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IFPTI Fellowship Cohort V: Research Presentation

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Possible Influences of MFRPS on the Planned Adoption and Implementation of the Preventive Controls for Human Food Rule

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The Manufactured Food Regulatory Program Standards (MFRPS)

- First published in 2007 by the U. S. Food and Drug Administration (FDA)
- Establishes a uniform foundation
- 10 Standards total:
  - Standard 1 – Regulatory Foundation
  - Standard 8 – Program Resources (used in study)

The Manufactured Food Regulatory Program Standards (MFRPS) (continued)

- Currently 42 programs in 40 states are implementing the MFRPS (FDA, 2016)
- States are at different levels of implementation and conformance due to enrollment dates and resources

MFRPS Audits Are Conducted By the FDA

- 18, 36, and 60 months
- Assess for Implementation: Partial or Full
  - Procedures and systems are in place, but state is unable to demonstrate use
- Conformance: Yes or No
  - State is using and can demonstrate use of procedures and systems
  - Partial Conformance was used in this study to allow State self identify

Food Safety Modernization Act (FSMA) – Preventive Controls for Human Food Rule (PCHF)

- Published on September 17, 2015 in 21 CFR Part 117
- Industry—one to three years to comply with the new requirements
- Manufactured food regulatory agencies—need to decide if they will adopt and/or implement the PCHF

Problem Statement

Whether implementation of and conformance with the MFRPS Standards 1 and 8 effects a state program's plan to adopt, or the state program's capacity to implement, the PCHF is not known.

Research Questions

1. What are the state programs' current levels of implementation/conformance with MFRPS Standard 1 – Regulatory Foundation, and Standard 8 – Program Resources?
2. What are the state programs' plans to adopt and capacity to implement the PCHF?
3. Does a state program's level of conformance with the MFRPS Standard 1 effect the likelihood that a state program will adopt the PCHF?
4. Does a state program's level of conformance with the MFRPS Standard 8 effect state programs' capacity to implement the PCHF?

Methodology

- Developed survey (23 questions total)
  - Responder and program (6 questions)
  - MFRPS cooperative agreement (6 questions)
  - MFRPS conformance (3 questions)
  - PCHF rule adoption and implementation (8 questions)
- Data collection
  - On-line survey (Survey Monkey and email)
- Analysis
  - Qualitative and quantitative responses

