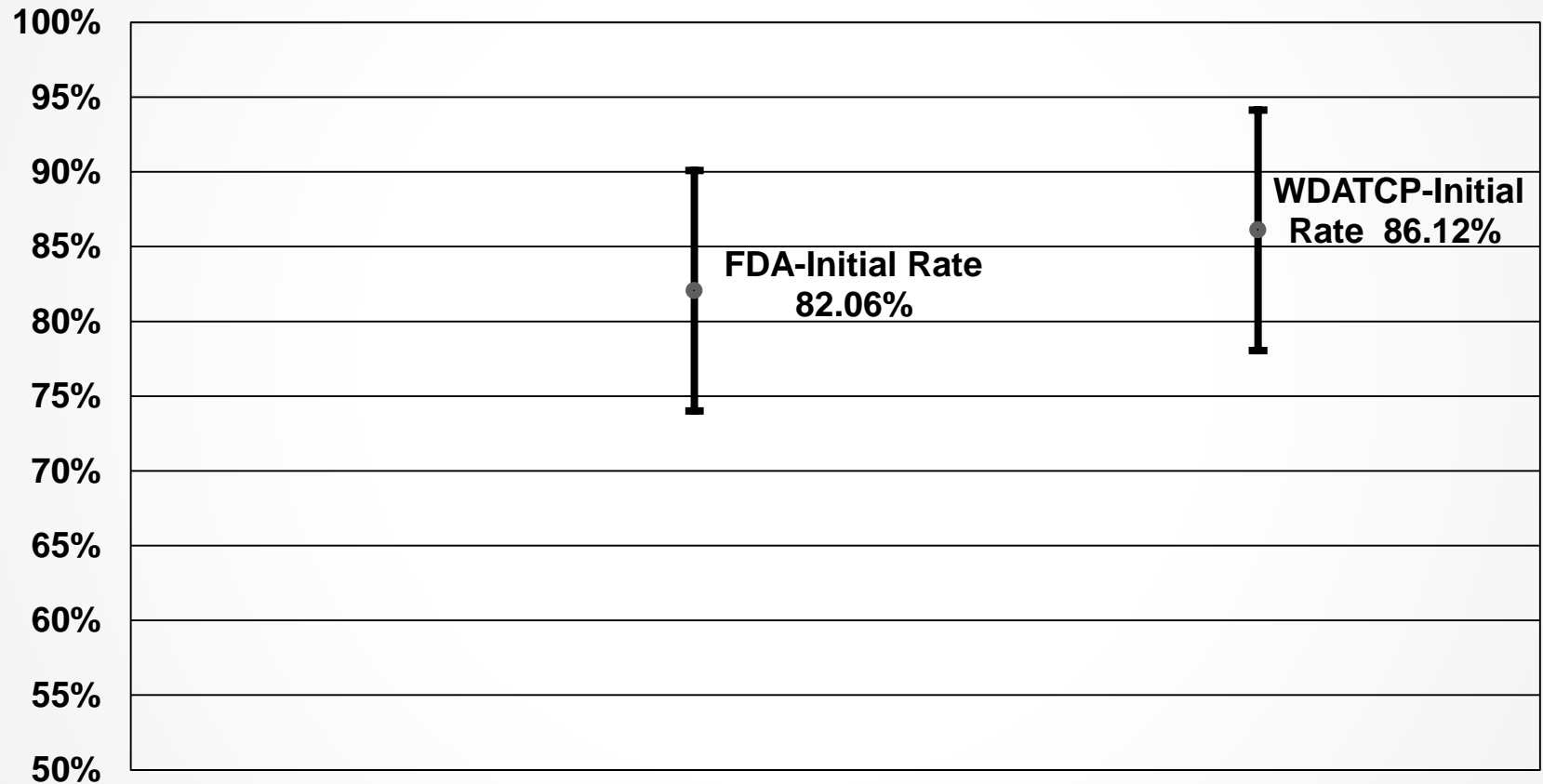
- Randomly-selected 2 sets of 40 pairs of inspections conducted in 2014-2016:



- Analyzed:
 - Initial inspection: How many violations were recorded?
 - Subsequent inspection: How many violations were observed again (uncorrected)?
 - Violations were counted as corrected, if they were not documented in the subsequent report
- Calculated:
 - Average compliance rates as number of corrected / number of observed violations.
- Performed:
 - A statistical comparison (paired t-test).

- Manufactured food establishment inspection reports written between 2014 and 2016:
 - At least 1 violation of 21 CFR 101, 110, 113, 114, 120,123
 - WDATCP Initial Inspection followed by WDATCP
 - FDA Initial Inspection followed by WDATCP

