Human and Animal Foods East 2 (HAF2E) Regional Sampling Project

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Overview

As FDA has moved to a regional approach to food/feed regulation based on program realignment there is a greater need for collaboration between the FDA, states, and local food/feed protection agencies within the region who may not have not previously worked together. States within HAF2E, a food program district covering firms in Delaware, Maryland, New Jersey, Pennsylvania, Virginia, West Virginia and the District of Columbia, are committed to the continuous improvement of coordinated multi-state response and effective mobilization to address common all-hazards food emergencies.

In 2017, to demonstrate the improvement of coordinated multi-state response and sample collection related to outbreaks, states with Rapid Response Teams (RRT) within HAF2E (Maryland, Pennsylvania, Virginia and West Virginia) proposed a regional sampling project to test their capabilities to follow FDA surveillance sampling protocol found in the FDA Investigations Operations Manual (IOM) and analysis following the FDA Bacteriological Analytical Manual (BAM).

Two Rapid Response Teams within HAF2E participated in this project, as others were limited due to both personnel and laboratory resources.

A total of fourteen samples were collected and analyzed by State Laboratories. FDA Office of Regulatory Science (ORS) provided laboratory concurrence for seven analytical packets.

Background

Smaller scale sampling exercises similar to the one proposed by the RRT's of HAF2E have been completed. In 2016, Pennsylvania Department of Agriculture (PDA) collected samples during the Political Convention and FDA and laboratories analyzed these samples. In 2018, ORA/ORS and Office of Partnerships (OP) proposed the potential development of federal state sampling exercise involving a RRT and an ORA/ORS Field microbiology laboratory. WV RRT partnered with Denver Lab for this exercise.

The RRTs of HAF2E discussed working towards the following milestone: "2.B. Develop and execute an inter-RRT project/collaboration, aimed at any RRT-related topic of mutual interest. Examples include: Regional RRT meetings, District-wide RRT collaboration, multi-RRT AARs/improvement plans, identifying and proposing solutions to regional/national needs/gaps (surveillance, response or prevention; training; exercise; data sharing), and working with relevant partners to propose outreach, education, legislative and other activities to prevent incident/contamination recurrence" [1].

In January 2018 a meeting was held to discuss the following topics: proposed language for the grant, number of samples collected per state, per month/entire project, identifying labs for sample analysis, responsible party for responding to positive sample.

In the grant, each RRT used similar language focusing on the individual function of each RRT and demonstrating the efficient transfer of samples to state or federal laboratories for analysis, the appropriate response to the results of lab testing, communications between RRTs and the FDA multi-state region, and appropriate response to the results of lab testing.

[1] **Flexible Funding Model; RRT Maintenance Funding Option: Annual Expected Goals (All Years), September 2017.**

Goals

- Provide a rapid response at the state and federal level in the event of the identification of adulterated food to keep the public safe
- Utilize the RRTs to work on a joint effort to mirror a significant incident.
- Practice a regional coordinated sampling project response
- Engage our State laboratory and/or FDA laboratory for the practice of sample submission, analysis and interpretation

Initial Discussions

At the August 2018 HAF2E Face to Face Meeting in Harrisburg, PA members from all four RRTs narrowed the potential product(s) to be sampled and created a sample schedule. Originally, it was proposed for the first year of the project to collect approximately 60-100 samples of one commodity throughout the year. Upon further discussion, the group determined that considering the number of sub samples required of one FDA sample, 60 total samples within one calendar year was unreasonable. It was also noted that collecting 60 samples of one particular product may place an unfair burden on that product specific industry and compete with other routine samples required by FDA/State contracts and FERN sampling. Pet Food labeled as human grade was of great interest to the RRTs, however an FDA-wide sampling assignment was already issued related to this product. State labs were chosen to be the analyzing labs, with the option for states without available laboratories to use FERN labs or an identified FDA lab.

