FSIS Strategic Data Analysis Plan for Domestic Inspection

United States Department of Agriculture
Food Safety and Inspection Service

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1.0 INTRODUCTION

The United States Department of Agriculture (USDA) is committed to ensuring Americans have access to safe, nutritious, and balanced meals. USDA is working to significantly reduce the number of foodborne illness annually. To fulfill this mission, USDA formulated its strategic objectives, goals and performance measures as outlined in the 2010-2015 USDA Strategic Plan. One of the USDA objectives listed in the Strategic Plan states: To Protect Public Health by Ensuring Food is Safe. To meet this objective, USDA is investing in its workforce and data infrastructure to prevent harm to consumers, minimizing the prevalence of food contaminants and quickly identifying and averting outbreaks. Effective food safety inspections and enforcement depend upon timely quality data and analysis.

The Food Safety and Inspection Service (FSIS) has established a strategic goal to enhance the development and maintenance of an integrated and robust data collection and analysis system to verify the effectiveness and efficiency of Agency programs. This directly addresses the Administrator's priority of Data and Risk Analysis. FSIS must rely heavily on data to promote proactive decisions affecting food safety and public health. FSIS has strengthened both its data collection and analysis activities to ensure valid, timely data is collected, carefully analyzed, and continually reported in a user-friendly manner.

FSIS also employs assessment and analysis of public health data to ensure that the Agency is meeting its strategic goals and objectives. Analysis of data obtained from FSIS' regulatory verification activities, compliance and enforcement activities, sampling, as well as other sources of data, over time, provide the Agency with evidence that shows whether or not our approach is working. FSIS therefore employs data analysis as a management verification measure in determining the success of our strategies to combat threats to food safety and defense and to help ensure that program components are effective in meeting our public health goals and objectives.

FSIS developed this Strategic Data Analysis Plan to communicate its strategy for a data-driven approach to domestic inspection and to seek input for improving this strategy. FSIS recognizes that a data-driven approach to inspection requires quality data collection mechanisms, continued data analysis to refine analytical decision making tools, and performance measures to assess the impact of policies and programs. FSIS believes that an integrated data infrastructure with high quality data and data feedback loops is essential to support a data-driven approach to inspection. This Strategic Data Analysis Plan is designed to directly support the strategic goals of the Agency by providing the data and analyses necessary to effectively allocate resources and measure performance.

Strategic planning is an iterative process that requires measurement of results and feedback to promote continuous improvement. A key part of that feedback is seeking input from all stakeholders (both internal and external). FSIS is committed to making its strategic planning as open and transparent as possible and seeking input from all relevant stakeholders. Input received from stakeholders provided critical requirements which drove the design of the Public Health

Information System. With the publication of this document FSIS is laying out its strategy for improved data collection and analysis based on input received from stakeholders. As further refinements to FSIS' approach to data collection and analysis are proposed, the Agency will seek input from outside stakeholders.

This plan is divided into three key sections: improving data collection (section 2 of this document), data analysis (section 3), and performance measurement (section 4). In each of these sections we address the actions to be taken in terms of the first two iterations of this Strategic Planning process, Phase 1 and Phase 2. Phase 1 describes actions in place now and those being put in place as part of the PHIS implementation. It is important to note that this document is not an implementation plan for PHIS nor does PHIS address all the limitations and changes described in this document. Some of the limitations described may require changes to business practices, program design or training. The changes put in place in Phase 1 are based on current information that identifies limitations in the data systems, collection, and analysis methods. These limitations have been enumerated in various FSIS reports, the 2007 review by the Office of the Inspector General (OIG), and two reports by the National Academy of Sciences (NAS). The goals, limitations, and necessary changes described here are some of the major business needs that drove the design of PHIS and the training of its users. Examples of how PHIS will address these items are noted throughout this report.

The Phase 1 changes will provide the operational details and data that are necessary to enable statistical evaluation our current systems and processes. The changes in Phase 1 have been identified based on prior analyses. Examples of analyses that have informed the Phase 1 changes are described. Once the Phase 1 changes have been implemented and are producing operational results (in the form of more complete and accurate data) FSIS will evaluate statistically our current systems and process. We will use this evaluation to inform the Phase 2 changes described in this document.

Phase 2 describes the future analysis and data collection improvements that FSIS has already identified to further refine and advance its data-driven approach to inspection. Prior to implementing Phase 2 changes, FSIS intends to publish our evaluations and planned modifications for stakeholder input. The results of these changes will then be used to guide the next iteration of planning. Section 5 of this document lists other areas of FSIS where data collection and analysis improvements are being made but are not described in this plan. These areas will be addressed at a future time.

This plan accompanies the release of the Public Health Decision Criteria Report which describes in detail FSIS' near-term approach to a data-driven process for the allocation of agency resources. These criteria provide a method for allocating agency resources in performing certain types of inspection procedures. These criteria are not dependent on the improvements to data collection outlined in this report. Once the improvements in this report have been implemented, the data will again be evaluated to determine if any of the current criteria should be replaced or augmented.

Leading up to the release of its revised report on the Public Health Decision Criteria, FSIS has sought a great deal of input on its proposal from stakeholders and from third parties such as the

National Academy of Sciences. In its March and April 2009 reports, NAS provided FSIS recommendations for advancing its proposed data-driven approach to inspection. Throughout this strategic plan, FSIS has referenced the NAS recommendations that each activity addresses (For a complete list of the NAS comments see Appendix A). The issuance of FSIS' revised Public Health Decision Criteria Report and this Strategic Data Analysis Plan directly address NAS comments 2.1, 2.3, and 7.1 regarding the need for transparency in the Agency's decision criteria methodology and intended use. In addition FSIS has continued to address the recommendations made by the Office of the Inspector General in its 2007 review of issues impacting the development of risk-based inspection systems. The actions outlined in this plan address many of those recommendations. The specific recommendations are noted in each section and a complete list is provided in Appendix B.

2.0 IMPROVED DATA COLLECTION

An essential foundation of a data-driven approach to inspection is high-quality data. FSIS is developing a new data infrastructure known as the Public Health Information System (PHIS), which will greatly enhance its ability to collect high quality data and to utilize external data sources for decision making. PHIS is a user-friendly, web-based application that will replace many of FSIS' existing systems, such as the Performance Based Inspection System (PBIS) and the Automated Import Information System (AIIS). It will integrate and automate stovepiped and paper-based business processes—often found to be inefficient, time-consuming and limiting—into one comprehensive and fully automated data-driven inspection system. PHIS has four components: domestic inspection, import activities, export activities and predictive analytics. The development of PHIS and specific actions that went into its design and the user training to improve data collection are discussed below. Phase 2 actions to further improve these areas are also described.

2.1 The Public Health Information System

The Public Health Information System (PHIS) was designed and developed to consolidate and integrate the critical Food Safety and Inspection Service (FSIS) business functions of inspection, surveillance, auditing, enforcement, scheduling, modeling and analysis to better protect public health.

The FSIS business objectives for PHIS include:

- Better use of technology to collect, analyze and predict likely outcomes, allowing Agency employees to better protect public health.
- Modernize Agency technology to move from client-server to web-based systems to get near real-time data collection and analysis.
- Apply predictive analytics capability for detection of and response to events of public health concern.
- Deliver a framework for future expansion plans.

By meeting these business objectives, the PHIS program goals include:

- Improved data collection that greatly enhances FSIS' ability to make and execute informed and timely decisions to protect the public health.
- Improved global food safety and security through integrated and coordinated flows of information, goods & payments (PHIS to Customs and Border Protection (CBP) and Gov-Gov interfaces).
- Reduced costs and improved cycle-times through paperless, automated business processes utilizing USDA Enterprise Shared Services (ESS).
- A reusable set of services, data sources, and User Interface (UI) components built on a Service Oriented Architecture (SOA).
- An integrated, expandable, web-based system that delivers the mission objectives with modules for domestic, import, and export inspection and predictive analytics.

The four major areas of FSIS mission critical functionality that have been incorporated into PHIS to address these business objectives and program goals include:

- **Domestic Inspection** - replaces the Performance Based Inspection System (PBIS); includes In-plant inspection activity, food safety assessments, laboratory sample scheduling, In-plant data and data from other public health systems and external information sources, and integration with Predictive Analytics and modeling functionality
- **Import Inspection** - replaces the current Automated Import Information System (AIIS); supports FSIS' strategic goal to protect the public health by establishing a mechanism to coordinate national and international food safety and food defense risk management for imported products;
- **Export Inspection** - automates the current manual processes; and supports FSIS' strategic goal to protect the public health by establishing a mechanism to coordinate national and international food safety and food defense risk management for exported products;
- **Predictive Analytics** - a new technology that combines internal and external data from inspection, pathogen sampling, surveillance, meat and poultry product importing and exporting, health, disease, and other food safety and food defense sectors to perform automated predictive analysis to more efficiently and effectively eliminate or reduce intentional or unintentional food borne illness.

The full System Development Life Cycle (SDLC) was followed for the PHIS project from the initiation of the project through the current stage of User Acceptance Testing (UAT) to meet the business objectives, achieve the program goals that will result in the critical success factors for PHIS for these four major areas of FSIS mission critical functionality. A Project Charter was written at the beginning of this project that included an overview of the PHIS initiative, defined the scope of the project, and named Project Primary Stakeholder from each FSIS Program Area to provide the functional system requirements, testing and evaluation criteria for the project, as well as subject matter expertise required to meet the project goals and deadlines, and both a primary and back-up business requirements leader from the FSIS Program Areas for each of the four PHIS functional areas that would be engaged for their business knowledge throughout the project life cycle.

In order to gather and document the business requirements (what business needs from the system) and functional requirements (what the system must to do to meet the business needs) for PHIS for these four major functional areas, the primary and/or secondary business requirements leader and other FSIS personnel named as additional subject matter experts for each of the functional areas were engaged in multiple working sessions, meetings, prototype reviews, presentations, and site visits, as needed. The requirements were built on a business process level from the information gathered during these working group meetings, existing FSIS documentation, interviews with stakeholders and other key personnel and site visits that resulted in the creation of first, a Business Requirements Document (BRD), followed by the creation of a Functional Requirements Document (FRD). The PHIS BRD and the PHIS FRD were both reviewed by the Project Primary Stakeholders and the business requirements leads, updated based on the review comments, and finalized.

The PHIS system was then designed and developed using the Rapid Application Development (RAD) methodology that involves the use of prototypes to speed up the development process. Four prototypes were created that met the functional requirements in the PHIS FRD for each of the four functional areas. Each of the four prototype teams consisted of an FSIS business requirements lead, an contractor team lead and developers. The FSIS business requirements leads and contractor leads defined the prototype content before the prototype cycle started. The FSIS business requirements leads and their business area users:

- Reviewed the prototypes
- Clarified and answered questions about the requirement
- Provided feedback on the prototype functionality
- Worked with contractor to address the feedback
- Approved the prototypes

This approach provided more visibility to the business user and provided continuous user community involvement for their feedback and testing. This approach gave the business areas early visibility to the different functionality in the application and helped to identify and address business user concerns and issues during the development stage.

At the time of this writing PHIS User Acceptance Testing (UAT) is taking place with the involvement of the business area leads and multiple internal users. Feedback and issues reported by the user community are being recorded, addressed and resolved as quickly as possible by the project support team.

PHIS was designed to reduce the latency in FSIS decision making by providing feedback loops that utilize the data input by the inspectors and labs to drive automated scheduling functions, automated reporting functions, and automated alerting of events (Figure 1).

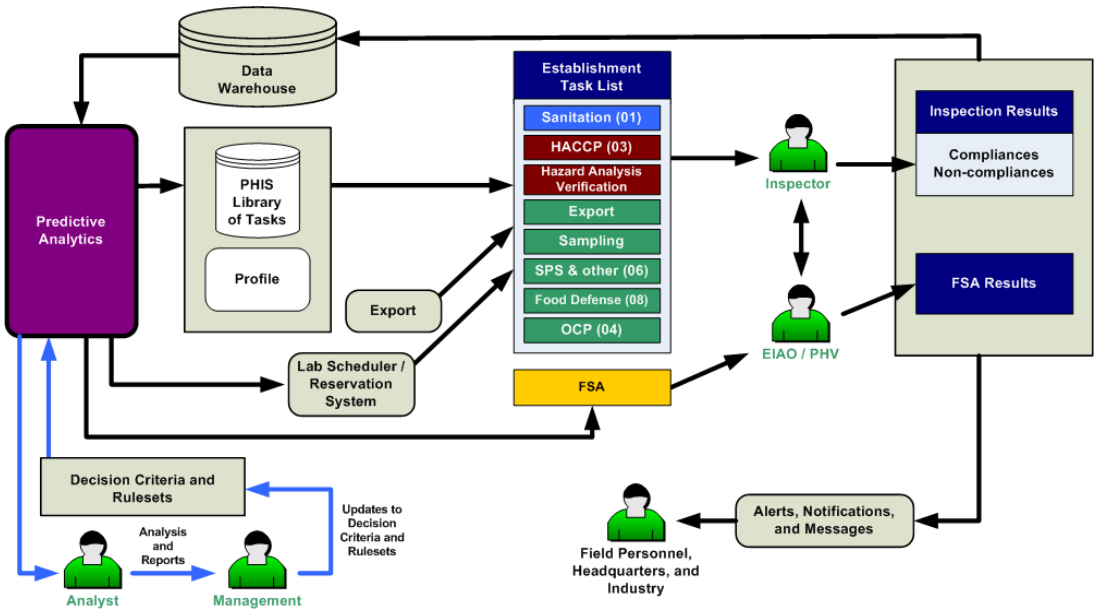

Figure 1: PHIS Architecture showing Feedback Loops

The starting point in this system of continuous feedback is Predictive Analytics (PA). PA uses the task library to develop task lists for each establishment. Each task arrives on an inspector's task list with a due date and a frequency for performing that task. The inspector then has the ability to pull assigned tasks onto their task calendars, scheduling them for completion. PHIS gives inspectors the flexibility to schedule tasks when they are most appropriate. This flexibility did not exist under the previous system.

As tasks are completed, inspectors record their inspection findings, compliances, and non-compliances. That information flows into the data warehouse where it is immediately available to PA for making further decisions. PA uses the results of inspection activities to schedule follow-up procedures and additional lab sampling as required. PA can also schedule non-routine, directed FSAs based on observed violations of public health decision criteria. The results of those FSAs are fed back to the data warehouse as well for use in analyses. The rule sets PA uses get reviewed and updated as a result of analyses and reports to management. In this manner PA becomes a better analysis tool and better informs the Agency's decision making.

The feedback loops in the system produce information vital to all levels of FSIS and external partners as well. Information and revised schedules will be fed back to field personnel. Reports will be generated for management at both Headquarters and the Districts to keep them aware of the current status and provide critical information for decision making. Alerts and notifications are issued to headquarters, field, and partner personnel as events occur. Reports will also be generated for Congress, stakeholder groups, and the public. All of these feedback mechanisms are designed to reduce delays by automating processes where appropriate and to have specific input points where human action is required.

PHIS will enhance the quality of establishment profile data, inspection procedure records, Food Safety Assessment (FSA) findings, and results of ad hoc surveys of inspection personnel. These data sources are critical for informing FSIS' data-driven inspection decision tools. PHIS will introduce improvements to the quality of FSIS data collection through 1) revised forms to aid Inspection Personnel (IP) in the entry of better quality information, 2) an infrastructure that ensures data collected are fully available and organized for analysis, 3) training on the collection of quality data, and 4) access to reference and historical information. These improvements over the existing paper and electronic processes are described below.

2.1.1 Establishment Profile

Currently, the establishment profile contains information about an establishment's location, size, and operating characteristics (e.g. slaughter, processing, ready-to-eat, etc.). Establishment profile data is used for data analysis projects, building of sampling frames, and Agency reporting. Reports and analyses that use this data to stratify or otherwise examine plant characteristics have identified weaknesses in the establishment profile. For example, the results of the 2008 *E. coli* Checklist and Reassessment showed that many raw beef grinding establishments were using "bench trim", a raw beef component created as a byproduct of other raw beef processing activities. As a result, FSIS initiated a bench trim sampling program in 2009 to sample this raw beef component for *E. coli* O157:H7. Attempts to accurately define a sampling frame for this

program were hampered however by the fact that the profiles did not identify establishments who were producing bench trim. Alternative approaches, based on different sources of volume data, were limited by the timeliness of the data and inconsistency among the various data sources. It was determined that a key requirement of PHIS would be an up-to-date catalog of production categories and the flexibility to modify the product catalog as needed.

