

Customizing Current Good Manufacturing Practices Training and Education for Small and Very Small Food Facilities Across the United States



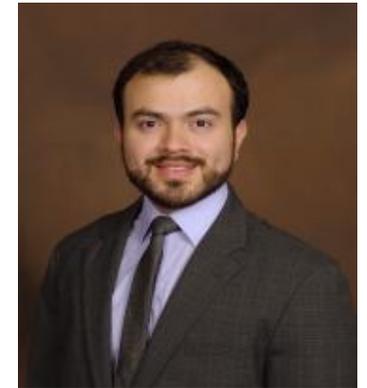
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USDA-NIFA-FSOP 2021-70020-35829
Accession Number: 1027498



USDA-NIFA FSOP Project Directors Meeting, Tampa, FL – May 31, 2023



United States
Department of
Agriculture

National Institute
of Food and
Agriculture

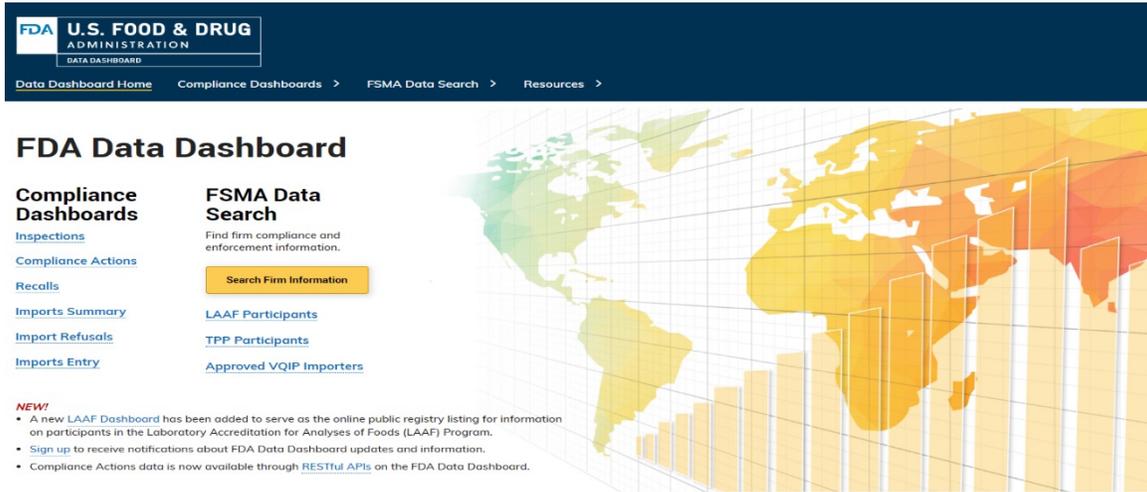
Problem Statement / Issue Definition:

- GMP outline the minimum sanitary, environmental, and operational standards to manufacture, process, pack, or hold food in a safe and wholesome way,
- cGMP violations at the national level continue to be extremely prevalent.
- Small and very small facilities difficulties with compliance
- Behavioral, cultural, educational, financial, geographical, infrastructural, linguistic, technological barriers are not often considered.
- Long-term goal: to improve the capacity of small and very small food facilities across the US to comply with cGMP.
- Hypothesis: targeting and customizing cGMP training will increase compliance with federal regulations and protect public health while contributing to food business continuity and expansion.