Study Population

Response Rate 29/42*

*Two agencies are enrolled in South Carolina and West Virginia

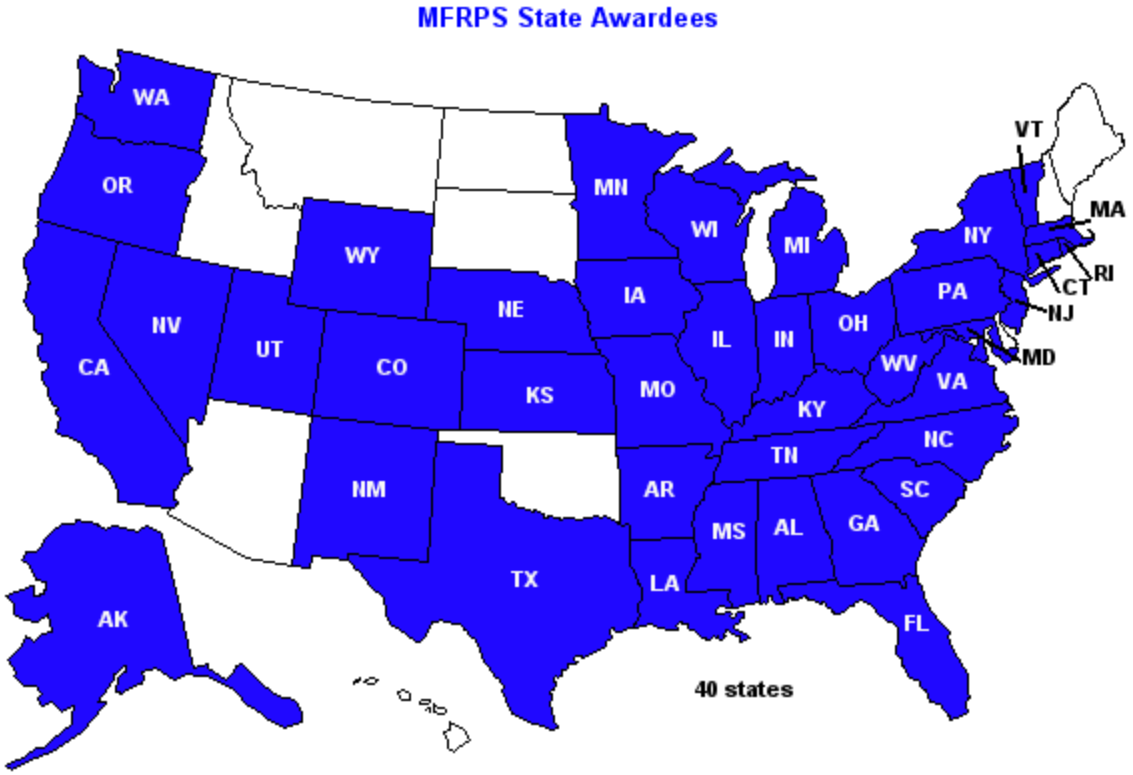
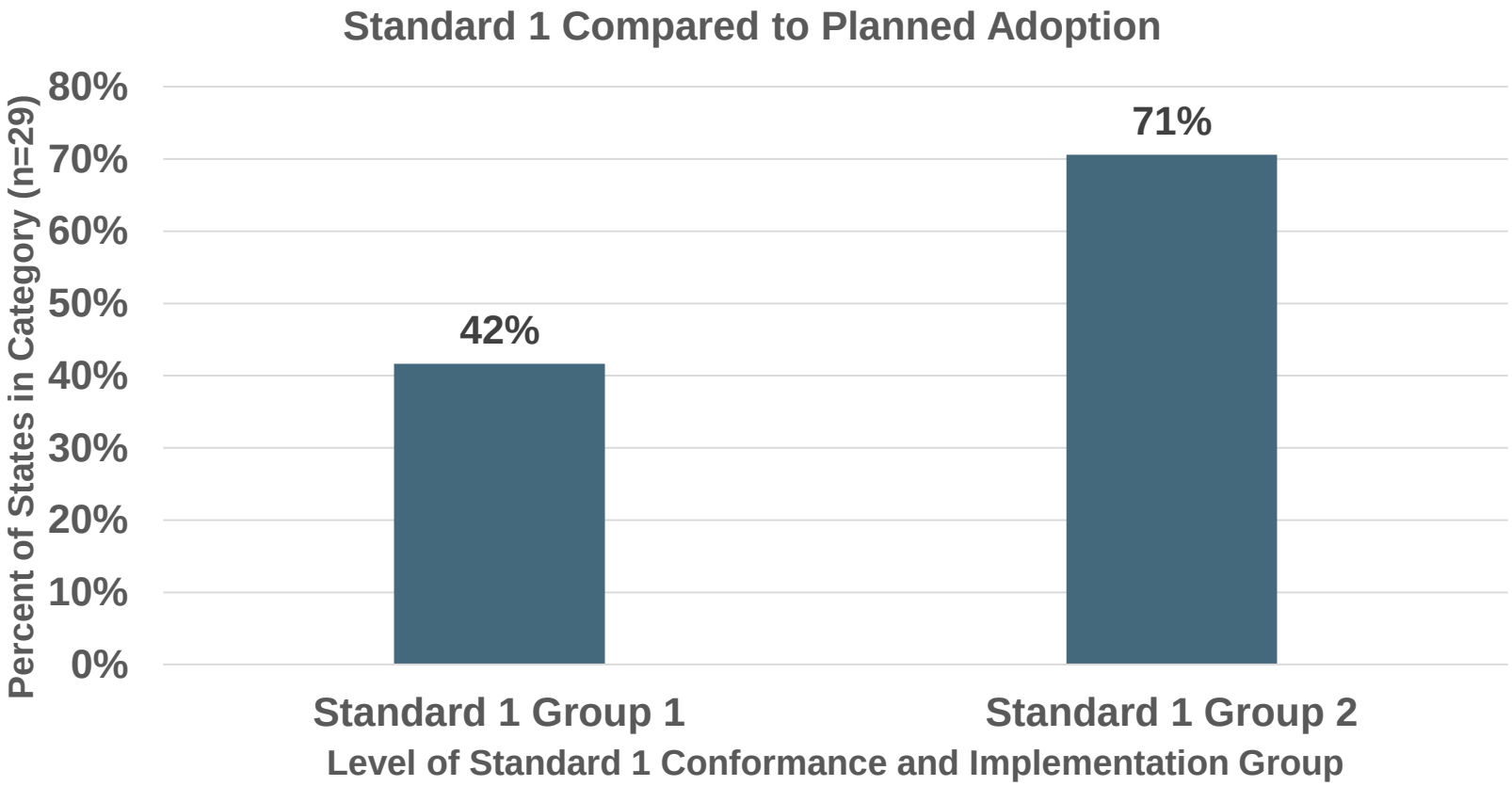