The variability in production volume data is also addressed by PHIS. Currently FSIS collects volume data using a variety of different sources. Slaughter volume data is collected using the electronic Animal Disposition Reporting System (eADRS). Production volume data is collected using the PBIS Extension Volume Profile. Select raw beef volume data is captured using responses on sampling forms. Ready-to-eat (RTE) data is collected on the "10,240-1 forms" submitted by establishments. Other volume data is collected via questionnaires that may represent only brief snapshots in time. The ability to produce a complete picture of an establishment's production is limited by the multiple sources, formats, and timeframes in which this volume data was collected. PHIS has been designed to provide a centralized and more standardized way to collect this production volume data.

Phase 1

High quality information on each regulated establishment is essential to FSIS. This information is used to schedule inspection and laboratory sampling activities, and is stored in the "establishment profile." PHIS will expand the amount and quality of establishment profile data available to FSIS. In PHIS the establishment profile will include critical up-to-date information about the establishment's size, products produced, production volume, recall history, food defense plans, geographic data such as latitude / longitude, and external information such as Dunn and Bradstreet corporate data. HACCP information for the establishments will be available in the profile including summary information, processing categories, food safety hazards, critical control points, prerequisite programs, etc. Ongoing reviews of establishment profile information by Inspection Personnel are required every thirty days to ensure that the data remains current. In addition, PHIS will alert all IP assigned to an establishment when changes are made to its profile. FSIS has undertaken initial collection of establishment profile data using a small group of third party representatives. FSIS has conducted an evaluation of the quality of this data to ensure that it is accurate and consistent across establishments. This data will be loaded into PHIS at implementation and then verified by IP.

Phase 2

After PHIS is implemented, FSIS plans to evaluate whether additional profile fields are needed to support data-driven decision making and whether existing numerical data fields are sufficient. FSIS will also examine whether IP profile updates are sufficiently frequent to support timely decision making and whether industry access to profile data will improve its quality. Additionally, analyses will be conducted to assess variability in inspector generated data (particularly volume data). The impact of this variability on other analyses will be determined and ways to reduce it will be examined.

2.1.2 Inspection Procedure Records

Currently, when an inspector conducts an inspection task, they record their activities and findings in the Agency's Performance Based Inspection System (PBIS). This system collects information about inspection procedures performed or not performed, whether the establishment was in compliance or non-compliance with applicable regulations and details about specific non-compliances. Multiple regulations may be verified when a single inspection task is performed. When any non-compliance is found a non-compliance record (NR) is created that includes information about the specific regulations found to be violated. NR findings are often analyzed to assess whether changes exist between types of establishments (e.g. large vs. small), geographic location, time of year, or other factors. Establishments with high rates of non-compliance for public health related reasons (W3NRs) may be scheduled for a For Cause Food Safety Assessment (FSA) to take a more comprehensive look at their food safety system. Analyses of past NRs issued have identified several limitations in the NR and in data collected on inspection tasks overall. For example, when an inspection task is recorded as compliant, no information about the specific regulations verified is recorded. This limits the Agency's ability to determine a true non-compliance rate at the level of the regulation. Currently FSIS assumes all applicable regulations are verified when a task is recorded as compliant, but this may not be an accurate assumption. Another limitation of the NR is the difficulty in determining where in the production process an NR has occurred. Specific details about the non-compliance are entered by the inspector into the NR including where the non-compliance occurred, but this is captured as unstructured, free text. Variability in terminology and the descriptive detail used by individual inspectors coupled with the complexity of mining free text have prevented the Agency from taking greater advantage of the information captured in these NRs. PHIS has been designed to collect better data about points in the process where tasks are performed and the specific regulations verified regardless of whether the task was found to be compliant or not.

<u>Phase 1</u>
PHIS will enhance the quality of information from inspection procedures recorded by IP that is available for analysis and decision making. FSIS has reworked the forms used to document inspection procedures in PHIS to make collecting the data easier and more accurate. When personnel document their inspection procedures and findings in PHIS, they will be required to record what point within the food safety system they inspected, what regulations they verified, and whether they found the establishment to be compliant or noncompliant. PHIS will allow IP to choose only those regulations that are applicable to the procedure performed and will not allow incomplete forms to be submitted. Because the entry of NR data provides information critical to many analyses and decisions, it will receive particular attention during the PHIS training sessions.

<u>Phase 2</u>
In Phase 2 FSIS will examine the documentation of inspection procedures to determine whether further refinement of procedure documentation is needed to minimize use of text. In addition, FSIS will evaluate whether additional data needs to be collected and whether existing procedure documentation formats can be further improved to facilitate high quality data collection.

2.1.3 Laboratory Sample Scheduling

A successful sampling strategy requires accurate identification of establishments subject to sampling, information about each establishment's production practices (including types of products and days of production), proper communication and reporting of sampling requests, and consideration for lab capacities. FSIS typically collects about 80% of the samples requested for a particular sampling program, but collection rates can be as low as 50% for some programs. FSIS has identified several technical, procedural and data collection improvements that are expected to increase the proportion of sample requests where a sample is actually collected.

Currently, sampling is a distributed function across multiple groups within FSIS and is not fully automated. The various groups that identify the establishments to be sampled must work with the staff that runs the sampling scheduler. Field personnel must coordinate with headquarters and the labs, usually by email, to obtain sampling supplies and address issues. The FSIS testing labs are, to a large extent, unaware of the exact numbers of samples en route to their facility on any given day. The current process relies on printed sample request forms which are mailed to the inspector at the establishment to be sampled. This paper based system sometimes results in delayed or lost forms. When a plant is not producing the product subject to be sampled the inspector must mail it back to the lab with a reason for non-collection. This precludes the ability to use the lab resources for a sample at a different facility. The sampling forms also request information about the product being collected and other related information but have limited space available to record it. These weaknesses led to specific requirements for PHIS to improve these processes. PHIS will enhance the scheduling and collection of laboratory samples by 1) automating sample scheduling; 2) distributing sampling forms electronically with enhanced capability to collect data about samples; 3) allowing more flexibility in sample scheduling to improve sample collection rates; and 4) providing more accurate establishment profile information for sampling frame determination.

FSIS collects samples of products from the establishments that we inspect throughout the year. These samples are divided into different sampling programs that focus on different pathogens and products. Each sampling program is assigned a Project Code. The numbers of samples taken for each sampling program over the last eight quarters are listed in Table 1 (based on data extracted from the FSIS Data Warehouse as of 9/13/2010). Appendix C provides a description of each of these sampling programs by Project Code.

	2008		**2009**				**2010**	
Project	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q
MT43S	600	362	371	674	1046	905	716	606
HC01	9427	6165	8747	9017	6898	4510	7443	8998
ALLRTE	781	779	786	700	682	593	677	807
INTCONT	408	358	492	385	532	214	426	280
INTENV	271	268	306	227	286	108	223	139
INTPROD	113	113	153	107	153	64	117	79
RLMCONT	805	950	904	732	1198	1690	1711	1663
RLMENVC	N/A	N/A	N/A	N/A	N/A	174	178	178

	2008		2009				2010	
Project	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q
RLMENVR	423	478	463	390	139	N/A	N/A	N/A
RLMPROD	236	280	275	221	345	510	501	482
RTE001	2238	2083	1992	2078	2065	2023	2164	2215
MT05	67	63	109	194	161	155	168	266
MT06	0	0	0	4	8	0	0	0
MT08	19	0	21	38	40	2	14	14
MT43	2602	2283	2602	2933	3067	2971	3282	3116
MT44	130	213	100	109	99	176	36	125
MT44T	0	0	0	0	0	8	16	0
MT50	365	305	326	321	311	269	280	359
MT51	140	115	180	153	69	388	89	94
MT52	269	229	131	127	144	538	86	126
MT53	58	58	33	24	73	51	42	7
MT54	67	54	54	63	61	53	36	46
MT55	N/A	N/A	N/A	N/A	21	128	95	99
EM31	77	79	90	86	82	55	89	85
EM32	107	108	121	123	115	68	124	106
EM33	38	40	40	42	39	28	44	43
EM34	84	79	97	92	81	55	94	80
EM35	25	24	32	32	29	18	36	35
EM36	21	26	24	33	24	21	33	25
EM37	2	3	4	2	3	2	2	4
AMR01	12	48	26	36	27	24	7	31
FAMR01	12	15	20	20	6	21	17	0

Table 1: Number of Samples by Sampling Program per Quarter

Phase 1

As discussed above, PHIS will provide greater information on the products an establishment produces, the process for producing those products, and its production volume. That information will allow FSIS to improve the definition of its sampling frames. For example, the PHIS establishment profile will provide information about whether an establishment produces bench trim and its production volume. Currently FSIS' bench trim sampling frame is based on the *E. coli* Checklist conducted in late 2007 as well as some broad raw beef processing categories in the PBIS Volume Extension Profile. The up-to-date information available from the PHIS establishment profile should provide a better source for determining the appropriate sampling frames. FSIS has already instituted a 30 day window for many samples to account for intermittent production schedules. PHIS will improve upon this process by better matching of inspection and production schedules for small processors.

In addition, PHIS will enhance the rate of collection for FSIS sampling programs through electronic forms that allow for sample tracking and flexible sample collection dates that are determined by IP. Presently, many of the samples requested by FSIS are not collected, and in

some sampling programs, the 'non-collection' rate is as high as 50 percent. This can be due to many reasons, but the most frequently reported are 1) the establishment has not produced the product in the 30-day window, or 2) the establishment does not produce the product at all. The improved, up-to-date data in the Establishment Profile is expected to reduce these unfulfilled requests by better identifying establishments subject to sampling.

PHIS will improve the selection, scheduling, and tracking of sampling requests through the use of electronic forms that will capture reasons for not collecting samples such as: the establishment is currently not producing the product, sample shipment was delayed by the carrier, sample integrity was lost (e.g. the collection bag was leaking), sampling instructions not followed, or request cancelled by headquarters. In addition, the PHIS Lab Reservation System has been designed to allow IP the flexibility to schedule samples on the days when the product is being produced and when the lab has the capacity to analyze the samples. If a scheduled sample is not able to be collected, PHIS can select an alternate establishment for sampling. The more flexible scheduling provided by this component will further enhance FSIS' collection rate. It will allow for more samples to be taken overall because the schedule is continuously checked against the lab's capacity. Analyses will be performed to determine how well these functions are operating and how efficiently the labs are able to perform.

Phase 2

After PHIS is implemented, FSIS intends to continue monitoring collection rates for laboratory samples and will work to identify solutions for further improving collection rates. After PHIS implementation is complete FSIS intends to prepare a new sampling plan based on statistical analysis of the data. FSIS will explore additional methods to increase sample collection success rates. FSIS will monitor its sampling programs to determine what additional data (e.g., food product categories, establishment information) should be collected to continue to improve sample frame design and understanding of sample results and trends. The sampling plan to reallocate sampling resources based on a statistical analysis of the data will be posted for public input and peer review prior to its implementation.

2.1.4 Ad Hoc Survey Capability of Inspection Program Personnel

FSIS has employed several approaches to collect data that is not typically captured as part of routine inspection. In late 2007, FSIS collected data for the *E. coli* Checklist and Reassessment via a questionnaire sent to inspection staff. The results of this questionnaire provided valuable information about specific characteristics of raw beef slaughter and processing establishments. FSIS has also collected data through the issuance of Notices. For example, in Notice 62-07, inspectors were instructed to send an email to a designated email address with responses to questions provided in Attachment 1 of that Notice. An analysis of the effectiveness of that Notice however found low compliance rates for submitting emails. Furthermore, the unstructured nature of emails required an analyst to re-enter the available data into an analyzable format. Other approaches to collecting needed data include the use of PDF forms whereby the information could be readily uploaded into a database. In order to collect better data in a manner that improves compliance, data quality, and data analysis, FSIS determined that a better solution was needed that was integrated with other Agency data.

Phase 1

PHIS will provide an electronic ad hoc survey capability for FSIS management to develop and deliver questionnaires to in-plant inspection personnel targeting information about an establishment's operations, equipment, and/or products. PHIS will allow FSIS to add one-time or recurring questionnaires to existing routine inspection tasks and to develop stand-alone questionnaires for IP. The data entered by IP for these surveys will be available immediately for analysis in PHIS leading to a much quicker and less laborious compilation of results. These surveys will provide a valuable source of new information that can be used to rapidly gather information in response to a potential public health concern and to precisely target inspection procedures and sampling to establishments that meet certain characteristics.

Phase 2

As FSIS moves into Phase 2, it will determine whether any ad hoc surveys that have been conducted need to become routine data fields for collection. These data fields will be incorporated into PHIS as enhancements. The data collected will be available for use in the system's scheduling programs. FSIS will determine whether additional ad hoc surveys are needed to further enhance the Agency's data-driven decision making tools.

2.1.5 Food Safety Assessment Data Collection

An FSA is a comprehensive examination of the design and implementation of an establishment's food safety system. FSAs are conducted by Enforcement, Investigation, and Analysis Officers (EIAOs), who are FSIS employees specially trained to conduct these procedures. The methodology and documentation for conducting an FSA is specified in FSIS Directive 5100.1. The Office of Inspector General (OIG, 2007) believes that FSAs yield the Agency's best evidence about the design and implementation of an establishment's food safety system. For the past two years, FSIS has transitioned towards a new FSA instrument that allows for better capture and analysis of this critical information.

Under current FSIS Directives, all meat and poultry slaughter and processing establishments receive an FSA at least once every four years. In addition, as described in FSIS' Public Health Decision Criteria Report, establishments that violate at least one of the Tier 1 decision criteria will be scheduled for a for-cause FSA within 30 days.

These assessments provide the most comprehensive picture of an establishment, yet they are also one of the most difficult datasets to analyze. FSA reports currently consist of lengthy Microsoft Word documents (often greater than 50 pages) containing detailed responses to a set of questions. The responses are largely unstructured text. The unstructured text is required to give the EIAOs the flexibility needed to fully document their findings. However greater analysis of the 1,200 to 1,500 FSAs performed each year could yield valuable information to better inform the Agency about the meat and poultry industries. Mining FSA data could identify trends that may be occurring over time, determine differences in establishment practices that impact public health, or find other valuable information not available from other sources. For this reason a more quantitative solution that still maintains the capability for full documentation is being designed into PHIS.

Phase 1
PHIS will automate the Public Health Decision Criteria to schedule for-cause FSAs and to maintain a four year cycle for routine FSA in every establishment. Within PHIS, FSIS will collect FSA data in an electronic format using FSIS' new standardized FSA instrument. This instrument will employ more structured responses and controlled vocabularies and facilitate data analysis for decision making. This transition to the new FSA instrument for data collection directly addresses the OIG finding that FSIS must move to electronic reporting of FSAs. This new electronic instrument also has organizational and question changes to provide for more precise data collection. In many cases selection boxes and drop-down lists are available to guide EIAOs to record their findings more accurately. Some free-text boxes are still provided to allow EIAO to justify further their drop down menu selections if needed.

Phase 2
In Phase 2, FSIS will evaluate the FSA data collection tool to determine if questions need to be revised to improve data collection or whether additional questions should be added to enhance FSIS' understanding of activities at establishments. Because the FSA is the most in-depth data that FSIS collects on establishments many different types of analyses will be performed to ensure that the most pertinent data are collected and that they are accurately reported.

FSIS' plans to improve the scheduling, performance, and utilization of FSA address the following recommendations from the OIG:

- OIG Recommendation 1 to implement an action plan with specific milestone dates for capturing the results of food safety assessments in an appropriate configuration that allows for effective analysis.
- OIG Recommendation 2 to perform food safety assessments, using the new configuration, in all establishments that will be in the universe of establishments where risk-based inspection may be used. The food safety assessments should be comprehensive assessments of the establishment's current operations.
- OIG Recommendation 3 to determine how the results of food safety assessments will be used by FSIS in estimating establishment risk.
- OIG Recommendation 12 to develop and implement criteria for prioritizing the scheduling of food safety assessments.
- OIG Recommendation 13 to develop and implement criteria for conducting periodic reevaluations of an establishment's food safety system to assess its progress after an initial food safety assessment.
- OIG recommendation 14 to develop and implement a system to track changes at an establishment over time and determine which changes will trigger FSIS to conduct a food safety assessment at an establishment prior to its periodic reevaluation.

2.1.6 Training

Training and education of the FSIS workforce is a cornerstone of public health protection. Training enables inspection program personnel to make sound and effective regulatory decisions based on appropriate scientific and public health principles. One of the Agency's top priorities, therefore, is to aggressively train and educate our workforce.

Phase 1

To ensure that high quality data is collected, FSIS is developing comprehensive training for all IP who will use PHIS. PHIS training modules will be provided by the Office of Outreach, Employee Education and Training (OOEET). Training will be classroom based with an FSIS instructor. Training will include: new directives, proper NR documentation, conducting the Hazard Analysis Verification (HAV) task, and interpretation of establishment test results. In addition to the topics already mentioned, the Domestic training topics will include introduction to PHIS and the establishment profile, overview of policy changes, and a basic review of microbiology.

