205(c) 1A - Final Report Summary

FSMA Federal-State Integration Team Leads

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Deliverable Title

Section 205(c) 1: Surveillance: Improving Food Safety and Defense Capacity at the State and local Level. (A) Improve foodborne illness outbreak response and containment.

Stakeholder Membership

Association of American Feed Control Officials (AAFCO)

Association of Food and Drug Officials (AFDO)

Partnership for Food Protection (PFP)

Mississippi State University

Alabama Department of Public Health

Maryland Department of Health and Mental Hygiene

New York Department of Health

U.S. Centers for Disease Control and Prevention (CDC)

FDA - Center for Veterinary Medicine (CVM)

FDA - Office of Foods and Veterinary Medicine

FDA - Coordinated Outbreak Response and Evaluation Network (CORE)

FDA - Office of Partnerships

FDA - Office of Regulatory Affairs

Summary

The charge to this group was to identify means to improve Food Safety and Defense Capacity in State and Local governments – specifically to improve foodborne illness outbreak response and containment. The burden of foodborne illness in the United States is substantial. There are many facets to responding and containing foodborne illness. This subgroup addressed this specific FSMA charge from an environmental health and regulatory program perspective in order to focus the scope of the project. However many facets of the work accomplished encompass epidemiology, communications, and other aspects that contribute to a successfully integrated system that detects, responds, and learns from foodborne disease outbreaks.

The group identified the Council to Improve Foodborne Outbreak Response Guidelines for Foodborne Disease Outbreak Response (CIFOR), and the Rapid Response Team Best Practices Manual (RRT) as the current best practices tools and resources related to response and containment resulting from collaborations amongst Federal, State, and local partners. The group also identified the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) and the Manufactured Food Regulatory Program Standards (MFRPS) as key documents that contain program elements intended for a high quality response system for State and local retail and manufactured food regulatory programs.

These existing documents are developed and recognized as best practices by FDA, CDC, State and local food regulatory programs and other leading agencies involved in foodborne illness response. <u>At this time, an integrated framework to merge and use these separate tools has not been developed. Also missing (in our Nations food safety system) is a matrix performance measuring system that State and local agencies can use to assess and understand their program's capabilities and effective levels of response. The work of the Subgroup focused on addressing these identified gaps.</u>

Using the previously developed tools mentioned above the Subgroup developed a visual cross-walk table primarily based on CIFOR Guidelines and the RRT manual, but elements of the response standard in the MFRPS and VNRFRPS were also included. The crosswalk is included in the addendum.

The subgroup then identified key performance indicators for a successful environmental program relative to foodborne outbreaks based on the cross-walk table in a narrative document entitled "Model Food Emergency Response Framework for Food Regulatory Programs" (Attachment A).

A self assessment checklist based on the model framework document was developed and tested using the current response standards in the VNRFRPS and MFRPS. This self assessment checklist actually enables State and local agencies to assess their level of response capability to a foodborne illness event. The test checklist is included in the addendum.

To describe how this assessment process could be applied from farm-to-table, a flow diagram was also developed showing the key steps in the continuous improvement process (Attachment B).

The tools included within the framework model (CIFOR, RRT, MFPRS, VNRFRPS) are currently funded, supported, and are in the process of being implemented across a wide range of governmental agencies and professional organizations. While the current infrastructure to support use of multiple tools is somewhat fragmented, this framework model provides an integrated structure that allows for long term monitoring of performance goals, tracking and trending of data, gap assessment, and a continuous improvement process for government agencies to utilize.

Although the Subgroup tested the self-assessment tool using the VNRFRPS and MFRPS, this model can be used at all jurisdictional levels. The Subgroup recommends a State program level test pilot or exercise be developed to determine the applicability of the framework model and self-assessment tools in measuring a State's capability to respond. The Subgroup is willing to work with the Office of Partnerships or the Partnership for Food Protection to develop the strategy for the pilot project implementation.

The Subgroup concluded that by using the CIFOR Guidelines and RRT Manual as a foundational piece for foodborne event response, a uniform method of assessing capacity and addressing gaps can be achieved. The CIFOR Guidelines and the RRT Manual can be routinely reviewed to determine additional key performance indicators that can be included in future revisions of the Regulatory Program Standards and allow for standardized, national data capture and assessment. The various national standards, which are program specific, help individual jurisdictions establish a uniform and systematic approach to response in the areas where they have regulatory oversight.