

Impact of FDA Core Courses on Texas Manufactured Food Inspector Written Observations

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(TDSHS)

Background

- Texas Department of State Health Services (TDSHS) began implementing the Manufactured Food Regulatory Program Standards (MFRPS) in 2009.
- MFRPS identifies 10 elements of high-quality regulatory program:
 - Training Program Standard 2
 - Inspection Program Standard 3
 - Inspection Audit Program Standard 4

Background (continued)

- MFRP Standard 2: Training Program
 - FD150 Food Core I: Good Manufacturing Practices (GMP) 110
 - FD151 Food Core II: Inspection Techniques and Evidence Development
 - FD152 Food Core III: Food Processing and Technology
- TDSHS began sending groups of inspectors through FD150, FD151, and FD152 from September 2010 through April 2012.

Problem Statement

The impact of FDA Core Courses FD150, FD151, and FD152 on TDSHS inspector reporting of significant violative conditions or practices during routine GMP inspections of food manufacturers in Texas is unknown.

Research Question

Did attending FDA Food Core Courses FD150, FD151, and FD152 have an impact on TDSHS inspector reporting of significant violative observations during routine GMP inspections of Texas food manufacturers?

Methodology

- Written inspection observations were compared pre-training and post-training.
- Written observations categorized by:
 - 110 GMP sections: Personnel, Plant and Grounds, Sanitary Operations, Sanitary Facilities and Controls, Equipment and Utensils, Production and Process Controls
 - Labeling: Allergen and No Firm Name and Location (critical)
 - Sub-categorized as “critical” or “noncritical”
 - Unable to Determine
 - Not Applicable

Study Population

- Inspection report selection
 - Inspection dates: 5/1/10-7/31/10 and 5/1/12-7/31/12
 - Type of inspection: routine GMP only
 - No specialized or focused types
 - No warehouses
- Inspector criteria
 - Conducted inspections before and after courses
 - Completed FD150, FD151, and FD152 between 9/24/10 and 4/27/12

Results

- 2010 Reports
 - 127 reviewed (41 wholesale, 86 retail)
 - 19 had no observations
 - 449 observations were categorized

- 2012 Reports
 - 127 reviewed (41 wholesale, 86 retail)
 - **38 had no observations***
 - 425 observations were categorized