IP and supervisors will be trained together. The training will be interactive, with workshops and scenarios as well as practice in using PHIS on the computer. IP will learn the policy as well as the navigation and data entry into the computer. The training will include an emphasis on gathering and assessing information, asking questions to determine compliance / noncompliance, documentation, and enforcement. The training on the Domestic Module is estimated to take two weeks, including travel time. Inspectors will be provided with laptops to use during the training to learn the "click-by-click" part of interacting with PHIS.

Specific ongoing training will be provided to all analysts (both at HQ and in the field) on how to use the analytical tools provided by PHIS, how to find the appropriate data, and how to use them effectively.

Phase 2

Following PHIS implementation, FSIS will evaluate whether PHIS training has been effective with regard to data collection quality and, in doing so, will identify future training needs for PHIS users.

FSIS' PHIS training plan addresses the following NAS and OIG findings:

- NAS Finding 4.1 to strengthen the oversight of the writing of NRs and improve the training of IP with special emphasis on quality and consistency of NRs.
- OIG finding 21 to provide ongoing training to district analysts on new or modified software and specific analytical techniques, including the type of data to collect, standard types of analysis to perform, format to present data, frequency of reporting the results, and follow-up actions the analysts are expected to take on any adverse issues noted. Also, establish a system to track when training is taken, the type of training taken, and a system to alert the appropriate managers if the minimal levels of training are not being achieved.
- OIG finding 34 to reassess the effectiveness of training programs for inspection personnel and frontline supervisors and revise the programs, as appropriate.
- OIG finding 35 to provide refresher training, at a minimum, to the inspection personnel and frontline supervisors assigned to the establishments with the recalls.(Note: Initial retraining of these personnel was completed between October and December of 2007.)

2.2 External Data Sources

FSIS conducts inspection at all meat and poultry slaughter establishments as required by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA). These slaughter and processing establishments represent the midpoint in the overall farm to fork continuum. In order for FSIS to maximize its impact on improving public health, it is therefore necessary to collaborate with other food safety agencies. FSIS coordinates with other food safety agencies through data sharing agreements and collaborative workgroups. FSIS has worked closely with other federal food safety partners in developing the Agency's strategic plan and annual performance goals.

One of FSIS' primary performance standards for the USDA Strategic Plan for 2010-2015 is the All-Illness Measure, which is a measure of the total number of *Salmonella*, *E. coli* O157:H7 and *Listeria monocytogenes* illnesses from FSIS-regulated products. To calculate objectives and goals for this measure and determine FSIS progress in meeting these objectives and goals, FSIS relies on CDC illness data to calculate foodborne illness attribution and determine FSIS progress in meeting objectives and goals. To properly utilize this data and refine the attribution methodology, FSIS has been meeting regularly with staff from the CDC since early FY 2010. These meetings have been highly productive and useful in refining the attribution methodology and incorporating new data sources not previously explored.

FSIS is also working closely with the CDC and FDA to develop High Priority Performance Goals (HPPG) for *Salmonella*. Staffs from FSIS and FDA communicate on a regular basis to develop the HPPG, as the goals are closely intertwined and require a coordinated effort. Consequently, FSIS and FDA are working to ensure that the goals complement one another, utilize the same datasets, and cover the same time period. FSIS is also working closely with the CDC to ensure that timely, accurate data will be available to measure progress in meeting the HPPG. Specifically, FSIS and FDA are working closely with CDC FoodNet staff to develop a timeline in which CDC will provide quarterly FoodNet case rate updates for both *Salmonella* and *Salmonella enteritidis* to both Agencies so that each Agency can measure progress in meeting their goals. To ensure consistency and accuracy, FSIS, FDA, and CDC technical staff will continue to meet to review the data being provided by CDC, discuss the methodology used to derive the estimates, and review the limitations of the dataset to ensure shared knowledge and understanding.

In developing the HPPG, FSIS frequently participates in joint meetings with OMB and FDA to ensure that the Agencies use a consistent approach when developing and reporting the HPPGs. FSIS has received feedback from OMB during these meetings and is seeking to include that feedback in the Agency's HPPG, such as common language used by both Agencies that describes how they are working together to reduce *Salmonella* exposures in the population.

To further enhance its approach to data-driven inspection, FSIS is working with these agencies to develop automated methods of sharing and integrating food safety data. Having access to this information via PHIS for analysts and FSIS management will aid decision making, resource allocation, and foodborne illness investigations.

Phase 1

In Phase 1, FSIS will work with other Agencies to integrate real-time feeds of the following data streams into its data infrastructure:

- Subtyping data on human illness outbreaks from the Centers for Disease Control and Prevention (CDC)
- FSIS product testing pathogen subtyping information from the Agricultural Research Service (ARS)
- Product laboratory testing results taken in FSIS-regulated establishments under the National School Lunch Program by the Agricultural Marketing Service (AMS)
- Laboratory data from State inspection programs that are considered equal to FSIS
- Industry data (as available)

These data feeds and their use are discussed further in the sections below.

2.2.1 Centers for Disease Control and Prevention

FSIS has amended an existing Memorandum of Agreement (MOA) with CDC to facilitate real-time data sharing. This MOA provides access to the PulseNet information on human illnesses and outbreaks. PulseNet is a national network of public health and food regulatory agency laboratories coordinated by CDC. The network consists of state health departments, local health departments, and Federal agencies (CDC, FDA, and FSIS). PulseNet labs perform standardized molecular subtyping (or "fingerprinting") of foodborne disease-causing bacteria by pulsed-field gel electrophoresis (PFGE). PFGE can be used to distinguish strains of organisms such as *Escherichia coli* O157:H7, *Salmonella*, *Listeria monocytogenes*, or *Campylobacter* at the DNA level. These DNA "fingerprints," or patterns, are submitted electronically to a database at the CDC.

Access to these data in the past has been limited to a manual process of logging into the CDC system. In Phase 1 this MOA has been amended to provide for integrated sharing of data. Under this agreement CDC PulseNet data will flow directly to FSIS in an automated manner and be available for use in analyses such as traceback investigations, prevalence studies, and attribution calculations. The PulseNet data collected by CDC that will be available to FSIS analysts includes items as shown in Table 2.

Field Name	**Description**
Key	A unique number that identifies the sample
IsolateDate	Date the isolate was collected
LabID	Laboratory identification number
Outbreak	Code assigned by CDC if the sample is deemed to be part of a named cluster of disease cases
PFGE pattern	PFGE pattern found in the sample
Serotype	The pathogen subtype found in the sample (O157:H7, Montevideo, etc.)
SourceSite	Type of Product (i.e. ground beef, beef trim, veal)

SourceState	State where the isolate was collected

Table 2: Fields Available in CDC PulseNet Data

The subtyping data will be provided to FSIS-regulated establishments in the *Salmonella* End of Set Letters. FSIS intends to amend those letters to contain information about the serotypes found in product testing and how commonly the serotypes cause human illnesses. Another use of this data will be in food safety investigations. Access to real-time human illness and product serotype data will facilitate more effective outbreak investigations by FSIS. In addition, FSIS will make analytical tools such as the t-cube web interface (discussed in section 3.4) available to CDC personnel and to the PulseNet partners at the State public health labs. This information sharing will improve their partners' data collection and therefore benefit overall food safety in the United States. This data sharing also supports the President's Food Safety Working Group (FSWG) initiatives for Federal agencies to work more closely together to protect the public from foodborne illness.

2.2.2 Agricultural Research Service

FSIS has amended its existing data sharing agreement with the Agricultural Research Service (ARS) to support timely data exchange. This MOA provides access to the VetNet data on *Salmonella* serotypes found in FSIS meat and poultry isolates. It also provides access to the National Antibiotic Resistant Monitoring System (NARMS) data on antibiotic resistance of these isolates. The objectives of the VetNet system are to: determine PFGE patterns of *Salmonella* isolates submitted to NARMS, compare USDA VetNet and CDC PulseNet PFGE patterns, and use the comparative data for surveillance and investigation of food-borne illness outbreaks.

For Phase 1, FSIS has worked with ARS to update this agreement. The revised agreement provides automated data flows to FSIS, allowing for ongoing analysis and use in modeling. FSIS will make data analysis tools such as the t-cube web interface (discussed in section 3.4) available to ARS researchers. The combined VetNet and NARMS data that will be available to FSIS analysts includes items as shown in Table 3.

Field Name	Description
Key	A unique number that identifies the sample
IsolateDate	Date the isolate was collected
LabID	Laboratory identification number
AntigenForm	Antigen form if present
ARS-pattern	ARS generated PFGE pattern
ARS-CDC-match	Pattern match between ARS-CDC
Resistance (one field for each antibiotic tested)	Interpreted results (resistant, susceptible, or indeterminate)

Table 3: Fields Available in VetNet and NARMS Data

2.2.3 State Laboratory & Inspection Data

Currently, there are 27 State Meat and Poultry Inspection (MPI) Programs that impose mandatory inspection and sanitation requirements that are "at least equal to" those in the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Humane Methods of Slaughter Act. These State MPI Programs are inspected by State personnel, who record their own noncompliance and laboratory data. Some of these States have used the FSIS PBIS system in the past for collecting this data but their laboratory data was processed in other non-FSIS systems. FSIS intends to offer to the States the ability to use PHIS to maintain establishment profile information, schedule inspection tasks and food safety assessments, record their inspection and food safety assessment findings, handle appeals, record animal dispositions, and create and manage their own resource management information.

2.2.4 Agricultural Marketing Service

FSIS has shared data on establishments providing products to the National School Lunch Program with the USDA's Agricultural Marketing Service (AMS) for many years. FSIS and AMS have formalized this data sharing in an MOA and plan to expand the sharing of this information. FSIS plans to work with AMS to receive more timely flows of data from AMS contract labs. As shown in Figure 3, the AMS data will be integrated into the FSIS data warehouse and used alongside data collected by the FSIS inspectors and labs. This integration of data will allow for automated analyses of the data, provide alerts, automated scheduling of lab and inspection procedures, real-time monitoring of management controls, and automated reports. Both agencies will use the results to improve communication, inform better decision making, allocate resources more effectively, and respond to events more quickly.

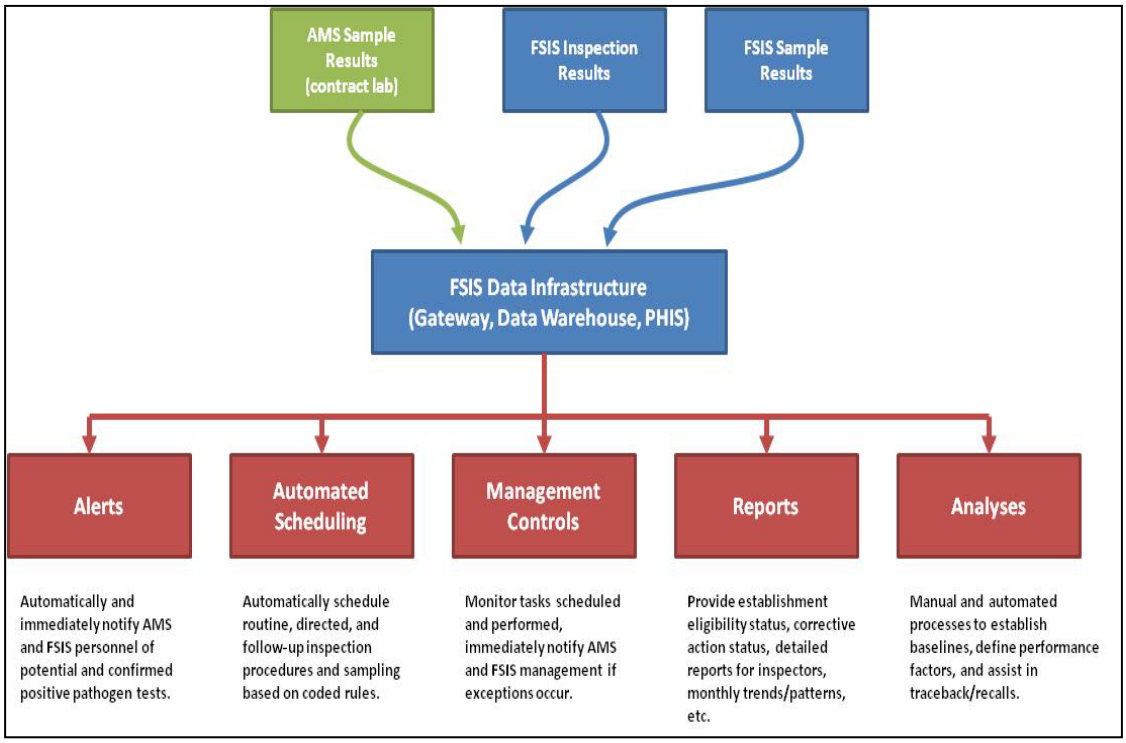

Figure 2: Diagram of AMS and FSIS Data Infrastructure

Phase 2

In Phase 2, FSIS will identify additional data sources that can be integrated into its data infrastructure to support data-driven decision making. One specific data source that FSIS will consider is industry laboratory testing data. FSIS believes that industry data could be used to supplement FSIS data or provide more detailed information on other pathogens or indicator organisms in FSIS-regulated products.

2.2.5 Industry Data

FSIS has a demonstration project underway to examine the utility of industry data for FSIS decision making. The program, known as the *Salmonella* Initiative Program (SIP), is voluntary and provides industry waivers for Category 1 establishments in return for submission of industry pathogen testing results to FSIS. Establishments participating in SIP are required to submit their *Salmonella*, *Campylobacter*, generic *E. coli*, and serotyping information to FSIS as outlined in Federal Register Notice Vol 73, pp 4767-4774. FSIS will analyze the data from SIP to inform Agency policies and programs. Other programs for industry data collection may be explored in the future.

FSIS' plan to evaluate the utility of industry data for its data-driven approach to inspection addresses the following recommendations from the NAS:

- NAS comment 2.4 to take advantage of data for other potential process indicators generated by industry or others.

- NAS comment 3.8b to consider analyzing industry data on *L. monocytogenes* or *Listeria* spp. in the environment and/or *Listeria* spp. on food contact surfaces or in the final product to determine whether these data could serve as a useful indicator of process control.
- NAS comment 5.5 to investigate the potential utility of industry data on generic *E. coli* as an indicator of process control.

2.3 Pathogen Testing Programs

A major source of data FSIS uses to inform its inspection activities comes from its laboratory verification sampling programs. The sampling programs provide data regarding *Salmonella* in raw products; *E. coli* O157:H7 in raw ground beef or its components; *Listeria monocytogenes* or *Salmonella* in ready-to-eat (RTE) products; and *Salmonella* in processed egg products. However, FSIS recognizes these sampling programs have significant limitations for deriving estimates of pathogen prevalence in FSIS-regulated products. Pathogen prevalence estimates are a critical input to assessing trends in industry performance and enabling data-driven decision-making and policy. Developing a robust methodology for estimating prevalence requires using risk-based and probability-based sampling information appropriately and is dependent upon the proper design of the sampling programs. To strengthen the utility of its sampling program results for prevalence estimation and decision making, FSIS is implementing a number of enhancements through PHIS. These enhancements will improve the rate of collection for sampling programs and ensure proper sampling frames are established and followed. In addition, FSIS is examining the Type I and II errors (false positives and false negatives) associated with its sampling programs in order to take proper account of those rates in decision making and analysis. FSIS is continuing to work with ARS and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to identify new sampling methodologies. The subsections below discuss the sampling programs and the changes being proposed in more detail.

Phase 1

2.3.1 Ongoing Baseline Programs

FSIS recognizes the importance of timely and accurate estimates of pathogen prevalence in order to assess trends in the industry, make informed policy decisions, and measure performance toward meeting the Healthy People goals. Traditionally, FSIS has used baseline studies to derive estimates of pathogen prevalence in FSIS-regulated products. This data is then analyzed to establish performance standards for industry. “Traditional” baselines are conducted on different commodities each year to cover the range of products FSIS regulates. Traditional baselines for any one commodity are often conducted many years apart. For example, the last baseline study in raw ground beef was conducted in 1994. In that baseline, roughly 600 samples were analyzed and FSIS found no *E. coli* O157:H7 positives limiting the utility of that baseline in current FSIS inspection of raw ground beef. Furthermore, these “traditional” baseline studies are fixed-time surveys, usually one year in duration, not designed to observe changes over longer periods.

Due to increased FSIS, consumer, and industry attention to control of *Listeria monocytogenes (Lm)* in Ready-To-Eat (RTE) products, *Salmonella* in raw meat and poultry products, and *E. coli* O157:H7 in raw beef products, the incidence of *E. coli* O157:H7 and *Lm* are statistically low.

Determining the true rates of prevalence can therefore require large numbers of samples. The design of traditional baseline studies does not generally include enough samples to provide precise statistical measures of prevalence given this low rate of occurrence.