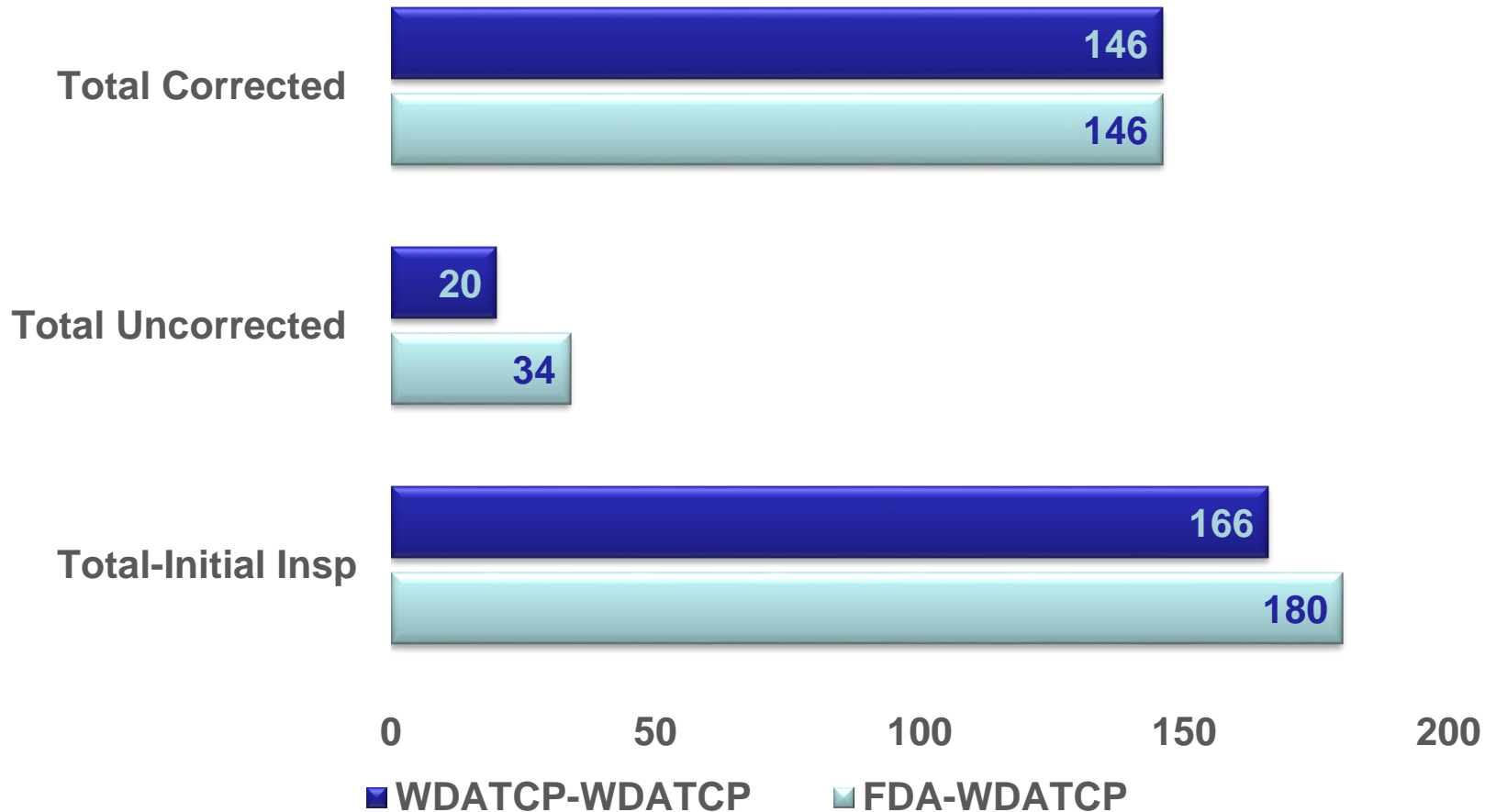
Mean Compliance Rates



Means ± Margin of Error (Confidence Intervals) and Proportions of Further Compliance

Variable Measured	Initial Inspection Agency	
	FDA	WDATCP
Compliance Rate	0.82 ± .08	0.86 ± .08
Days between inspections	272.1 ± 49.34	471.5 ± 51.84
% with 483 issued (FDA) Reinspection or Follow-Up to Follow (WDATCP) (as marked on initial inspection)	30%	20%
Number of Items included in Verbal Discussion with Management (FDA) or Non-Critical Violations in Initial Inspection Report (WDATCP)	3.65 ± 0.8	3.85 ± 1.2
Total Number of violations Initial Inspection	4.5 ± 0.82	4.15 ± 1.32
Number of Corrected Violations as per subsequent Inspection Report	3.65 ± 2.33	3.65 ± 4.00
Uncorrected Violations, as per subsequent inspection report	0.85 ± 1.17	0.5 ± 0.75
Percentage of with new violations detected at subsequent inspection	85%	85%
Number of new violations	4.43 ± 1.5	4 ± 1.5

Violations Comparison



- The results of this study show that there is equivalency in the compliance outcomes achieved by routine inspections between the FDA and WDATCP.



Image source: Courtesy of WDATCP

- Study shows equivalence and room for improvement.
- Results emphasize importance of the exit interview to communicate inspection findings.
- The majority of reports analyzed did not explicitly reference the other agency's report even when the other agency's inspection was the most recently-conducted routine inspection.

1. Continue current practices to maintain equivalent compliance rates.
2. WDATCP could save resources by accepting more written documentation of corrections, as FDA recommends in response to FDA Form 483.
3. Review most recent routine inspection report, regardless of which agency conducted it.
4. Scheduling inspections: Continued room for improvement to schedule at least 5 months apart.

- WDATCP: Ronesha Strozier, Peter Haase, Dr. Steve Ingham, and Troy Sprecker
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- Association of Food and Drug Officials (AFDO)

Questions?

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