Product	Month to be Sampled	Number of samples each Participating State	Analyses	Total Number of sampling units (subs) to be Collected	Total Number of Tests
Candied and Caramel Apples	October/ November	5 candied, 5 caramel	*Listeria*	100	20
Nut Butter (non-peanut)	December	10	*Salmonella*	150	10
Dried Cereal	January	10	*Salmonella, e. coli*	300	120
Frozen Berries (i.e. mixed berries, blueberries, strawberries, raspberries)	February	10	*Listeria*	100	20
Flour	March	10	*Salmonella, e. coli*	150	110
~~**Pet Food labeled as human grade**~~	~~April~~	~~10~~	~~*Salmonella, e.coli, listeria*~~	~~300~~	~~140~~

Table 1. Sample schedule displaying potential products to be collected, month of collection and suggested number of samples.

Implementation

At the start of each phase, a WebEx was held to discuss strengths and limitations from the previous phase (if applicable), to discuss final number of samples to be collected, minimum sample sizes for analysis and collection time frame. Considerations for time frame of collection included, field and laboratory resources.

After further discussion, due to field staff resources and laboratory priorities, the number of samples for each Phase of the project were reduced. During Phase 1, three samples were collected. During Phases 2 and 3 the number of samples was reduced two samples.

All samples were maintained under chain of custody. State laboratories were used to analyze samples collected by their respective RRTs.

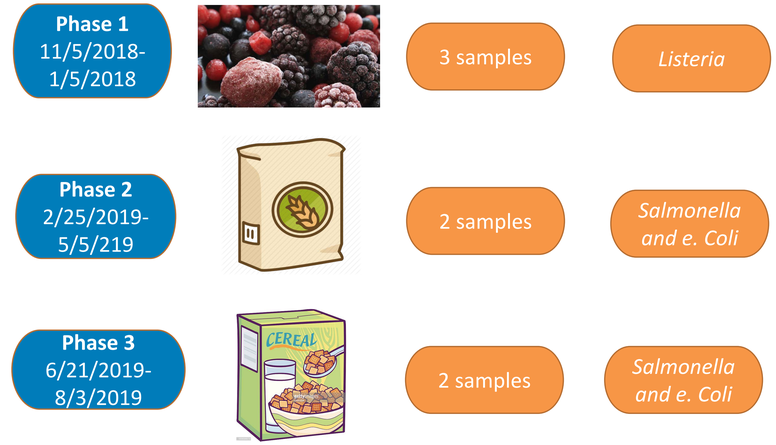

Figure 1. Phases, product, number of samples, analysis to be performed

Results and Discussion

SMarRRT collected a total of seven samples for this project. Each sample was collected from different retail locations and all traceback to different manufacturers. SMarRRT utilized their RRT Coordinator to collect samples and hand deliver samples to MDH Laboratory Administration. Of the seven samples collected and analyzed by SMarRRT all seven were negative.

VA RRT collected a total of seven samples for this project. Each sample was collected from a different retail location and all traceback to different manufacturers. VA RRT utilized local field staff to collect samples. Depending on the location of field staff, the sample may have been shipped to DCLS instead of hand delivered. Of the seven samples collected by VA RRT, six were negative. One sample was positive for *Salmonella* with ORS concurrence. It was later noted the sample was not aseptically collected at the retail location, which was a local flour mill.

ORS reviewed one analytical packet from each state, for each product sampled for a total of six analytical packets, in addition to the positive sample from a flour sample collected by VA RRT. ORS concurred with results of all analytical packets reviewed.

Limitations

- Furlough during Phase 1 made coordination and follow up with FDA difficult
- Requirements of FDA IOM related to number of subs to collect- difficulty finding 15 subs of same lot
- Field staff may not be as experienced in sample collections; opportunities for training

Strengths

- Coordination between sample collector and laboratory availability
- RRT funding for sample collections and laboratory analysis
- ORS concurrence with results of analytical packets

Conclusion

This project was a unique opportunity for participating RRTs to focus their individual RRTs capacity for sample collection per FDA IOM and analysis per FDA BAM. Continued areas of interest include: Import samples, spices, raw pet food and other emerging trends. Areas of improvement include predetermined response to positive laboratory analysis results. Although, the positive sample in this exercise was caused due to lack of aseptic techniques, there was no set protocol on how to handle positive sample results. Additionally, with RRT funding dedicated to sample collection, laboratories were able to utilize FERN funds for sample analysis. This could prove a productive use of resources as Laboratory funding progresses towards a flexible funding model. Based on results of this project, in the future, RRTs may be able to assist FDA in SCOPE surveillance sampling.

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