The concept of "ongoing" baseline programs has therefore been proposed to meet this need. "Ongoing baseline programs" refers to the application of randomly based, continuous sampling methodologies to FSIS verification sampling programs thereby embracing many of the concepts of traditional baselines. FSIS has critically evaluated its existing verification testing programs and developed proposals to either 1) improve their design so that they can be appropriately used to estimate pathogen prevalence in FSIS-regulated products (while maintaining their existing verification capacity) or 2) to create new sampling programs that provide ongoing baseline estimates of pathogen prevalence for selected organisms in FSIS-regulated products.

Under this initiative, both traditional and ongoing baselines will continue to be part of the Agency's overall sampling strategy. Traditional baselines will be used to estimate pathogen prevalence of new classes of products and/or in new species and collect data on indicator organisms including quantitative data on each organism, where possible. Traditional baselines will also continue to be used to provide enhanced data for use in risk assessments and other specialized Agency needs. In comparison, ongoing baseline programs will be used to estimate pathogen prevalence in FSIS-regulated products in the major product categories for which FSIS currently does verification sampling activities

The paragraphs below outline the changes to FSIS laboratory verification sampling programs in order to derive prevalence estimates for pathogens on regulated products.

E. coli O157:H7: The current sampling program (MT43) for measuring *E. coli* O157:H7 in raw ground beef already encompasses several characteristics of an ongoing baseline program. For example, this program randomly samples all establishments in a stratified manner and is designed to sample each establishment multiple times per year. It does however include some sources of potential bias such as limits on the number of samples that can be taken and some potential announcement bias issues. "Announcement issues" refers to the potential for establishments to adjust production practices to make it less likely to detect the target pathogen in response to an upcoming sampling activity.

FSIS currently uses a volume weighted percent positive rate as its measure of product contamination. At the end of FY 2009, the volume weighted percent positive for *E. coli* O157:H7 in raw ground beef as measured by the FSIS sampling programs was approximately 0.32%. The FSIS 2013 performance objective is a percent positive less than 0.16%. The current number of samples taken under this program may be inadequate to measure these rates with sufficient precision to make public health based decisions. Therefore FSIS will continue to look at sample numbers with a goal of improving their statistical relevancy. FSIS is considering sample sizes intended to measure volume weighted percent positive rates with an confidence interval of ±50% of the 2013 performance objective. FSIS has requested additional funding in the FY11 budget request to collect and analyze any additional samples required. Increased sampling could also have an effect on in-plant personnel and establishment production that must be considered. FSIS

intends to work with industry to minimize these effects while still providing enough samples to better characterize prevalence and meet Agency goals.

Salmonella and *Campylobacter*: The current *Salmonella* in raw products sampling program has several design issues that make it unsuitable for measuring prevalence rates. These limitations include 1) FSIS sampling exclusion periods for better performing establishments, 2) FSIS sampling exclusion criteria for low production volumes, and 3) announcement bias related to sampling in the form of consecutive sets.

FSIS plans to develop a new sampling program for *Salmonella* that would be better designed for prevalence estimation and measuring FSIS performance. This program would consist of randomly scheduled individual samples and would include all raw product categories. This program is expected to include all plants that produce the 8 raw product classes subject to sampling for *Salmonella*. It is likely that sampling would be stratified by production volume.

FSIS also intends to institute a testing program for *Campylobacter* in young chickens (broilers) and turkeys. It is anticipated that for both the current PR/HACCP testing and the new ongoing baseline testing, the same sample taken for *Salmonella* testing (rinsate/swabs) would also be tested for *Campylobacter*. The *Campylobacter* laboratory test is designed to be both qualititative (i.e. positive/negative) and quantitative (i.e. amount) and will further inform the Agency about the presence of this pathogen. Traditional baseline studies have already been conducted to determine the prevalence of *Campylobacter* in these products. The results of these studies have been used to propose performance standards for this pathogen and also update the performance standard for *Salmonella* in broilers and turkeys. These standards were published in a May 14, 2010 Federal Register Notice (Vol. 75, No. 93). The implementation of an ongoing baseline for *Campylobacter* would enable FSIS to assess changes in prevalence in subsequent years. Specific sample sizes for *Campylobacter* testing have not been calculated at this time. When performance objectives based on human illnesses or case rates are set for *Campylobacter*, FSIS will reassess the sampling needs for *Campylobacter*.

The new *Salmonella* and *Campylobacter* performance standards under public review will be used to define new criteria for performance categorization of establishments and drive continuous improvements in process control. PHIS will calculate categorizations for establishments based on these new standards.

Listeria monocytogenes in Ready-to-Eat products (RTE): The current *Listeria monocytogenes* sampling programs have some design issues that need to be addressed in order to make them suitable for ongoing baseline studies. Two programs, RTE001 and ALLRTE, are currently in use to sample intact finished products for *Listeria monocytogenes*. These two programs have a high degree of overlap in their coverage both of establishments and product types. But these two programs are scheduled differently and have some differences in the products sampled which presents problems for combining the data. These programs may also be subject to some announcement bias issues and possible biases in the collection of samples for the two programs.

Changes to these programs are being proposed in order to meet the design objectives of an ongoing baseline study and address these limitations. One change being considered is unifying

the two programs. The unified *Listeria monocytogenes* sampling program would 1) include all product categories of RTE and 2) continue to allocate more samples to higher risk products and establishments. Additional samples would be introduced as well in order to achieve an improved level of precision for assessing sampling results against Agency goals. Merging these two programs and ultimately initiating a new combined sampling program would require public notice and comments from the public prior to implementation.

2.3.2 Type I and II Errors

Sampling is by nature a subset of all the possible samples and therefore has some level of uncertainty in the measurement. When using FSIS verification test results for measuring Agency performance and data-driven decision making, FSIS recognizes the importance of measuring and understanding the overall uncertainty of those sample results. Type I errors are false positives (i.e. the sampling produces a positive result when no pathogen was actually present) while Type II errors are false negatives (i.e. the sampling returned a negative result when in fact a pathogen was present). Statistically the rates of type I and II errors determine the specificity and sensitivity of the methods, respectively. To determine the magnitudes of these errors, it is necessary to have some idea of the true underlying distribution of the entity being sampled.

Understanding Type I and II errors is important for proper interpretation of sample results. It is also necessary for gauging the significance of any single positive or negative test result. Note that in this context the Type I and II errors are a measure of the overall sampling program – not just the laboratory analytical method. For the FSIS sampling programs the overall Type I and II errors are due to a combination of sampling program design, data used in sample frame selection, sample collection methodology, and laboratory test performance. FSIS does not at this time have good estimates of its Type I and II errors which are representative of this entire process.

<u>Phase 1</u>
In phase 1 FSIS intends to look for ways to measure the Type I and II errors of its sampling programs. Statistical analyses will be performed on available sources of information (including industry sampling data if available) to estimate the error rates. FSIS is also considering specific tests, such as repeated analysis of single samples, to measure contamination uniformity and enhance estimation of these errors. Once properly assessed, measurements of the errors may be published in reports that provide sampling program results. They will also better inform decision making and improve future sampling program design.

FSIS' proposed changes to its sampling plans address the following recommendations from the NAS and OIG:

- NAS comment 3.1 to describe the characteristics of the microbiological criteria being used as determinants of loss of process control including in-depth consideration of the statistics underlying the specific microbiological testing protocols used and the assumptions that are made in using such data.
- NAS comment 3.7 to provide a more in-depth description of the sampling and testing statistics that are the basis for the *Salmonella* verification testing program.

- NAS comment 3.11 to provide a more in-depth description of the sampling and testing statistics that are the basis for *L. monocytogenes* regulatory testing programs.
- NAS comment 3.12a to provide a more in-depth description of the sampling and testing statistics that are the basis for the *E. coli* O157:H7 regulatory testing program.
- NAS comment 3.13a to provide a more in-depth description of the sampling and testing statistics that are the basis for the *Salmonella* and *E. coli* O157:H7 testing programs including the magnitude of Type I and Type II errors and the specificity and sensitivity of the microbiological protocols.
- OIG finding 8 to develop and implement at least an annual process to verify how establishments control Lm in RTE product and that establishments report when there is a significant change in the method they use to control Lm or volume of product they produce.
- OIG finding 23 to provide pathogen test results data in a searchable format to the appropriate district office personnel.

Phase 2

FSIS will further examine its laboratory sampling programs in order to determine what additional sampling methodological changes need to be made to FSIS programs in order to enhance the use of sampling program data for prevalence estimation. Based upon its development of ongoing baseline studies in phase 1, FSIS will evaluate in phase 2 how often industry performance standards should be regularly updated. FSIS will also evaluate how additional information about establishment and product risk can be incorporated into sampling programs (e.g. serotype information from FSIS testing programs). In addition, FSIS will explore how enhanced testing methodologies can be employed to reduce Type I and II errors and how measurement procedures be made more accurate and standardized.

3.0 DATA ANALYSIS

As described in FSIS' Public Health Decision Criteria Report, the Agency has defined criteria that identify establishments warranting heightened inspection attention. This may be because they are not in compliance with specific Federal regulations, have tested positive for pathogens considered adulterants, or are performing worse than their peers. FSIS intends to continue to refine its decision criteria through further data analyses as more data becomes available to the Agency. To support its proposed decision criteria and to inform inspection activities in a dynamic fashion FSIS has developed a data infrastructure that supports zero-latency data analysis. The data is collected and analyzed in real-time. As soon as enough data has accumulated to make a decision the system acts on it or presents it to a user for action. The data infrastructure will provide real-time alerts and notifications, automated scheduling, management controls, and automation of FSIS rule sets, such as the Public Health Decision Criteria. The criteria and other data analysis topics are discussed in more detail below.

3.1 Public Health Decision Criteria

FSIS is using a decision tree approach based on decision criteria to identify processing and slaughter establishments that will receive additional inspection activities to ensure process control is being maintained. The decision criteria were selected to identify establishments that:

- have produced product that tested positive for pathogens known to cause human illness;
- are not in compliance with specific Federal laws and regulations; or
- are performing worse than their peers with respect to FSIS inspection findings.

Phase 1

FSIS uses the Public Health Decision Criteria to prioritize and schedule Food Safety Assessments (FSAs) currently and Hazard Analysis Verification (HAV) procedures with the implementation of PHIS (the decision criteria are described in the Public Health Decision Criteria Report). Under Phase I, FSIS has defined the basis for selection of the decision criteria, determined the decision criteria, shown that the decision criteria can be linked to public health impacts, and applied the decision criteria to a set of FSIS data to demonstrate applicability of the criteria. Review of the data needs for application of the decision criteria (e.g., verification testing data, inspection non-compliance data, enforcement actions, establishments linked to disease outbreaks) revealed that while the data FSIS currently collects are sufficient for this purpose, changes in data collection and utilization could improve the timeliness, quality and usability of the data. As a result of this analysis, PHIS was developed to introduce improvements to the quality of FSIS data collection through 1) revised forms to aid Inspection Personnel (IP) in the entry of better quality information, 2) electronic forms for improving data collection from Food Safety Assessments, 3) monthly checks on the accuracy of data in the establishment profile, 4) an infrastructure that ensures data collected are fully available and organized for analysis, 5) training of inspection personnel on the collection of quality data, and 6) access to reference and historical information.

Phase 1 addresses the following NAS recommendations:

- NAS comment 2.1 to improve transparency and clarity of the description of the decision tree approach and the scientific basis and analysis of the data used.
- NAS comment 2.2 to clearly define all terms used in developing the decision tree approach.
- NAS comment 5.1 to include foodborne disease outbreaks linked to FSIS-regulated establishments as a decision criterion.
- NAS comment 5.2 to include enforcement actions resulting from a failure of process control as a decision criterion.
- NAS comment 5.3 to only include health-related recalls and enforcement actions as decision criteria.

Phase 2

In Phase 2, FSIS will (1) refine its decision criteria and (2) through multivariate analysis attempt to identify establishment performance parameters that are predictive of public health impacts. FSIS will conduct further analyses to continue to refine its decision criteria as recommended by NAS (8.1). The Agency will evaluate whether additional decision criteria are necessary and whether existing criteria need to be modified [e.g. Non-compliance Record (NR) cutpoints). FSIS will also examine whether additional data sources can be incorporated in the criteria (e.g. industry, State laboratory and inspection findings.) This evaluation will address the following NAS recommendations:

- NAS comments 5.5 and 5.6 regarding additional decision criteria data sources.

3.2 Predictive Models

One significant finding from the NAS report was that FSIS had not demonstrated that the models being proposed were predictive in nature. NAS came to the conclusion that several improvements were needed in the collection and utilization of FSIS data. While FSIS agrees that current data and approaches do not support a predictive model, the Agency intends to continue exploring their development. Consequently, FSIS developed a proposal to improve its data collection and utilization infrastructure and these improvements are addressed in the previous sections of this report. However NAS also questioned the models themselves including the choice of factors for input and the metrics being used to measure their predictive power. FSIS analyzed these comments from the NAS report and is currently improving the models in parallel with the data improvements noted above. These improvements to the models are discussed below.

Phase 1

While PHIS and the other data improvements noted here were being put into place FSIS began developing a revised set of models. These models were run extensively to assess their predictive power; however the improvements discussed above were not in place therefore these analyses were limited to using the data from the legacy systems. The data was divided into two sets: one for training the models and a second for testing their predictive power. Subject Matter Experts (SMEs) were polled to identify the points in the data likely to provide some predictive power. These SMEs were chosen from FSIS Senior Staff. Input from the NAS report findings was also used to identify the input parameters. These inputs to the models were called the “behaviors”.

These behaviors included having an NR for fecal contamination, high rates of NR with public-health significance (W3NR), or having a positive *Salmonella* test with a serotype of human health concern. These input behaviors are shown in the columns of Figure 2 below.

In addition, FSIS used the NAS report findings and the input of the SMEs to develop a list of "events" that are desirable for the models to predict. These events are negative occurrences that all establishments should avoid, including having a positive lab test for *E. coli*. O157:H7, recalling product, and being placed in *Salmonella* category 3. Being able to identify establishments at risk of these events would allow FSIS to reallocate resources or intervene in some other manner to prevent them happening. The events to be predicted are shown as the rows of Figure 3 below.

A variety of different statistical methods were employed to develop and assess models using the behaviors as input and attempting to predict the risk of the events. In some cases univariate regression was used and in other cases multivariate logistic regression was used. The colors of the cells in Figure 3 reflect the statistical method employed for that combination of behavior and event. For some combinations it was not possible to develop any model relating the behavior and the event. In some cases this was due to insufficient data while in other cases the behavior and events were too closely related. These cells are left white in the figure.

Some of the analyses were tightly guided by the SMEs and the NAS findings while others were allowed to utilize the data to determine the best set of input events on their own. In particular, the multivariate logistic regression analyses shown in the last row of the table (yellow cells) in Figure 3 were allowed to assess the predictive power of any regulatory citation within an NR (and all possible groups of citations). There were more than 13,000 possible combinations that the model had to assess.

Behaviors / Events	NR				Positive Pathogen Test					
	Fecal NR	Sanitation NR	HACCP NR	W3 NR	Salmonella	E.Coli	Lm	Recall (Public Health)	Serotype of Human Health concern	NOIE
E. coli O157:H7 on ground beef or raw ground beef components	+	+		+				+		+
Lm, Salmonella or E. coli positives in RTE or positive Lm contact surface		+					+	+		+
Public health recall				+		+	+			+
NOIE				+	+	+	+	+	+	
STEPS entry as sole supplier or more than 2 times in past 120 days	+	+		+		+		+		+
Salmonella category three	-	+			+				+	+
Salmonella percent positive rate				+	+				+	+
Salmonella serotype of human health concern (top 20)				+	+				+	+
Human illnesses linked to FSIS regulated establishment										
Public Health NR rate (W3)					+		-?		+	+

Legend

- Multivariate Logistic Regression
- Univariate Logistic Regression
- Differences in data split by Events
- Differences in data split by Behaviors
- Differences in data split by Category
- Not Evaluated

+/- : significant relationship found
colored blank : no significant relationship found

Figure 3: Matrix of Input Variables and Future Negative Events

The cells that contain a plus (+) or minus (-) indicate areas where the models demonstrated some predictive power. A plus sign indicates that the behavior predicts an increased risk of the event and a minus indicates a reduced risk. In many cases the models assessed were not able to derive a significant relationship (cells that are colored but have no plus or minus). None of the models assessed demonstrated strong predictive power. This is to be expected given the shortcomings in the data that have been noted. There were however enough results with some evidence of predictive power (the plus signs) to indicate that the development of predictive models may be possible once improvements have been made.

Phase 2

As the improved data and analyses outlined in this report are implemented, FSIS will assess the collected data and conduct further predictive analyses using the techniques outlined here and in the NAS report. All new data, such as the expanded information available in the Establishment Profiles, will be evaluated as inputs to the models. The models will be reviewed by SMEs for logical causative links with the eventual goal being a system that ties the input data to objective measures of improved public health. Any models found to have significant predictive power and causative links will be reviewed with stakeholders and considered for use in the decision criteria.