Specific Objectives:

1. Conduct cGMP compliance readiness assessments in small and very small food facilities in four different U.S. geographical regions.
2. Determine cGMP preferred training and education delivery methods for food workers in small and very small food facilities across the U.S.
3. Examine barriers to the consistent and sustainable implementation of cGMP in small and very small food processing operations across the U.S.
- 4. Reconcile the content of GMP training and education materials with the most commonly reported GMP violations in food processing operations.**
- 5. Customize, develop, and/or expand current cGMP training materials in English and Spanish suitable for small and very small food manufacturers across different U.S. geographical regions.**

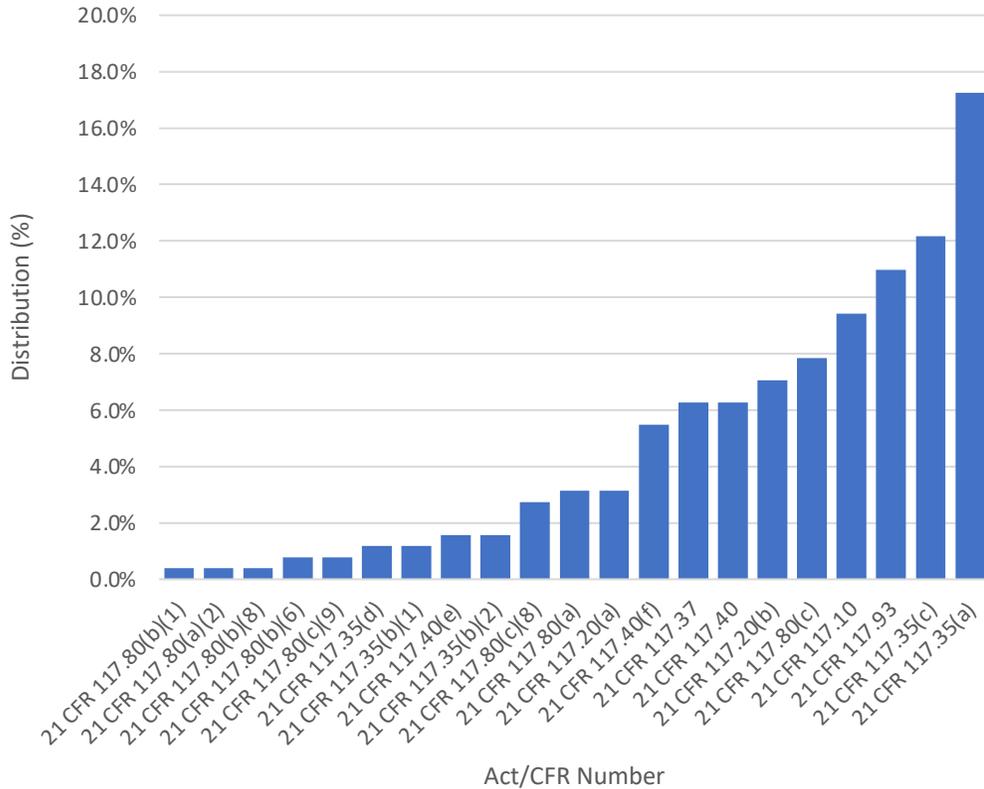
Approach / Methods:



- 1) Generate practical metadata using publicly available FDA records for each subsection of the cGMP regulation;
- 2) Provide clarification on regulatory compliance based on cGMP violation data; and
- 3) Draft a user-friendly document that small and very small food operators may use to increase regulatory compliance

- American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the US Virgin Islands.
- 2016 to 2022
- Restrict searches to:
 - 117.10 Personnel
 - 117.20 Plants and Grounds
 - 117.35 Sanitary operations
 - 117.37 Sanitary facilities and controls
 - 117.40 Equipment and utensils
 - 117.80 Processes and controls
 - 117.93 Warehousing and distribution
 - 117.95 Holding and distribution of human food by-products for use as animal food
 - 117.110 Defect action levels

Results / Outcomes:



21 CFR 117.35 (a) **General maintenance.** Buildings, fixtures, equipment and utensils must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated.

21 CFR 117.35 (c) **Pest Control.** Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests.

- Limited available resources via Cooperative Extension
- NECAFS Food Safety Clearinghouse
- Industry guidelines

21 CFR 117.93 **Warehousing and Distribution.** Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

- Draw guidance and resources from the FSMA Sanitary Transportation of Human and Animal Food Rule