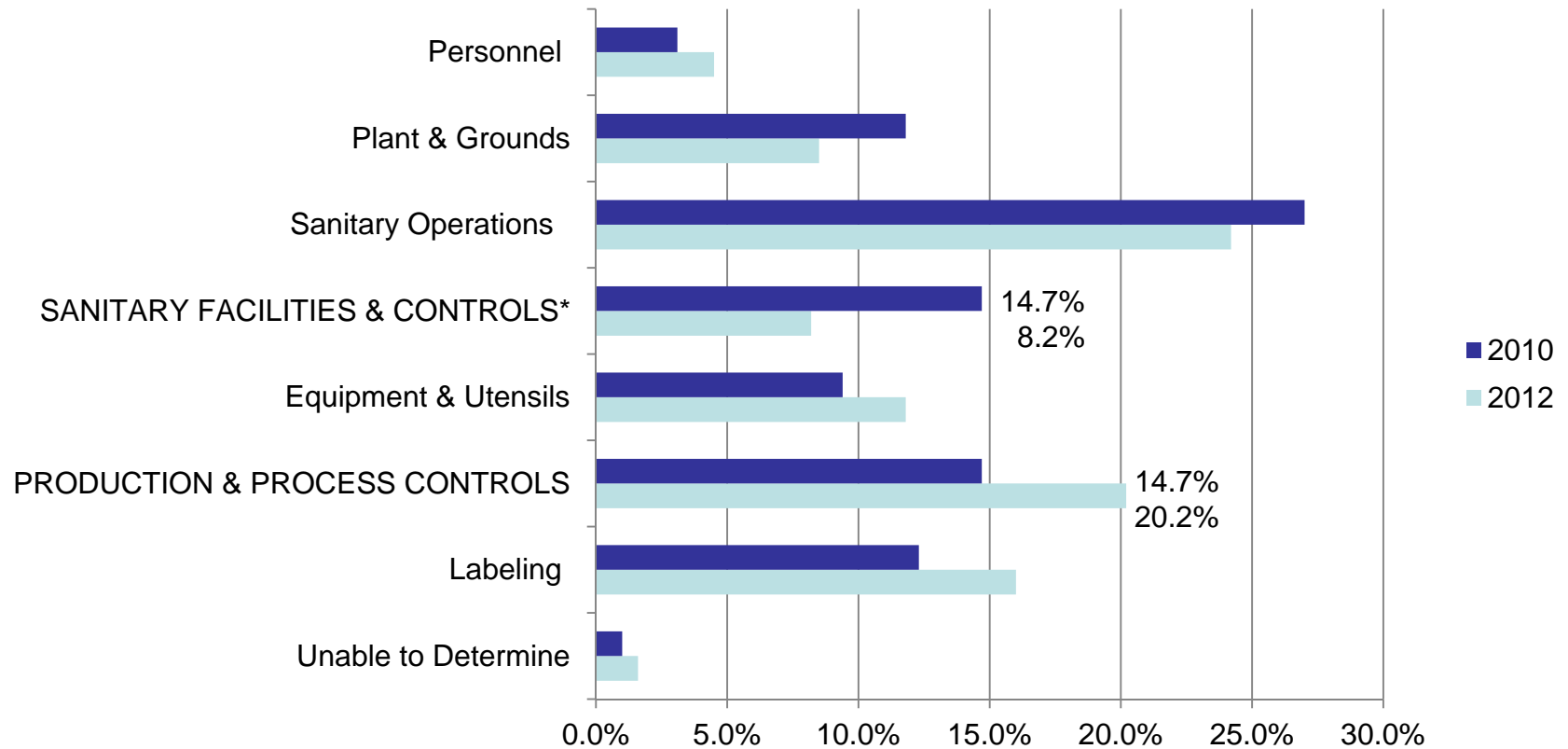
**statistically significant*

Results (continued)

	2010 (449 total)	2012 (425 total)
% Total Critical Observations	34.3 % (n = 154)	34.6% (n = 147)
Ratio of Critical to Noncritical Observations	0.586 (154:263)	0.588 (147:250)