FSIS' implementation of the Public Health Decision Criteria and Predictive Models addresses the following OIG findings:

- OIG finding 4 to conduct and document analyses that support the data windows selected for each of the components in the risk control measure, which assesses an establishment's ability to control risk.

- OIG finding 5 to ensure that the basis for decisions made regarding the components included in the risk-based inspection program are thoroughly documented and evaluated with limitations mitigated and are transparent to all stakeholders.
- OIG finding 7 to determine why NRs were not correctly accounted for (i.e., one counted twice and one omitted) when calculating an establishment's level of inspection. Implement the necessary controls to ensure that these types of errors do not occur and that data are complete and accurately processed.
- OIG finding 9 to include the enforcement action "NOIE Under Deferral" in the calculation.
- OIG finding 10 to validate the accuracy of the risk-based inspection data (e.g., species, product type, public health NRs, and control of Lm in RTE product) used for calculating an establishment's level of inspection.

3.3 Attribution

FSIS has been meeting regularly with staff from the CDC to develop and refine attribution methodology. FSIS currently uses CDC illness outbreak data associated with single food products to estimate foodborne disease attribution. This method is the same as that used by CDC in its annual publication of the number of human outbreak illnesses due to specific food products.

Phase 1

FSIS uses foodborne disease attribution estimates to 1) identify FSIS-regulated food items that are major contributors to human disease, 2) estimate annual number of illnesses from FSIS regulated products, and 3) measure progress in meeting established performance goals including 2010 Healthy People Goals and the future 2020 goals.

In Phase I, FSIS has relied on a methodology outlined in Painter et al. (2009) and Pires et al. (2010) to develop attribution estimates based on CDC illness outbreak data for single food products. Outbreak data is used to estimate attribution since it is one of the few datasets where the food item causing an illness is identified. Simple foods are defined as those that are made from a single food category while complex foods are those whose ingredients come from more than one food category. For example a chicken breast or a cut of beef are simple food products. A beef burrito or chicken salad is a complex food product. FSIS and CDC are currently only using simple food products to conduct attribution analyses.

The complete approach used in estimating attribution is described in detail in Appendix E of the Public Health Decision Criteria Report. However, the steps can be summarized as follows: 1) obtain the CDC outbreak data for *Salmonella*, *Listeria monocytogenes*, and *E. coli* O157:H7 for the years 2001-2007; 2) separate outbreaks into those associated with complex foods and those associated with one of 15 simple food categories; 3) determine the total number of illnesses for each simple food category; 5) determine the fraction (percent) of total illnesses in each simple food category. The end result is attribution estimates for each simple food category. For FSIS, the major simple food categories of concern are beef, poultry, pork, deli products, and pasteurized egg products. These attribution estimates will be updated every 1-3 years as additional CDC data becomes available, addressing the NAS comment 8.1.

In light of the NAS comment 8.2 to work collaboratively with CDC and FDA to develop a common approach to attribution and the recommendation of the Food Safety Working Group to increase consistency across Federal agencies in attribution methodologies, FSIS is having bimonthly meetings with CDC to review and refine its attribution methodology. In addition, FSIS and the Food and Drug Administration (FDA) are jointly developing *Salmonella enteritidis* attribution estimates for poultry and egg products. This work builds off of the previously published FSIS study on attribution estimates for *Salmonella* in eggs.

Phase 2

In Phase 2, FSIS intends to (1) continue to collaborate with CDC and FDA to develop attribution estimates based on complex food products, and (2) work with CDC to develop approaches to using CDC sporadic illness data, together with FSIS verification testing serotype data to estimate attribution based on sporadic illness data. FSIS will further refine its attribution method by evaluating how complex food products influence attribution estimates, and how sporadic illness and serotype data can be incorporated in its attribution method. FSIS will also conduct analyses to characterize the uncertainty around its attribution estimates and to identify additional data sources that can be incorporated into the Agency's approach. FSIS will continue to work collaboratively with CDC and FDA to develop common approaches for estimating attribution.

FSIS' work on attribution addresses the following NAS recommendations:

- NAS comment 8.2 to work on attribution collaboratively with CDC, FDA, and other federal and state agencies to develop a common set of definitions, a coordinated approach, a process that allows for regular updating of estimates, and a standardized coding scheme for multi-component foods.
- NAS comment 10.1 to work collaboratively to use data more effectively to estimate population-based attribution of sporadic cases to specific agents.

3.4 Alerts and Reports

Two key outputs produced by PHIS are alerts and reports. Alerts are used when specific events occur that require immediate attention. An alert consists of a trigger and a notification. The trigger is a small program that automatically scans the data for a specific event and upon finding it issues the notification. The notification can take the form of an email sent by PHIS, a message on the user's PHIS dashboard, or both. Email alerts are not limited to FSIS and may be sent to personnel in partner agencies who require this type of notification. Reports are produced by the system for less time sensitive information and generally include aggregated data representing a period of time rather than a single specific event. Reports can be scheduled to automatically run at a set frequency (monthly, quarterly, etc.) or may be produced on demand. Reports can be created to be viewed online or offline. Online reports allow users to drill-down to underlying data if required. Reports can also be set up to flag anomalous data so that users can investigate further and take corrective action. Not only does PHIS come with a large number of alerts and reports already operational, but the system is configurable, so that new alerts and reports can be added as needed.

Examples of key events that would trigger an alert are: a large number of inspection activities not completed in an establishment, high rates of noncompliance in an establishment, and a positive pathogen test result in an establishment (e.g., *E. coli* O157:H7 in ground beef or *Listeria monocytogenes* in ready-to-eat products). Alerts can also be used to identify data entered into PHIS that might be erroneous (such as unusually high production volumes or carcass weights) or long term processes that have exceeded their schedule (such as a *Salmonella* sample set that has not been finished). The text of the alert describes the problem that triggered it and gives directions to personnel on how to respond appropriately by pointing them to the appropriate regulations and directives.

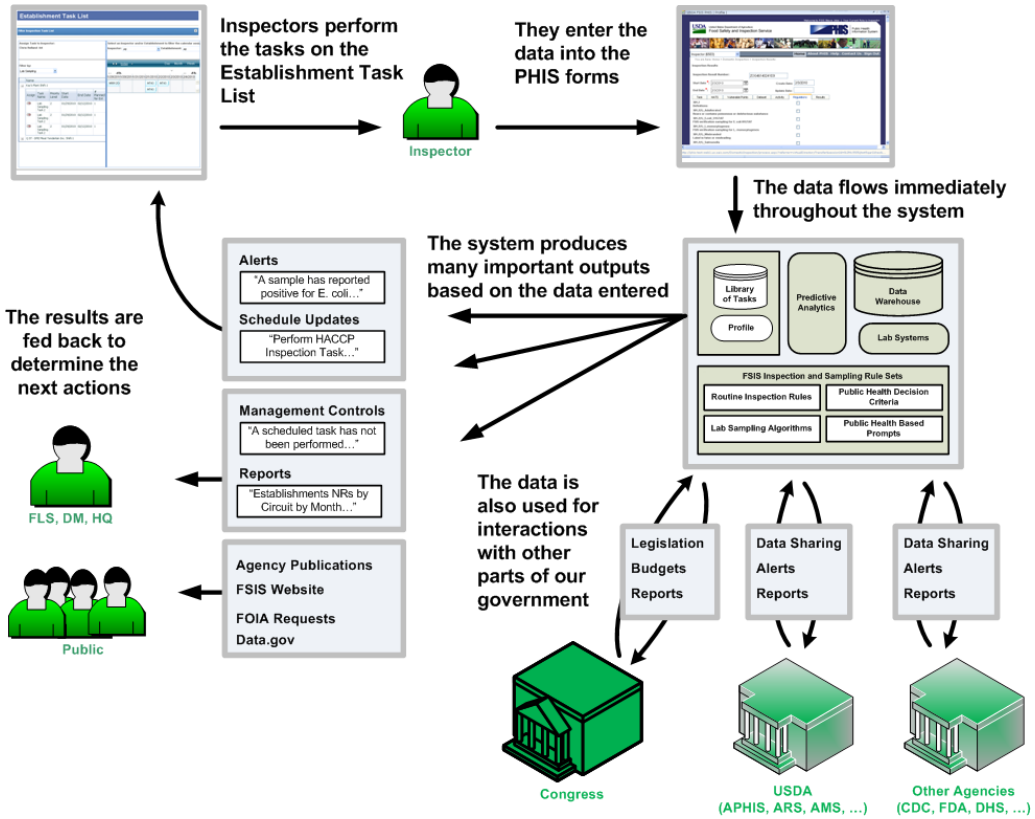

Figure 4: PHIS produces Alerts and Reports

Examples of reports include such things as monthly report of non-compliances by District, a quarterly report of performance metrics, or a yearly report of establishments in each *Salmonella* performance category. These reports are used at all levels of FSIS to manage the processes and identify areas needing corrective action. They are also used to communicate progress towards goals with other agencies and stakeholders. PHIS contains a full suite of reporting functionality capable of producing any report required. The report functionality has access to all data in the FSIS data warehouse.

<u>Phase 1</u>
FSIS has developed an initial list of alerts and reports that will be in PHIS at startup. This list consists of over 50 alerts and 100 reports. Each alert and report has been designed to include the associated directives and the follow-up actions required. Distribution lists for these alerts and

reports are being developed and put into the system. Once implemented, the functionality will be monitored and evaluated to determine that it is functioning correctly, that alert thresholds and report flags are set at the correct level, and that the correct response is being communicated.

Phase 2
In Phase 2, FSIS will examine whether additional alerts and reports are needed in PHIS and will seek input from field personnel and stakeholders. FSIS will evaluate whether correct actions are taken by FSIS personnel in response to alerts and reports

FSIS' implementation of the PHIS Alerts and Reports addresses the following OIG findings:

- OIG finding 24 to provide officials at each level with written guidance on the use of the AssuranceNet system, particularly with regard to follow-up actions and adherence to the established system thresholds.
- OIG finding 25 to establish procedures to ensure that warning "flags" provided by AssuranceNet are timely and effectively followed up on, particularly in cases in which deficiencies are repeatedly noted at the same establishment, circuit, or district.

3.5 Outbreak Investigations

PHIS will support data-driven decision making by providing analytical tools to support foodborne illness outbreak investigations. An outbreak investigation is an investigation of a possible association between human illnesses and an FSIS-regulated product. It involves collecting and analyzing data from epidemiologic, laboratory, and environmental assessments. FSIS performs foodborne illness outbreak investigations for products it regulates working closely with CDC and State public health and agricultural agencies. Suspected products are traced back to their source (traceback) and forward through the food supply chain (trace forward). Tools used in the past to perform the investigations including desktop software (Excel, etc.) and manual flowcharts were often cumbersome and not as effective as desired. The data needed for the investigations includes information collected by FSIS inspectors, investigators, and laboratories and also includes data from States, CDC and ARS. Integrating all these data without proper tools also slowed investigations.

Phase 1
In phase 1 FSIS has improved its ability to perform outbreak investigations by making data more accessible and improving the tools available for data analysis. FSIS has amended its MOAs with CDC and ARS to provide for electronic transfer of data for outbreak investigations. This allows them to be merged with FSIS data and constantly ready for use. FSIS participates in ongoing working groups with CDC and FDA where improvements to foodborne illness outbreak investigations are reviewed and coordinated.

To support improved outbreak investigations, FSIS has developed prototype network diagramming tools (not currently part of PHIS). These tools replace manual flowcharts and allow investigators to visualize the relationships between various suppliers and consignees in the supply chain. In complex investigations this tool makes the web of relationships much easier to understand and improves communication among investigators.

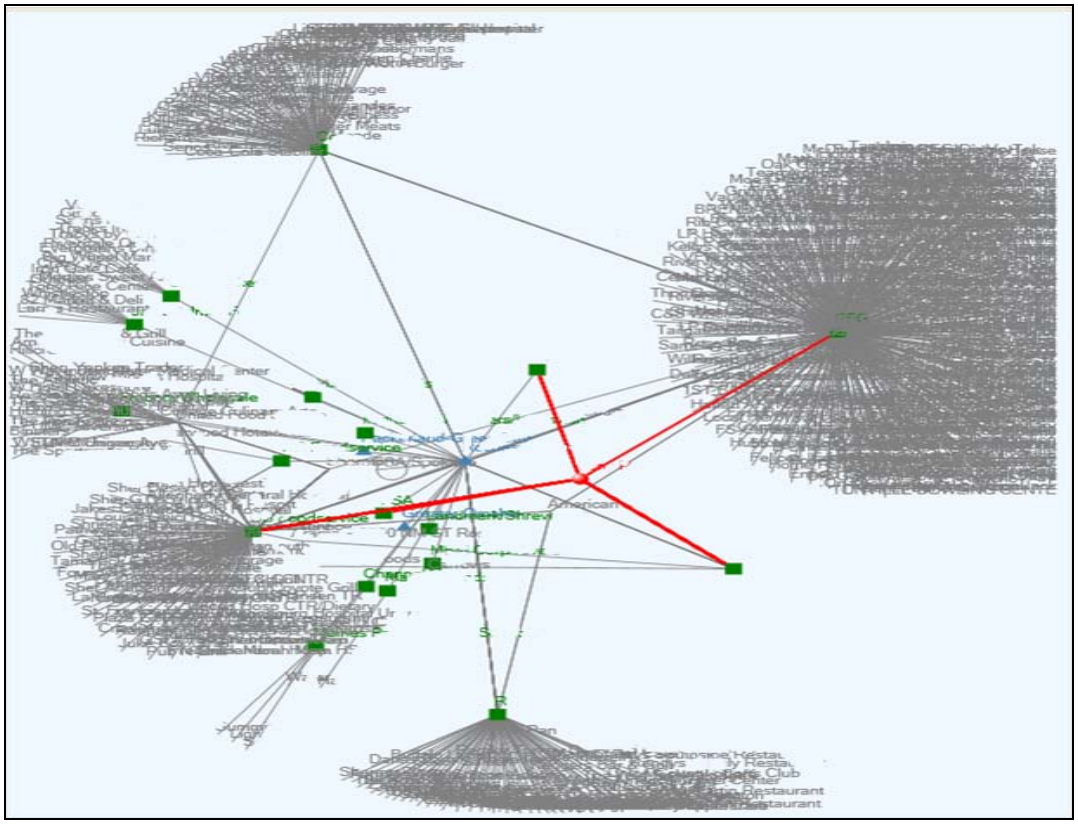

Figure 5: Network Diagram of an Actual Food Safety Investigation

Figure 5 illustrates the supplier – consignee relationships found in a single foodborne illness outbreak investigation. (Note: all readable names have been removed to preserve confidentiality.) In this example the product in question had already entered commerce by the time FSIS became aware of the problem. FSIS needed to quickly trace the contaminated product back to the source and remove the contaminated product from commerce. The green squares represent illness locations. The red lines show that four of the locations where illness occurred shared a common supplier. FSIS was able to focus the investigation at this point and much more quickly respond to the problem.

When FSIS identifies a positive *E. coli* O157:H7 sample from a grinder (ground beef producer), the Agency must quickly identify the source of all raw beef trim supplied to the grinder. These data have historically been recorded in a database called STEPS (System Tracking *E. coli* Positive Suppliers). Per FSIS Directive 10,010.1, any establishment that is listed in this database twice within 120 days is subject to additional inspection and sampling.

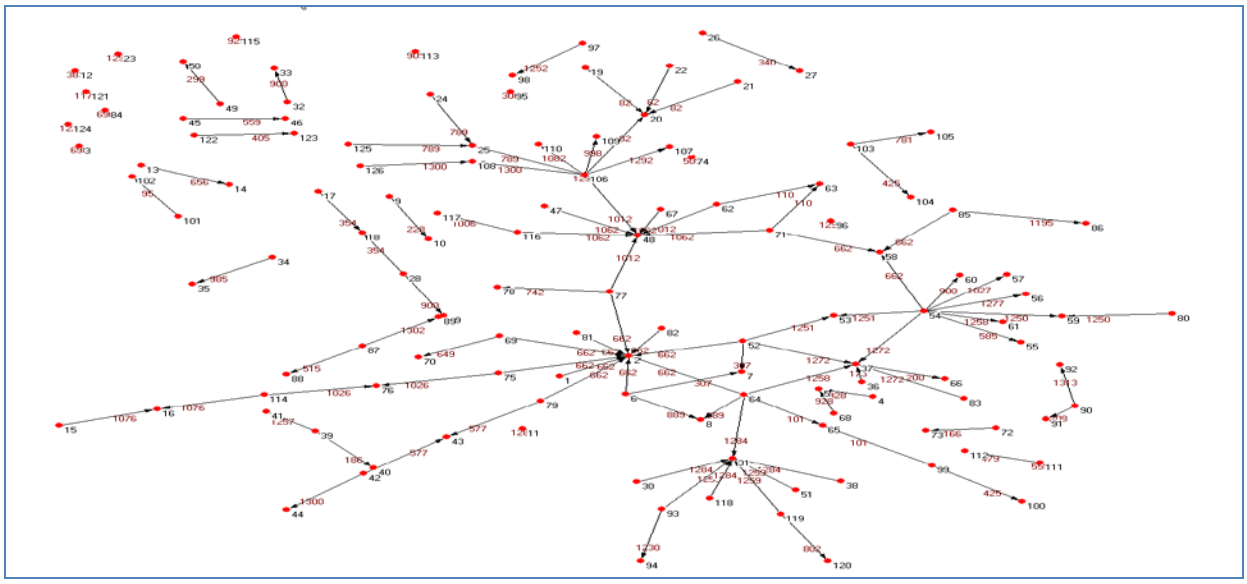

Figure 6: Network Visualization of Potential *E. coli* O157:H7 Suppliers and Receivers

Figure 6 shows the network of grinders and trim suppliers involved in potential contamination *E. coli* positive ground beef.(Note: The establishment identities in this diagram have been replaced with random numbers to preserve confidentiality.) The arrows indicate the supplier – receiver (grinder) relationship and the red numbers indicate dates (as measured from 1/1/2005). Organizing the information into a network diagram has allowed FSIS to more easily identify suppliers that appear repeatedly within the data (establishments that have large numbers of outward bound arrows) and establishments that frequently are the receivers of contaminated trim (those that have many inbound arrows).

