Strategic Assessment of Sampling Resources
Briefing Paper
April 16th, 2020

Summary

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) leverages robust sampling projects to verify the safety of products regulated by the Agency. In fiscal year (FY) 2018, the year this evaluation began, the Agency collected over 120,000 samples for microbiological and chemical residue analysis through these projects. FSIS reported over 500,000 different analytes from these results, as well as collected and analyzed almost 4,000 samples for further examination of veterinary diseases.

As a science-based agency, FSIS uses data to inform decision making and drive continuous improvement of processes. To maximize the efficiency, effectiveness, and value of these sampling projects, the Agency undertook a systematic evaluation to fully account for and prioritize resources. The Strategic Assessment of Sampling Resources (SASR) evaluation team (or SASR workgroup) within FSIS was formed to design and conduct this evaluation. The SASR Workgroup incorporated broad, cross-cutting participation from multiple program areas, including the Agency's pathogen and chemical residue workgroups. FSIS supplemented its expertise with contracted work to conduct and develop portions of this strategic evaluation. The evaluation was conducted from September 2017 to May 2019. The assessment compiles information from a variety of different sources, including Public Health Information System (PHIS) sampling data, Agency reports, FSIS notices and directives, and relevant *Federal Register* notices, among other sources.

The underlying premise guiding the SASR workgroup through the evaluation was that FSIS sampling only fulfills its purpose when the data it generates is used by the Agency. Relying on that guiding principle, the SASR workgroup developed a framework to assess whether data generated under each of the Agency's sampling projects are analyzed, and if the results of those analyses are factored into the Agency's decision-making.

The workgroup used a multiphase approach, with a sixth and final phase noted for future development:

- Phase 1: identify and describe all current sampling projects and the reason behind each.
- Phase 2: develop weighted categories and criteria to use for scoring and ranking the potential benefits of each project.
- Phase 3: determine whether each sampling project, as implemented, could satisfy the stated policy objective or its intended purpose.
- Phase 4: assess whether data from ongoing sampling projects is being used by the Agency as originally intended.
- Phase 5: conduct a cost assessment across all sampling projects.
- Phase 6 (future phase): conduct a semi-quantitative evaluation, based on work from Phases 1-5, to provide rankings for current and future sampling projects.

Findings and Recommendations

Based on the results, the SASR workgroup identified nine major findings and made recommendations to address them, including some related to internal FSIS workgroups.

Process Improvements

Finding	Recommendation(s)
The Sampling Coordination Committee (SCC) is underutilized. The current SCC Annual Sampling Plan Change Request Form could be improved upon by collecting additional information.	**1.1:** The SCC should revise the current Annual Sampling Plan change request form to include evaluative information about sampling projects. **1.2:** New sampling project sponsors and the SCC should ensure that a sampling project's design has been optimized and is collected consistently.
Office of Public Health Science (OPHS) field laboratories do not have a centralized and robust cost projection tracking system for all laboratory related costs.	**1.3:** Use OPHS expertise to create and continuously refine a repository that projects and tracks resource requirements by lab and project.

Sampling Project Sunsetting

Finding	Recommendation(s)
The Agency does not have a consistent, formal process to assess when a project or portions of a project should "sunset".	**2.1:** Review existing exploratory/baseline sampling and determine when to discontinue sampling or incorporate the exploratory portion into a routine sampling project. **2.2:** Future projects should have a specific sunset date.

Sampling Project Inventory

Finding	Recommendation(s)
There is no single, comprehensive inventory of sampling projects that includes how they are designed and why they are initiated and sustained.	**3.1:** The SCC should annually review a complete inventory of projects as part of the development of the FSIS Annual Sampling Plan and determine whether the inventory should be available internally and/or externally.

Implementation of Weighted Criteria

Finding	Recommendation(s)
The **semi-quantitative approach**, developed by the SASR workgroup, is an **appropriate and useful method to evaluate the benefits of each sampling program.**	**4.1:** Sampling projects that had a benefit score below 0.30 should be further evaluated by the various Data Coordination Committee (DCC) pathogen/chemical workgroups and require approval from the FSIS Enterprise Steering Board (ESB) to continue. **4.2:** Project proposers and the SCC should adopt the SASR-developed weighted benefits criteria to evaluate the potential benefits of future projects. **4.3:** Project proposers and the SCC should ensure that sampling projects are optimized, consider how the information will be used by the Agency, and account for the costs of the sampling plan.

Outreach and Communications

Finding	Recommendation(s)
SASR workgroup recommendations will **change processes for sampling projects and could cause confusion** during implementation.	**5.1:** Coordinate with Office of Public Affairs and Consumer Education (OPACE) to develop both an internal and external communication plans before implementing new processes and tools.

Alignment of Statistical and Policy Goals

Finding	Recommendation(s)
Agency sampling projects have differing levels of utility and cost-effectiveness, and some sampling projects could be optimized by adjusting scope.	**6.1:** Requests for new or revised sampling projects should optimize sample allocation using the SASR-developed tool as a starting point, then adjust (if needed) based on Agency policy goals.

Sampling for Products with Very Low Pathogen Rates

Finding	Recommendation(s)
For domestic sampling projects with very low positive rates, it is not feasible to collect and analyze enough samples to produce reliable estimates.	**7.1:** Consider the statistical claims that can be made based on the number of samples collected and analyzed (if no positives detected). **7.2:** Clearly document the reasoning and the potential statistical claims that are associated with each sampling project.

Prevalence Estimation

Finding	Recommendation(s)
FSIS does not have a standard for what constitutes adequate confidence to call an estimate "prevalence."	**8.1:** Develop clear standards for determining whether a prevalence estimate can be calculated for each in-plant sampling project. **8.2:** For all sampling projects, clearly document the reasons a prevalence estimate can or cannot be calculated.

Sampling Project Specific Results

Finding	Recommendation(s)
Sampling of imports at reinspection serves different purposes and has different statistical design challenges than domestic sampling.	**9.1:** Conduct a separate evaluation of import sampling to maximize the benefits it provides to the Agency.
FSIS egg product sampling projects are well positioned to utilize SASR tools to improve sampling efforts.	**9.2:** Complete review of the egg product sampling proposal and implement any changes by FY2020.