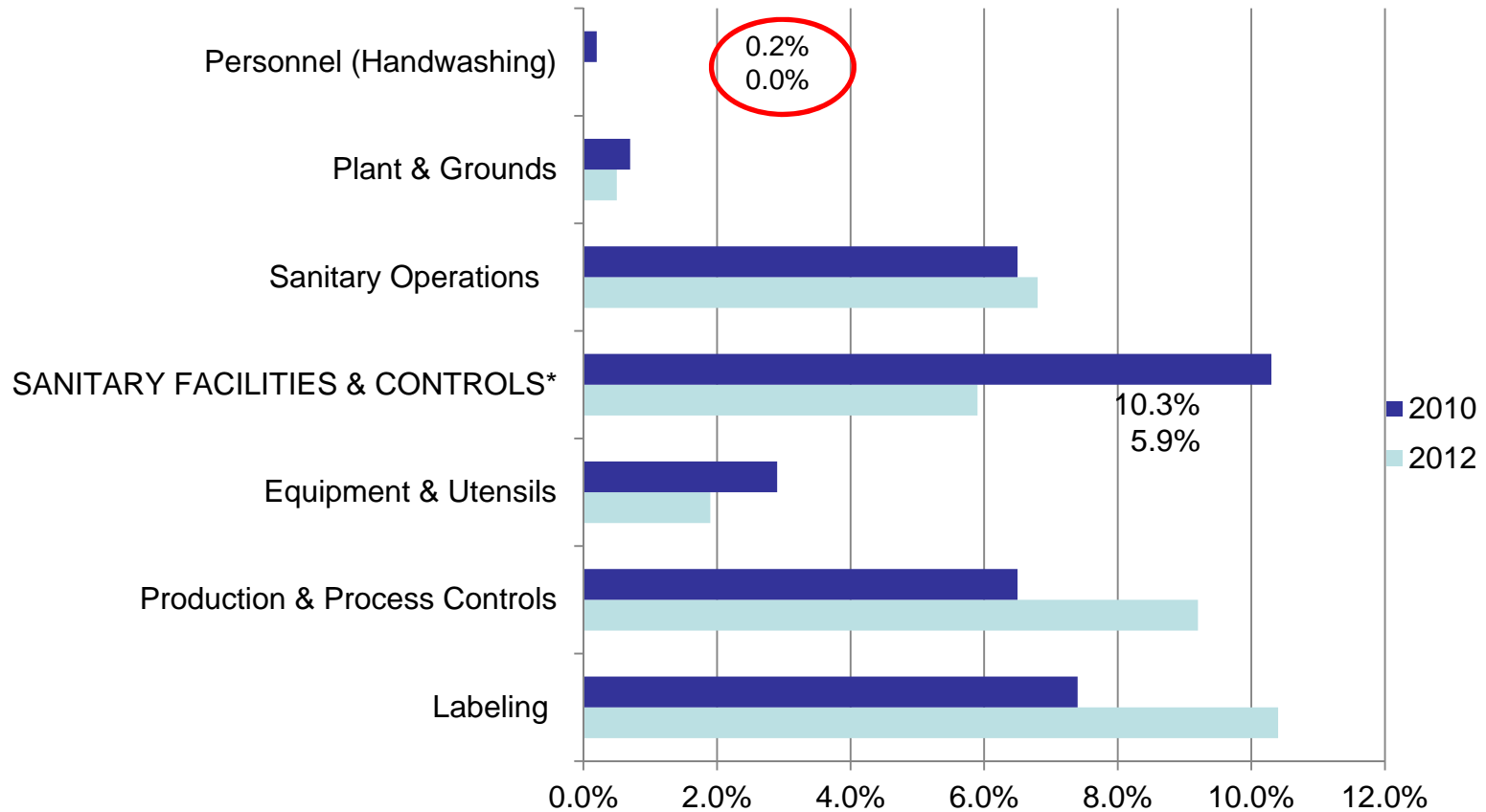
Results (continued)

PERCENTAGE OF TOTAL OBSERVATIONS BY CATEGORY



Results (continued)

PERCENTAGE OF CRITICAL OBSERVATIONS PER TOTAL YEAR OBSERVATIONS BY CATEGORY



Results (continued)

Ratio of Critical to Noncritical Observations by Category	2010		2012		χ^2
110.10 Personnel	0.077	1:13	0.000	0:19	1.462
110.20 Plant & Grounds	0.060	3:50	0.059	2:34	0.001
110.35 Sanitary Operations	0.315	29:92	0.392	29:74	0.690
110.37 Sanitary Facilities & Controls	2.300	46:20	2.500	25:10	0.113
110.40 Equipment & Utensils	0.448	13:29	0.190	8:42	3.855*
110.80 Production & Process Controls	0.784	29:37	0.830	39:47	0.054
Labeling	1.500	33:22	1.833	44:24	0.762

Conclusions

- Too many uncontrolled variables to conclude the FDA courses had or did not have an impact.
- Findings within data warrant additional exploration.
- Challenges identified:
 - Written observations lack detail.
 - Determining applicable rule for observation.
 - Lack of guidance defining a critical observation.

Recommendations

- In-depth analysis of category data.
- Continuing education and/or feedback mechanism for written observations.
- Guidance tools and training specific to GMP rule identification and critical vs. noncritical observations.
- Ensure training enables inspectors to perform job tasks against which they are evaluated.

References

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Questions?