In addition to the network diagrams, a new data structure and interface will be implemented in PHIS that allows investigators to explore data interactively. Data from FSIS, CDC, and ARS (and potentially other sources such as FDA, AMS, States, etc.) will be combined in a custom data cube known as t-cube. A data cube is a way of organizing data in a computer's memory that allows extremely fast interaction to support real-time queries by investigators. To reduce latency as much as possible the cube will be frequently refreshed as new data becomes available.

These advanced tools will improve the capability of FSIS to use internal and external data to perform outbreak investigations. They will allow FSIS investigators to communicate more effectively with their counterparts at CDC, FDA, and ARS when joint investigations are underway.

Phase 2

In Phase 2 FSIS will continue to enhance data utilization by further expanding the tools available (such as GIS analytical tools). FSIS will examine whether there are additional data sources and tools to further augment the outbreak investigations. FSIS will continue to work with CDC, ARS, States, and FDA on joint methods for improving investigations and attribution.

4.0 PERFORMANCE MEASUREMENT

A critical part of Strategic Planning for FSIS is to identify public health objectives related to food safety and from there to establish metrics with which to measure progress towards meeting those objectives. Establishing the proper objectives and metrics requires coordination with other Agencies involved in food safety. FSIS has been an active participant in President Barack Obama's Food Safety Working Group and is working closely with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) to develop these measures.

The establishment and maintenance of these objectives also requires an active governance process. Towards this end FSIS has established three Enterprise Boards to review and vet decisions before taking them forward to the Management Council. These Boards ensure that all proposals have been fully researched and maintain alignment with strategic objectives.

Calculating the metrics that measure progress towards the objectives requires careful analysis and constant attention to the data being collected. FSIS has established two groups, the Data Analysis and Integration Group (DAIG) and the Data Coordination Committee (DCC) to oversee these processes.

The sections below address these subjects in more detail and show how they contribute to FSIS's performance measurement. One particular measurement, the All-Illness Measure, is explained in detail.

4.1 Food Safety Working Group

The United States Department of Agriculture has worked extensively over the past year to help establish a government-wide performance plan for food safety oversight through the Agency's active participation in President Barack Obama's Food Safety Working Group (FSWG). The FSWG seeks to advise the President on how to upgrade and improve the U.S. food safety system and develop a nationwide performance plan for food safety oversight. The Working Group, which is co-chaired by the Secretaries from the Department of Agriculture and Health and Human Services, recommended that a new, public health-focused approach to food safety be developed based on three core principles:

- prioritizing prevention;
- strengthening surveillance and enforcement; and
- improving response and recovery.

To address these principles, FSIS, the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) worked jointly to develop food safety metrics based on these three core principles that represent federal food safety activities along the food supply chain using a farm-to-table framework. By developing metrics, FSIS, CDC, and FDA are demonstrating a coordinated, holistic approach to food safety oversight. In addition, this

framework allows for the identification of data gaps to measure the impact of food safety activities, and helps Agencies like FSIS target areas in the farm-to-fork continuum where more attention is needed. The framework and the metrics developed to support the framework were shared with federal partners, as well as consumer groups and industry at the July 21st, 2010 public meeting—"Measuring Progress on Food Safety: Current Status and Future Directions" in Chicago, IL.

Using these metrics and the framework FSIS developed a set of proposed measures within each of the three core principles to evaluate the Agency's progress. A preliminary version of these measures was shared at the above-mentioned public meeting and a final version is currently being vetted within the FSIS Management Council oversight process. It is anticipated that a set of these measures will be made available publicly at the next FSWG public meeting in Portland, OR in October 2010. Once the vetting process is complete, FSIS intends to measure its progress against the goals developed and routinely report these results both to the FSWG and publicly via the FSIS website.

4.2 Governance Process

The FSIS Administrator establishes the Agency's long term vision and leads the FSIS Management Council in setting annual and long term priorities and a strategy to meet performance measures within those priorities. In 2009, FSIS adopted an Enterprise Governance model to enhance the efficiency of its decision making process. FSIS established three Governance Boards--the Enterprise Architecture Board (EAB), the Enterprise Steering Board (ESB), and the Enterprise Investment Board (EIB) to fully research, cost and review issues and proposals before presentation for action to the FSIS Management Council. Each Board is comprised of members from FSIS senior management, and is governed by the Enterprise Governance (EG) Board Charters signed by the Administrator.

Per the EG Charters, the ESB was established to take the lead role in implementation of external or internal, new or revised policy and/or business practices that impact or require assets from multiple program areas. To meet this goal, the ESB ensures the alignment of Agency strategic plan, priorities and performance measures. The EG Charters state the ESB and its subcommittees/work groups ensure the integration of mission needs statements, program area initiatives, performance management and measurement, investments, projects, policy, and special interest issues. The focus of the ESB is to ensure that the business processes of the Agency align with the FSIS mission, and are validated as meeting those objectives on an ongoing basis. The ESB promotes and integrates the linkages between internal business components and the achievement of expected business outcomes. These linkages will be enhanced by developing processes for identifying, managing, and closing gaps between strategic plan goals and the current state.

4.3 DAIG and DCC

Because all FSIS program areas are involved with the collection, analysis, or utilization of data, it is necessary that FSIS have a process in place to ensure that Agency activities involving data are consistent, are statistically valid, do not duplicate other efforts, and are aligned with FSIS

strategic goals and policy development. Therefore, two groups were formed in the Agency to ensure that it is analyzing its data in a coordinated and efficient manner. The two groups are the Data Analysis and Integration Group (DAIG) and the Data Coordination Committee (DCC).

The DAIG consists of a staff dedicated to working with all program areas on data analysis issues to ensure data analyses are consistent and of high-quality; ensure data analyses are relevant to program offices' business processes and the Agency mission; provide assistance in data analysis; and provide a new level of sophistication for data analysis. The DAIG has developed information sheets to describe the data streams within the Agency. The sheets provide detailed information on the data streams, including how the information is collected, its limitations, the reports generated from the data, and the audience for dissemination of those reports. The DAIG has also developed a summary table – the FSIS Data Analysis and Reports Project Matrix – of all data analysis and reports that are being conducted by the Agency. This documentation of the Agency's data and the analysis and reports being conducted or developed by the Agency provide a clearer picture of what data are available and what is currently being done with the data to avoid redundancies.

The DCC is responsible for coordinating Agency activities involving the collection, analysis, and use of FSIS or other data. The DCC convenes at a minimum of once per month to review significant data issues for the Agency and the policy ramifications of those issues.

4.4 All-illness Measure

A key component of strategic planning is the development of measurements to assess the results. One of FSIS' primary performance measures for the 2010-2015 USDA Strategic Plan is the All-Illness Measure. The All-Illness Measure represents all foodborne illness for *Salmonella, E. coli* O157:H7*, and Listeria monocytogenes* in FSIS-regulated meat, poultry and processed egg products. This measure is used to track performance in meeting established goals including the 2010 Healthy People Goals and, in the future, 2020 goals. Objectives for the All-Illness measure are set using a combination of data from published annual case rates from CDC's FoodNet data and CDC outbreak data. They are aligned with Healthy People 2010 goals and the Agency's High Priority Goal for *Salmonella*. FSIS uses the published FoodNet pathogen-specific case rates to determine the estimated total number of foodborne illnesses from *Salmonella*, *Listeria monocytogenes*, and *E. coli* O157:H7.

FSIS calculates how many illnesses are attributed to FSIS-regulated products by utilizing attribution estimates calculated from the CDC's Outbreak data for simple food products using the method outlined in Section 3.2 above. Then, by combining this information with the reported annual case rate from FoodNet (the case rate is converted into an illness estimate), FSIS estimates how many illnesses are attributable to FSIS-regulated products at baseline.

Objectives are then set starting at baseline with annual reductions in the number of illnesses from FSIS-regulated products in each year. This is done so that FSIS can meet the Healthy People 2010 goals for *E. coli* O157:H7 and *Listeria monocytogenes* and the FSIS High Priority Goal for *Salmonella*, which targets a four percent reduction in the case rate of sporadic foodborne *Salmonella* illnesses by the end of FY2011. After FY2010, for *E. coli* O157:H7 and *Listeria*

monocytogenes and after FY2011 for *Salmonella*, FSIS' goal is to reduce the total illnesses by one percent each year out to FY2015.

Annual estimates of number of illnesses from FSIS-regulated products are based on illness case rates from the CDC FoodNet program, along with attribution estimates based on CDC outbreak data. To obtain quarterly estimates for the quarters between the annual publications of FoodNet case rates, FSIS currently uses its volume weighted percent positives from its verification testing to project the number of illnesses caused by its products. In the near future FSIS will obtain quarterly case rates from CDC's FoodNet program to measure performance as these data are an actual measure of the burden of foodborne illness in the country.

The FSIS performance standards are shown in table 5 below.

		Measures						Objectives					Goal
Pathogen		Baseline 2005-2007[1]	FY 2008	FY 2009	FY 2010 Q1	FY2010 Q2	FY2010 Q3	FY 2010 Q4	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
Salmonella	Illnesses	576,436	636,266	596,598	600,953	579,179	627,081	559,053	553,379	547,845	542,367	536,943	531,574
	Case Rate[2]	5.00	4.95	4.90	4.89	4.88	4.87	4.85	4.80	4.76	4.71	4.66	4.62
	Percent Change From Baseline		10.38%	3.50%	4.25%	0.48%	8.79%	-3.02%	-4.00%	-4.96%	-5.91%	-6.85%	-7.78%
Listeria monocytogenes	Illnesses	1,236	1,222	1,432	1,432	1,313	1,074	1,053	1,043	1,032	1,022	1,012	1,002
	Case Rate	0.20	0.19	0.19	0.18	0.18	0.18	0.17	0.17	0.17	0.17	0.17	0.17
	Percent Change From Baseline		-1.14%	15.91%	15.91%	6.25%	-13.07%	-14.77%	-15.63%	-16.47%	-17.30%	-18.13%	-18.95%
***E. coli* O157:H7**	Illnesses	20,415	19,214	16,984	13,799	13,269	12,207	17,155	16,984	16,814	16,646	16,479	16,315
	Case Rate	0.34	0.32	0.30	0.30	0.29	0.29	0.28	0.28	0.28	0.27	0.27	0.27
	Percent Change From Baseline		-5.88%	-16.81%	-32.41%	-35.01%	-40.20%	-15.97%	-16.81%	-17.64%	-18.46%	-19.28%	-20.08%
All-Illness[3, 4, 5]	Illnesses	598,087	656,702	615,014	616,184	593,761	640,362	577,262	571,406	565,691	560,035	554,434	548,890
	Percent Change From Baseline		9.80%	2.83%	3.03%	-0.72%	7.07%	-3.48%	-4.46%	-5.42%	-6.36%	-7.30%	-8.23%

[1] FSIS measures its performance in terms of total *E. coli* O157:H7, *Listeria monocytogenes* and *Salmonella* illnesses from all FSIS-regulated meat and poultry products. FSIS previously reported goals and objectives for each individual pathogen as a volume-adjusted percent positive rate based on our pathogen testing data. FSIS has moved to the All-Illness measure since it is more understandable to the public, aligns with illness data reported by CDC, and is a direct measure of a public health outcome.

[2] The All-Illness baseline data is the average of 2005-2007 data from CDC's FoodNet data. This baseline average is used as it corresponds to the Agency's High Priority Goal for *Salmonella*. This approach also reflects the goals and projects from the President's Food Safety Working Group and harmonizes the USDA approach to performance measurement with the FDA's current approach.

[3] Objectives for the All-Illness measure of total illness from all FSIS-regulated meat and poultry products are calculated using the baseline number of foodborne illnesses as reported in FoodNet and attribution estimates calculated using CDC outbreak data. For *E. coli* O157:H7 and *Listeria monocytogenes*, FSIS objectives for FY2010 are linked to the Healthy People 2010 goals. For *Salmonella*, FSIS objectives are linked to the USDA High Priority goal, which is, starting with the 2005-2007 average baseline from FoodNet, decreases the number of foodborne illnesses from *Salmonella* by 10% by the end of 2011. After FY2010, FSIS' goal is to reduce the total illnesses by one percent each year out to FY2015. FSIS quarterly progress in reaching these objectives is measured using CDC's FoodNet data on *E. coli* O157:H7, *Listeria monocytogenes* and *Salmonella* illness case rates per 100,000 people.

[4] In the future, FSIS will initiate pathogen reduction activities for *Campylobacter* and non O157:H7 STEC and illnesses associated with these pathogens will be incorporated into the All-Illness measure. Further, FSIS will update its attribution estimates on an annual basis, and, as estimates are not likely to significantly change from year to year, performance objectives will be re-evaluated on a 3 year cycle. Finally, the All-Illness Measure will be updated as new estimates of foodborne illness become available from the CDC and when Healthy People 2020 goals are released.

NOTE: The values presented in each of the cells are as follows: Top: Illness estimate, Middle: Case Rate (cases/100,000), Bottom: Percent Decline in Illnesses from 2005-2007 average baseline.

Table 5: FSIS Performance Measures, Goals, and Objectives Using FoodNet data and Mead et al. Scaling Factors

FSIS measures its progress in meeting the Agency's public health performance measures, such as the All-Illness Measure, on a quarterly basis. However, while FSIS firmly believes that the day-to-day activities of the Agency have a direct impact on the burden of foodborne illness in this country it is often challenging to quantitatively relate FSIS activities, such as Pathogen Verification Testing, to reductions in foodborne illness. Consequently, FSIS is developing an Operational Performance Measures Report to supplement the public health performance measures reported by the Agency. This report will allow the Agency to assess whether FSIS is carrying out its regular, routine activities to reduce or prevent contamination of the products it regulates, ensure import activities are carried out appropriately, and provide educational material to the public, amongst other activities. These operational performance measures allow the Agency to prioritize activities, inform resource allocation, and identify program area gaps. Finally, as the Operational Performance Measures report will be produced on a monthly basis, it will allow the Agency to measure its progress towards meeting its corporate objectives before the end of a quarterly reporting period and allow for mid-reporting updates in a more timely and effective manner. The Operational Performance Measure report is currently under review within FSIS, but once complete, FSIS intends to include several key operational performance measures in each Quarterly Report delivered to the Office of Management and Budget.

5.0 AREAS NOT ADDRESSED

This plan addresses the data improvements and analyses associated with domestic inspection. It does not address the areas below. FSIS intends to incorporate these areas into future versions of the Strategic Data Analysis plan.

Import and Export
FSIS has made a major effort to integrate import and export inspection activities with those of domestic inspection. Though in the past these areas represented isolated "stovepipes" of data, both of them are addressed by PHIS and will have their data and analyses integrated into the unified view of overall inspection activities. There are however processes, analyses, and reports that are unique to the international inspection activities that make them unique. At this time the Import and Export teams within FSIS are performing a review of all procedures associated with their inspection activities.

National Residue Program
The National Residue Program is a sampling program that is designed to detect contamination of meat and poultry with residual veterinary drugs, pesticides, and heavy metals. Under this program FSIS inspectors sample meat and poultry processed through slaughter plants for residue testing and compare the results with tolerances established by the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) to prevent adulterated meat and poultry from entering into commerce. Each year, FSIS publishes the "National Residue Program Scheduled Sampling Plans" (the Blue Book) and "National Residue Program Data" (the Red Book) as a means of reporting the results of its national residue program tests. The Blue Book provides detailed discussions describing the principles and methods used to plan and design the national residue program sampling plans. It also summarizes the planned scheduled domestic and import sampling plans for the upcoming calendar year and includes a summary of adjustments to the previous year's national residue program. The Red Book presents details on the testing results of the various national residue program sampling plans conducted throughout the prior calendar year. Taken together, these books provide a comprehensive view of the program and the analyses of the data.