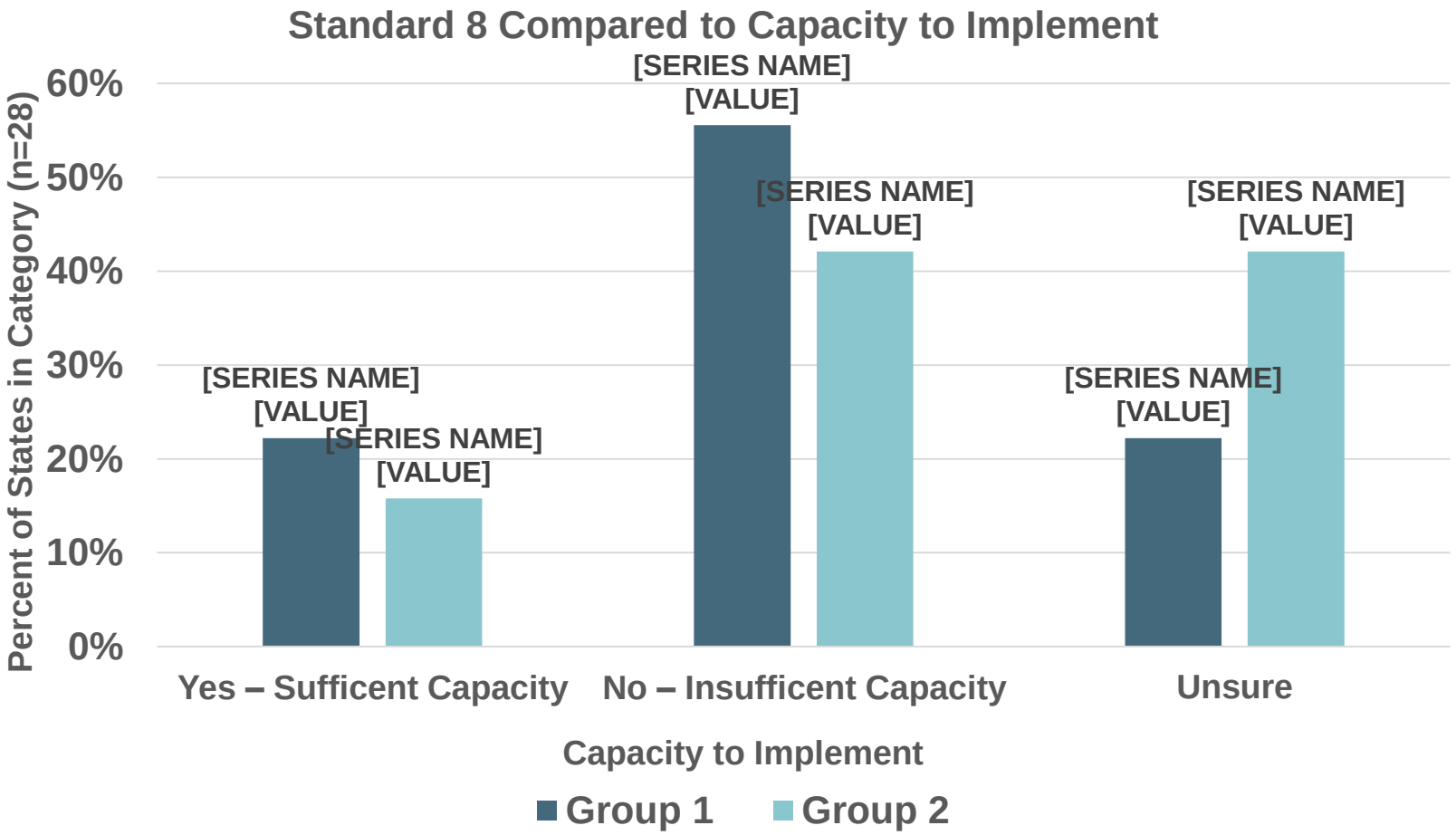
Image source: http://www.fda.gov/forfederalstateandlocalofficials/programsinitiatives/regulatoryprgmstnds/ucm475064.htm

Results



Group 1: Partial Implementation
Group 2: Full Implementation, Partial Conformance, and Full Conformance.

Results (continued)



Group 1: Partial Implementation
Group 2: Full Implementation, Partial Conformance, and Full Conformance.

Results (continued)

Additional Resources to Implement PCHF:

- 90% inspection funding
- 80% inspection staff
- 55% industry partnerships
- 38% equipment
- 21% office space

Conclusions

Standard 1 – Regulatory Foundation Compared to Planned Adoption of PCHF

- Level of implementation/conformance with Standard 1 appears to be related to state program's intent to adopt the PCHF

Standard 8 – Program Resources Compared to Capacity to Implement

- Level of implementation/conformance with Standard 8 does not appear to correlate to the perceived capacity to implement the PCHF

Conclusions (continued)

- 35% of States are unsure of capacity
  - Do not have a full understanding if they have the capacity to implement the PCHF
  - Resources are a main concern to state programs
- Many confounding variables
  - State funds
  - Political climate in states
  - Enrollment time in the MFRPS

Recommendations

1. Additional research should be conducted.
2. Outreach, training, and support should be provided.
3. State programs and the FDA should create additional guidance.
4. Funding mechanisms should be created for States.
5. Resources should be provided to assist state programs in the adoption and implementation of the PCHF.
6. MFRPS should be updated to reflect the new requirements related to the PCHF.

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Questions?

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