In-Commerce
The FSIS Office of Program Evaluation, Enforcement and Review (OPEER), Compliance and Investigations Division (CID) Investigators conduct surveillance to protect the health and welfare of consumers by ensuring that meat, poultry, and egg products in commerce are safe, wholesome, correctly labeled and packaged, and secure from intentional acts of contamination. These activities are carried out at in-commerce locations such as warehouses, distribution centers, and retail establishments, as well as ports-of-entry and United States borders, to verify that persons and firms, whose business activities involve FSIS-regulated products, prepare, store, transport, sell, or offer for sale or transportation such products in compliance with FSIS statutory and regulatory requirements. These activities require data collection and analysis that differs from that required for the Domestic Inspection activities covered by this plan.

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APPENDICES

Appendix A- Major NAS Findings and Recommendations

Listed below are the findings and recommendations from the two NAS reports. The first report (RBI), titled "Review of Use of Process Control Indicators in the FSIS Public Health Risk-Based Inspection System: Letter Report" can be found in its entirety here: http://www.nap.edu/catalog/12617.html and the second report (Attribution), titled "Letter Report on the Review of the Food Safety and Inspection Service Proposed Risk-Based Approach to and Application of Public-Health Attribution" may be found here: http://www.nap.edu/catalog/12650.html
The numbering of the findings and recommendations below is slightly different from that of the original reports. This has been done to enable combining recommendations of the two reports, the grouping of similar recommendations (for example where the same recommendation was applied to several different pathogens), and the tracking of sub-recommendations that were not numbered in the original. Page numbers have been provided to reference the locations of each finding in the two reports where they can be seen in their original context. (Page numbers provided refer to the page within the PDF rather than the page numbers supplied by NAS which did not include the opening material).

Major NAS Findings/Recommendations on the Decision Criteria Document

1. ***Finding:*** *Although the use of a model to categorize plants in levels of inspection is appropriate, the descriptions of the algorithm, the scientific basis for the use of the process indicators, the description and analysis of data, and the use of the process control indicator algorithm as it is integrated in the overall inspection system are not clearly articulated in the FSIS technical report.(Page 19)*

   Recommendations:
   1. FSIS uses the term "algorithm" to describe its decision-making tool to categorize plants into levels of inspection […] However, in the context of a risk-based system, the term algorithm implies a mathematical model. Since FSIS did not construct a mathematical model, it would be more precise to use the designation decision tool or framework. (Page 18)

2. ***Finding:*** *Lift analysis is a data-mining tool that is appropriate to use for finding initial associations among events that occur infrequently. However, the identification of process control indicators requires more complex statistical analysis as well as data that have been collected for the purpose of identifying such indicators. The committee emphasizes that, although mining or extracting data from currently existing data sets to design the inspection system is commendable and the use of lift statistics for data mining justified, the system could be significantly improved if more complete statistical analyses were conducted in addition to the lift analysis and additional data for more useful predictors were collected. Also, the*

proposed algorithm does not currently include an adequate process control indicator for some foods (e.g., RTE foods).(Page 29)

Recommendations:

1. The committee recommends that in addition to the improvements in data collection and analysis presented below, FSIS revise its proposal to improve the transparency and clarity of the description of the overall inspection system—in particular, the process control indicator algorithm, its scientific basis, and the type and analysis of data used. Further, FSIS should consider tailoring the proposal to its target audiences (e.g., plant managers, FSIS inspectors and supervisors, FSIS managers and scientists, outside expert panels) and providing them with supplemental information or reports. (Page 19)
2. Prior to analyzing the available data and selecting the indicators to develop a risk-based inspection system, the committee recommends that FSIS clearly define the terms (and their limitations) that are critical to the development of the inspection system proposed in the technical report *PHRBIS*, such as algorithm, process control, and process control indicator. FSIS should seek external advice from experts, especially on risk and risk-ranking, on the reliability and accuracy of various attributes to predict public health hazards, but also from experts on the subject matter; this information should be used to evaluate the utility of potential indicators of process control. Further, FSIS should distinguish which indicators are suitable for different classes of meat and poultry products. Once a suitable decision-making tool (e.g., a decision tree) has been adopted, it should be validated for its purpose. (Page 23)
3. The committee recommends that FSIS clearly describe in its proposal the nature of the inspection for each different level, the decision-making process that would result in a change in inspection level, and the relationship between level-of-inspection designation and the state of process control as specified by current FSIS regulations. The FSIS personnel responsible for making such decisions and their expertise should also be designated in the proposal. If the system is completely automatic (e.g., input from an inspector automatically results in a specific LOI decision, involving no subjective judgment on the part of the inspector), the committee recommends that studies be carried out to ensure that the model includes all possible scenarios. (Page 25)
4. The committee recommends that FSIS perform further statistical analysis for the purpose of validating proposed indicators of process control as well as exploring the utility of new process control indicators through new studies, expert consultation, and literature review. In some instances, FSIS should take advantage of data for other potential process indicators generated by industry or others. After a preliminary association with an outcome is established (predictability is demonstrated statistically), FSIS should conduct further analysis to confirm the utility of product-based process indicators and ultimately conclude the analysis with a multivariate model or similar method. FSIS should then modify the algorithm as new predictors are identified and test the adequacy of its current (and future) algorithm. (Page 29)

3. ***Finding:*** *FSIS currently tests different classes of products for different microorganisms, for different purposes, and with different underlying assumptions. The applicability of these data to the FSIS algorithm is dependent on the specific protocols, assumptions, and statistical characteristics of each testing program. (Page 31)*

Recommendations:

1. The FSIS technical report should describe the characteristics of the microbiological criteria being used as determinants of loss of process control. These characteristics include in-depth consideration of the statistics underlying the specific microbiological testing protocols used and the assumptions that are made in using such data (e.g., the magnitude of type I and type II errors; assumed pathogen concentration means and standard deviations). As recommended in the following sections, FSIS should also consider investing in research to find and validate alternative microbiological indicator tests whose target microorganism occurs at a substantially greater frequency than those currently in use. If successful, this would provide FSIS with a better process control indicator that could be used to analyze trends and to take actions (e.g., perform an in-depth inspection) before public health limits are exceeded. (Page 32)
2. The committee recommends that FSIS provide a more detailed analysis of how it will employ the results of the *Salmonella* verification testing program, including a consideration of the underlying statistics of its application. FSIS would also benefit from the following data collection and research activities to alleviate some of the limitations of *Salmonella* verification testing as an indicator of process control. (Page 37)
3. Sponsor research programs to develop and validate faster, quantitative testing methodologies for *Salmonella.* Inclusion of newer, molecular-based methods for typing and subtyping *Salmonella* isolates may also help distinguish the underlying reasons for loss of process control (see also below). (Page 37)
4. Continue to develop a process- and commodity-specific national baseline for *Salmonella* levels to verify the effectiveness of FSIS efforts to ensure food safety. (Page 37)
5. Collect data on *Salmonella* serotypes by raw product and at different steps throughout the process, including the incoming step. *Salmonella* serotype data could help determine whether a loss of control has occurred within an establishment. It could provide evidence of the source of contamination (by traceback investigations) and a contamination pattern in an establishment. In addition to their potential value in foodborne disease attribution (i.e., determining which products are more likely to be associated with foodborne disease), FSIS should evaluate the use of *Salmonella* serotype data as a potential indicator of process control. (Page 37)
6. Explore the use of prevalence and load of *Salmonella* in the incoming raw material as an indicator of process control. (Page 38)
7. FSIS should provide a more in-depth description of the sampling and testing statistics that are the basis for the *Salmonella* verification testing program, as well as how these characteristics and assumptions influence the use and interpretation of the data for categorizing establishments. This should include consideration of the magnitude of type I and type II errors, assumed pathogen concentration means and standard

deviations, specificity and sensitivity of the microbiological protocols, and so forth. (Page 38)

8. Given the limitations of the use of *L. monocytogenes* testing results as a process indicator, the committee recommends that FSIS do the following:
    a) Consider redesigning the testing protocols by prioritizing inspection of RTE products according to product risk, that is, with consideration of a product's ability to support the growth of *L. monocytogenes* (e.g., the food's acidity level, the use of preservatives). This risk-based approach is being adopted by others (e.g., the Codex Alimentarius Commission) and merits consideration by FSIS. (Page 41)
    b) Consider analyzing industry data on *L. monocytogenes* or *Listeria* spp. in the environment and/or *Listeria* spp. on food contact surfaces or in the final product to determine whether these data could serve as a useful indicator of process control. For example, FSIS could use data collected more frequently for routine sampling of processing environments that may be reservoirs of *L. monocytogenes.* Although unpublished results of PFGE analyses of *L. monocytogenes* isolates from samples taken from 127 plants suggested that contamination of product or contact surfaces did not originate in the plant environment (E. Dreyling, FSIS, personal communication, December 13, 2008), further analysis is needed to confirm or refute this finding due to the small sample size. This is particularly important when considering that the scientific literature is replete with examples suggesting that controlling harborage sites in the processing environment is critical to managing this foodborne pathogen (Giovannacci et al., 1999; Lundén et al., 2003; Peccio et al., 2003; Thévenot et el., 2006; Keto-Timonen et al., 2007). (Page 41)
9. Conduct lift analysis and other appropriate analyses by product class to determine whether there is a correlation between *L. monocytogenes* and specific NRs for products with inherently high public health risks. This will allow comparisons with statistical analyses already conducted for all products. (Page 41)
10. Sponsor research programs to develop and validate improved and quantitative testing methodologies for *L. monocytogenes* as a potential means of increasing the discriminatory power of this indicator. Improved sampling and testing methods might increase the confidence in the methodologies and decrease the number of false positives and false negatives. Rapid methodologies will decrease the temporal gap between the loss of control and the inspection, and therefore it is more likely that the associated problem (and the solutions) could be found. These kinds of improvements will enhance the reliability of the algorithm. (Page 41)
11. FSIS should provide a more in-depth description of the sampling and testing statistics that are the basis for *L. monocytogenes* regulatory testing programs, as well as how the characteristics and assumptions of the sampling and testing statistics influence the use and interpretation of these data for categorizing establishments based on this metric. This should include consideration of the magnitude of type I and type II errors, assumed pathogen concentration means and standard deviations, specificity and sensitivity of the microbiological protocols, and so forth. (Page 42)

12. The committee recommends improving the use of the presence of *E. coli* O157:H7 as an indicator of process control in raw ground beef by the following measures:
    a) Provide a more in-depth description of the sampling and testing statistics that are the basis for the *E. coli* O157:H7 regulatory testing program and of how the characteristics and assumptions of the sampling and testing statistics influence the use and interpretation of the data for categorizing establishments based on this metric. This should include consideration of the magnitude of type I and type II errors, assumed pathogen concentration means and standard deviations, specificity and sensitivity of the microbiological protocols, and so forth. (Page 44)
    b) Assess the association of the practice of trim testing with the frequency of *E. coli* O157:H7 in final product to evaluate the use of trim testing as a risk determinant. This can be done by using appropriate study designs to address potential confounders and interactions. If such an association is found, incorporate this into the algorithm as applied to ground beef as a simple predictive criterion based on whether an establishment tests incoming trim to a sufficient degree. (Page 45)
    c) Because of the low frequency of *E. coli* O157:H7 isolations in ground beef, evaluate data on other potential indicators of fecal contamination such as generic *E. coli* (see below). (Page 45)
    d) Support research to develop and validate improved sampling and testing methodologies for *E. coli* O157:H7. Improved sampling and testing might increase confidence in the methodologies and decrease the number of false positives and false negatives. Rapid methodologies will decrease the temporal gap between the loss of control and the inspection, and therefore it is more likely that the associated problem (and the solutions) could be found. These kinds of improvements will enhance the reliability of the algorithm. (Page 45)

13. The committee recommends improving the use of the presence of *Salmonella* and *E. coli* O157:H7 as an indicator of process control in RTE products by the following measures:
    a) Provide a more in-depth description of the sampling and testing statistics that are the basis for the *Salmonella* and *E. coli* O157:H7 testing programs in RTE foods as well as how the characteristics and assumptions of the sampling and testing statistics influence the use and interpretation of these data for categorizing establishments based on this metric. This should include consideration of the magnitude of type I and type II errors, assumed pathogen concentration means and standard deviations, specificity and sensitivity of the microbiological protocols, and so forth. (Page 47)
    b) Because of differences in the inherent risk of various subcategories of RTE products, the product classes should be subdivided to determine whether better predictors can be identified for specific products. Because of the low frequency of *Salmonella* and *E. coli* O157:H7 isolations in RTE products, evaluate data on other potential indicators of process control. For

example, and in conformance with the committee's recommendation below, deviations from control point limits in an RTE HACCP plan may be better suited as indicators of process control. (Pages 47-48)

c) Support research to develop and validate improved sampling and testing methodologies for *Salmonella* and *E. coli* O157:H7. Improved sampling and testing methods might increase the confidence in the methodologies and decrease the number of false positives and false negatives. Rapid methodologies will decrease the temporal gap between the loss of control and the inspection, and therefore it is more likely that the associated problem (and the solutions) could be found. These kinds of improvements will enhance the reliability of the algorithm. (Page 48)

4. ***Finding:*** *The use of selected NRs as process control indicators in a risk-based inspection system offers potential. However, because current NRs are written to document failure to comply with regulations, not all of them are predictors of loss of process control. The subjective nature of NR issuance also limits their use as process control indicators. The description of the association between NRs and other measures of process control would benefit from a more effective communication of which NRs are employed for specific commodities, and which ones are pertinent to all meat and poultry products.(Page 53)*

Recommendations:

1. To reduce the subjectivity implicit in the current NRs, the committee recommends supporting the improvement of the inspection force (inspectors and supervisors) by strengthening the oversight of the writing of NRs to determine not only that the appropriate information on regulatory citations is provided, but that the information is both factual and properly documented to support the noncompliance; and improving the training and testing of inspection personnel themselves, with special emphasis on quality and consistency of NRs and on any new NRs to be developed. (Page 54)

5. ***Finding:*** *The use of enforcement action, recalls, and outbreaks to rank establishments in different levels of inspection has been justified based on their suggesting a past loss of control, a valid risk-management decision criterion. However, the initial data analysis has not provided scientific support for use of this decision criterion to predict a loss of process control or its association with other indicators. Enforcement actions currently prompt regulatory action, so they already result in categorization in LOI3.(Pages 57, 59, 61)*

Recommendations:

1. The committee recommends including foodborne disease outbreaks in the algorithm to categorize plants in levels of inspection. The committee also strongly recommends that FSIS systematically work with other appropriate federal and state agencies to routinely disseminate public reports of the results of the investigations into the plant and process failures associated with these outbreaks. (Page 61)

2. The committee recommends using those enforcement actions resulting from a failure of process control to categorize establishments in levels of inspections, but not as predictive indicators of loss of process control. (Page 57)
3. Only health-related product recalls should be included in the model for ranking public health risks and assigning inspection resources. FSIS should continue to conduct assessments and take regulatory enforcement actions in plants following a recall. (Page 59)
4. In concurrence with previous NAS reports (NRC, 1987; IOM, 1990, 1998, 2003), the committee recommends focusing on those inspection activities that foster the implementation of and compliance with HACCP systems and sanitary requirements. The committ*ee* strongly recommends that additional NRs be developed to reflect indicators of process control, instead of relying entirely on NRs that were created for purposes of regulatory compliance. The committee recommends that FSIS identify, validate, and adopt those NRs that are truly predictive of future contamination problems—for example, those being triggered by process deviations from HACCP plan critical control point limits. This exercise should be conducted under the guidance of a non-FSIS expert panel. (Page 54)
5. FSIS should investigate the potential utility of industry data on generic *E. coli* as an indicator of process control. The committee recognizes the challenges of this approach, but encourages FSIS to act promptly to complete the analysis of the data it has already acquired, collect additional data as necessary, and analyze them for their predictive ability as potential indicators of process control. (Page 63)
6. The committee recommends that FSIS consider using specific critical control point deviations as indicators of process control. Process deviations should be integrated into an algorithm to categorize plants according to the level of inspection needed. Because of inherent problems in the use of NRs described above, the committee recommends redefining public health-related NRs and creating new ones where appropriate so that they reflect the current view of HACCP as a food safety control approach. This approach should identify true science-based indicators of process control. This concept should be included in inspection training programs. USDA should conduct a pilot study in a few plants to determine if the new NRs based on HACCP critical control point adherence are valid and useful parameters to be considered as predictors of loss of process control. This should be followed by longitudinal studies designed to validate the new NRs. (Page 64)

Major Findings/Recommendations on the Attribution Document

6. ***Finding:*** *In the proposed public-health risk-based ranking algorithm, FSIS's method of categorizing facilities on the basis of their LOI (indicators of process control) before incorporating public-health attribution (public-health effect) ranks facilities according to inspection-based risk (for example, recalls, enforcements, and verification testing). This ranking may not reflect public-health risk. In the current system, attribution has little influence on an establishment's rank, inasmuch as rank is determined primarily by LOI*

categorization, which pinpoints hotspots, and the system then ranks establishments with a given LOI primarily according to the product of attribution and fractional volume. It is unclear how the public-health effect component of the algorithm will improve the ability to set priorities among high-risk facilities.(Page 31)

Recommendations:

1. Recognizing that it is difficult to estimate food attribution given the small amount of available data and its relatively poor quality, FSIS should consider alternative prioritization methods for their PHRBIS. This might include ranking methods that do not rely on attribution data per se or risk-ranking models that approach the attribution problem in an alternative manner. (Page 31)

7. ***Finding:*** *The committee applauds FSIS's efforts to develop a Public Health Risk-Based Inspection System; however, FSIS should present a more transparent algorithm to rank slaughtering and processing establishments according to public-health risk. Despite considerable effort, the committee had great difficulty in understanding the rationale behind the proposed approach and in precisely reproducing FSIS's calculations because of a lack of transparency in the model. In addition, failure to characterize the uncertainty in the attribution estimates and other inputs of the risk-ranking algorithm is a critical weakness in the proposed PHRBIS. (Page 30)*

Recommendations:

1. Once FSIS has selected a means of ranking, it should provide transparent documentation that describes the primary data used in the risk-ranking calculations; step-by-step instructions on how to perform the calculations, with examples; characterization of uncertainty in the data; sensitivity analysis of the risk-ranking algorithm; and strengths, limitations, and clear justification of the approach selected. To the extent practicable, the risk ranking should consider the importance of differences in disease severity associated with different pathogens. Documentation should be provided to allow interested stakeholders to reconstruct FSIS's approach. (Page 31)

8. ***Finding:*** *The precision implied in FSIS's public-health risk ranking, produced in part by using attribution estimates and production volume, appears to be quite low. Because FSIS estimates public-health effects on the basis of a small number of observations, the estimates have large uncertainties that should be communicated in the ranking algorithm. FSIS should also recognize that attribution estimates will need to be updated as disease incidence in humans changes to retain their relevance when used for risk-based inspection. (Page 30)*

Recommendations:

1. FSIS should state that it will update the risk-ranking algorithm and reevaluate the PHRBIS every 1-3 years, and the agency should specify how this will be done. The periodic evaluations should use newly available data and methods and should evaluate model inputs and the model itself. A main focus of the regular

evaluations should be to ensure that the dynamic nature of attribution is factored into the model. In addition, FSIS should articulate the metrics that it will use to demonstrate public-health outcomes; the metrics should be evaluated by using data sources that are independent of those generated by USDA. (Page 31)

2. Recognizing that food-attribution data are of interest to many agencies, FSIS should work collaboratively with CDC, FDA, and other federal and state agencies to develop a common set of definitions for microbial foodborne-disease attribution; a coordinated approach to improve the quality and consistency of data used among agencies in determining food-attribution estimates; a process that allows for regular updating of attribution estimates; and a standardized coding scheme for food vehicles, including multi-component foods. (Page 32)

9. ***Finding:*** *The data sources currently available for assessing attribution are insufficient to be used independently. FSIS has not used some data that are readily available to supplement the CDC outbreak data and expert elicitations. This could help in the development of better-informed attribution estimates.(Page 30)*

Recommendations:

1. If FSIS continues to include attribution as a component in its PHRBIS, FSIS in conjunction with CDC staff and others, should review the CDC outbreak database, including information not considered in the initial FSIS attribution model, to improve attribution of illnesses to regulated food products. Routine use of the CDC outbreak data for purposes of food-attribution modeling may provide further incentives to state and local jurisdictions to report outbreaks accurately and quickly for use by CDC. (Page 31)

10. ***Finding:*** *Attribution estimates based on outbreak data which reflect disease occurring at the "point of consumption" do not directly translate to attribution at the point of slaughter and processing. In fact, other points along the farm-to-fork continuum that are outside of FSIS's jurisdiction (for example, the farm and the end-user) contribute substantially to disease associated with FSIS-regulated products. Because the risk-ranking algorithm does not explicitly consider the contribution of non-regulated attribution sources to FSIS-regulated products, it can under or over-estimate the proportion of illnesses actually attributable to slaughter and processing. This oversight may result in inappropriate risk-based allocation of resources.(Page 31)*

Recommendations:

1. If FSIS continues to include attribution as a component in its PHRBIS, FSIS staff should work collaboratively with FoodNet and PulseNet staff to use sporadic-case and outbreak data in conjunction with subtype data more effectively to facilitate estimation of population-based attribution of sporadic cases to specific agents. (Page 32)

11. ***Finding:*** *The development of performance measures is premature, given the limitations of the attribution estimates and the lack of uncertainty characterization. That is of particular concern because imprecise estimates of attribution are being used to support specific performance objectives, and the proposed system may not reflect the changing or uncertain nature of the attribution estimates.(Page 31)*

12. ***Finding:*** *Salmonella serotyping and molecular subtyping not only will be critical for improved attribution efforts but will enhance the agency's ability to monitor pathogen trends, such as emergence of new subtypes. Salmonella serotype-based and subtype-based attribution models are not yet at a stage where they should be used for policy decision-making. (Page 31)*

Recommendations:

1. FSIS should continue to collaborate with CDC and other appropriate organizations in the serotyping and molecular subtyping of all *Salmonella* isolates, with emphasis on those obtained from specific food products. To the extent feasible, subtype data should also be collected for isolates from environmental samples and other sources of human exposure to *Salmonella* (for example, reptiles and pets). Recognizing that *Salmonella* serotyping and molecular subtyping will not only be critical for improved subtype-based attribution efforts, but will also enhance the agency's ability to monitor pathogen trends (for example, emergence of new subtypes), FSIS should try to include serotyping and/or molecular subtyping in all of its future baseline studies. As part of these efforts, FSIS should establish and support collaborative arrangements with FDA to assure that *Salmonella* isolates obtained by USDA or FDA are characterized using the same molecular subtyping approaches and that results are available in a comprehensive database with harmonized nomenclature of human, animal, food, and environmental *Salmonella* isolates. In the future, it may be appropriate to expand such studies to other pathogens. (Page 32)
2. FSIS should continue to support the collection of serotype and molecular subtype data for *Salmonella* and perhaps other relevant pathogens, and the development of mathematical models that use these serotype and subtype data for understanding food (and source) attribution of human *Salmonella* infections. These efforts need to include research on developing new models, evaluating and validating existing models, and developing better quality data to populate the models. (Page 32)

Appendix B- OIG Findings and Recommendations

The following findings and recommendations are excerpted from the Office of Inspector General report "Audit Report, Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments" Report No. 24601-07-Hy December 2007

1. Implement an action plan with specific milestone dates for capturing the results of food safety assessments in an appropriate configuration that allows for effective analysis.
2. Perform food safety assessments, using the new configuration, in all establishments that will be in the universe of establishments where risk-based inspection may be used. The food safety assessments should be comprehensive assessments of the establishment's current operations.
3. Determine how the results of food safety assessments will be used by FSIS in estimating establishment risk.
4. As FSIS moves forward to develop and implement risk-based inspection, conduct and document analyses that support the data windows selected for each of the components in the risk control measure, which assesses an establishment's ability to control risk.
5. Ensure that the basis for decisions made regarding the components included in the risk-based inspection program are thoroughly documented and evaluated with limitations mitigated and are transparent to all stakeholders.
6. Develop a process to obtain more accurate, verifiable production data (e.g., pounds of product produced by product type) and regularly update the data from FSIS-regulated establishments.
7. Determine why NRs were not correctly accounted for (i.e., one counted twice and one omitted) when calculating an establishment's level of inspection. Implement the necessary controls to ensure that these types of errors do not occur and that data are complete and accurately processed.
8. Develop and implement at least an annual process to verify how establishments control Lm in RTE product and that establishments report when there is a significant change in the method they use to control Lm or volume of product they produce.
9. As FSIS moves forward to develop and implement risk-based inspection, include the enforcement action NOIE Under Deferral in the calculation.
10. Prior to implementation, validate the accuracy of the risk-based inspection data (e.g., species, product type, public health NRs, and control of Lm in RTE product) used for calculating an establishment's level of inspection.
11. Institute the appropriate oversight and control during the development of critical IT systems needed to support risk-based inspection.
12. Develop and implement criteria for prioritizing the scheduling of food safety assessments.

13. Develop and implement criteria for conducting periodic reevaluations of an establishment's food safety system to assess its progress after an initial food safety assessment.
14. Develop and implement a system to track changes at an establishment over time and determine which changes would trigger FSIS to conduct a food safety assessment at an establishment prior to its periodic reevaluation.
15. Develop and implement procedures to ensure sufficient, timely follow-up work is performed in response to findings in food safety assessments.
16. Closely monitor the administration of the PHIS contract and the development, testing, and implementation of the new system to ensure it is progressing as intended and to attain satisfactory assurance that it can support the operations necessary to carry out a complex, scientifically-based risk-based inspection program.
17. Complete a comprehensive, agency-wide examination of national, divisional, and district level analytical and informational needs and establish a process to periodically reassess needs. This should include implementing management controls to specifically define what analysis and information is needed, who should perform the analysis and collect the information, who needs to be provided the analysis or information (customers), how often the information needs to be collected and analyzed, what is the most useful format to present the information or analysis to the final users, and, finally, who is responsible to ensure follow-up actions are taken to correct problems identified. The study should also include an action plan for making the necessary changes to the agency's operating procedures and the estimated timeframes for implementing these changes.
18. Complete the in-depth analysis of all the data information streams within FSIS. Also, establish a mechanism to assure that once the analysis is performed for a system it is updated on a regular basis and that new systems are fully analyzed before they come on line.
19. Implement management controls to ensure effective distribution and full use of the results of all data analyses and reports to other affected program areas, including field operations, in order to allow for follow-up actions to correct problems identified and to establish performance goals for inspectors.
20. Perform an analysis of all reports currently generated (including those generated by the OPPED) and determine if any would be beneficial to other divisions/levels in improving compliance and operations. Further, determine if modifications could be made to the reports to make them more beneficial to other program areas, including field operations.
21. Provide ongoing training to district analysts on new or modified software and specific analytical techniques, including the type of data to collect, standard types of analysis to perform, format to present data, frequency of reporting the results, and follow-up actions the analysts are expected to take on any adverse issues noted. Also, establish a system to track when training is taken, the type of training taken, and a system to alert the appropriate managers if the minimal levels of training are not being achieved.

22. To the extent feasible, focus the activities of district analysts primarily on their data management and analysis responsibilities and promptly fill vacant district analyst positions.
23. Provide pathogen test results data in a searchable format to the appropriate district office personnel.
24. Provide officials at each level with written guidance on the use of the AssuranceNet system, particularly with regard to follow-up actions and adherence to the established system thresholds.
25. Establish procedures to ensure that warning "flags" provided by AssuranceNet are timely and effectively followed up on, particularly in cases in which deficiencies are repeatedly noted at the same establishment, circuit, or district.
26. Provide guidance to officials, particularly at the district level, to use AssuranceNet to view performance data down to the establishment level, as well as the circuits and districts.
27. Modify AssuranceNet to monitor the completion and results of all required elements and sub-elements assessed during IPPS reviews.
28. Implement features within AssuranceNet that will allow the system to (1) identify employees who have not worked in an IPPS-rated position for an entire rating period (e.g., retired or new employees), and (2) identify, for corrective action, instances in which employees have not received the required IPPS reviews.
29. Implement procedures and controls as needed to ensure that supervisors limit their use of the "follow-up" box on the IPPS review forms to instances involving documented performance deficiencies.
30. Continue the increased diligence for achieving management decision and final action on the remaining prior recommendations. In addition, apply this increased diligence to future recommendations to ensure timeframes are met.
31. Develop and implement requirements for inspection personnel to document their reviews of establishment testing results. At a minimum, the inspection personnel should document when they reviewed the test results, the type(s) of results they looked at (*E. coli* O157:H7, *Salmonella*, etc.) and the time period reviewed.
32. Ensure that the inspection personnel's reviews of establishment testing are periodically verified by responsible supervisory officials and noncompliance is specifically identified in IPPS.
33. Expedite the development of the specific criteria to inspection personnel that provide a basis for establishing when corrective actions are inadequate and appropriate enforcement actions should be initiated for repetitive deficiencies. The criteria should also define when progressive enforcement actions should be taken.
34. Reassess the effectiveness of training programs for inspection personnel and frontline supervisors and revise the programs, as appropriate.

35. Provide refresher training, at a minimum, to the inspection personnel and frontline supervisors assigned to the establishments with the recalls (i.e., United Food Group LLC and Topps Meat Company LLC).

Appendix C- Sampling Program Descriptions

Program Code	Type	Source	Product	Pathogen
MT43S	Routine	Domestic	Ground Beef in Low Production Volume Plants	*Salmonella*
HC01	Routine	Domestic	Broilers, Cows, Bulls, Turkeys, Market Hogs, Ground Beef, Ground Chicken, and Ground Turkey	*Salmonella*
ALLRTE	Routine	Domestic	RTE Meat and Poultry Products	*Listeria monocytogenes*, *Salmonella*, and *E coli* O157:H7
INTCONT	FSA Directed	Domestic	Intensified RTE Food Contact Surfaces	*Listeria monocytogenes* or *Salmonella*
INTENV	FSA Directed	Domestic	Intensified RTE Food Environmental Surfaces	*Listeria monocytogenes* or *Salmonella*
INTPROD	FSA Directed	Domestic	Intensified RTE Products	*Listeria monocytogenes* or *Salmonella*
RLMCONT	Risk Based	Domestic	Risk Based Verification testing Program Food Contact Surfaces	*Listeria monocytogenes*
RLMENVC	Risk Based	Domestic	Risk Based Verification testing Program Environmental (Composited)	*Listeria monocytogenes*
RLMENVR	Risk Based	Domestic	Risk Based Verification testing Program Environmental	*Listeria monocytogenes*
RLMPROD	Risk Based	Domestic	Risk Based Verification testing Program Product	*Listeria monocytogenes*
RTE001	Risk Based	Domestic	RTE Meat and Poultry Products	*Listeria monocytogenes*, *Salmonella* and *E coli* O157:H7
MT05	Routine	Retail	Raw Ground Beef	*E coli* O157:H7
MT06	Follow-up (MT05)	Retail	Raw Ground Beef	*E coli* O157:H7
MT08	Routine	Imports	Comminuted Beef Products	*E coli* O157:H7
MT43	Risk Based	Domestic	Raw Ground Beef	*E coli* O157:H7
MT44	Follow-up (MT43)	Domestic	Raw Ground Beef	*E coli* O157:H7

Program Code	Type	Source	Product	Pathogen
MT44T	Traceback	Domestic	Raw Ground Beef	*E coli* O157:H7
MT50	Routine	Domestic	Raw Ground Beef Components	*E coli* O157:H7
MT51	Routine	Imports	Raw Ground Beef Components	*E coli* O157:H7
MT52	Follow-up (MT03)	Suppliers	Raw Ground Beef Components or Beef Manufacturing Trimmings	*E coli* O157:H7
MT53	Follow-up (MT50, MT52, or MT54)	Domestic	Raw Ground Beef Components or Beef Manufacturing Trimmings	*E coli* O157:H7
MT54	Routine	Domestic	Raw Ground Beef Components or Raw Beef Patty Components	*E coli* O157:H7
MT55	Routine	Domestic	Bench Trim used to Make Ground Beef	*E coli* O157:H7
EM31	Routine	Domestic	Egg Whites (w/wo added ingredients)	*Salmonella*
EM32	Routine	Domestic	Whole Eggs or Yolks (<2% added ingredients)	*Salmonella*
EM33	Routine	Domestic	Whole Eggs w/ Added Yolks or Whole Egg Blends	*Salmonella*
EM34	Routine	Domestic	Whole Eggs W/ Added Yolks (w/ > 2% salt or sugar)	*Salmonella*
EM35	Routine	Domestic	Dried Yellow Egg Products	*Salmonella*
EM36	Routine	Domestic	Spray-Dried Egg Whites (w/wo added ingredients)	*Salmonella*
EM37	Routine	Domestic	Pan Dried Egg Whites	*Salmonella*
Program Code	Type	Source	Product	Tissue
AMR01	Routine	Domestic	Advanced Meat Recovery Monitoring	Central Nervous System Tissue
FAMR01	Follow-up (AMR01)	Domestic	Advanced Meat Recovery Monitoring	Central Nervous System Tissue