EXHIBIT 41

Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs

United States Department of Agriculture

Food Safety and Inspection Service

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Executive Summary

Background

The mission of the Food Safety and Inspection Service (FSIS) is to ensure that meat, poultry and processed egg products are safe, wholesome and properly labeled and packaged. Further, as FSIS is a public health agency, one of the primary goals of the Agency is to reduce and ultimately prevent foodborne illness in the population.

The overall purpose of FSIS inspection and sampling is to ensure that establishments maintain control of their production processes and adhere to FSIS regulations, policies and performance standards, which the Agency believes helps protect the public from foodborne illnesses. Ensuring that products are free of pathogen contamination and chemical residues is a responsibility of industry, but on-going sampling in FSIS-regulated domestic and import establishments allows the Agency to assess the effectiveness of industry process controls, compliance with performance standards and efforts to control the presence of pathogens on products being produced for American consumers. Additionally, sampling provides a strong incentive for the meat, poultry and processed egg product industries to reduce the presence of pathogens on products they produce. It also provides the regulated industries with critical information to improve current processes and focus its resources as efficiently and effectively as possible.

FSIS Sampling Programs

Currently, FSIS maintains sampling programs in three major venues: 1) Domestic, federally inspected establishments, 2) In-Commerce and 3) Import. FSIS also conducts an outbreak investigation and consumer complaint sampling program. Further, FSIS conducts two distinct types of sampling: 1) Microbiological and 2) Chemical Residues.

Purpose of Report

In September 2011, FSIS published the FSIS Strategic Plan for 2011-2016. The Plan, as a part of FSIS' goal to ensure that food safety inspection aligns with existing and emerging risks, identifies the Agency's commitment to develop an annual sampling report that comprehensively identifies and describes the Agency's sampling programs. This report was developed to address that commitment and is being released now, subsequent to the release of the Strategic Plan, to reflect FSIS' commitment to transparency and provide information on the Agency's sampling programs in a timely manner. This report was developed with input from all FSIS program areas and includes information on how the Agency's sampling programs were carried out in fiscal year (FY) 2011. Specifically, with the publication of this report, FSIS is documenting its current approach to microbiological and residue sampling. This report includes information on the historical basis, design, statistical/policy basis and limitations of FSIS' current sampling programs.

However, the development and maintenance of robust, responsive and meaningful sampling programs requires an iterative process, including review of sampling results, incorporating new technological and methodological advancements, new and modified FSIS policy and feedback from all stakeholders to promote continuous improvement. As such, this report is the first of two publications developed by FSIS. The second part of this effort, which is currently in development, is the FSIS annual Sampling Program Plan, which will identify programmatic sampling changes that will be implemented by the Agency in FY2012. FSIS anticipates that it will share this plan publicly by early calendar year (CY) 2012.

1.0 Introduction

Background

The mission of the Food Safety and Inspection Service (FSIS) is to ensure that meat, poultry and processed egg products are safe, wholesome and properly labeled and packaged. Further, as FSIS is a public health agency, one of the primary goals of the Agency is to reduce and ultimately prevent foodborne illness in the population.

Product testing, whether performed by industry or FSIS, is particularly important in gauging the safety of regulated product. Ensuring that products meet pathogen contamination standards and chemical residue levels is the responsibility of industry. The routine sampling in FSIS-regulated domestic and import establishments allows the Agency to assess the effectiveness of industry process controls, compliance with performance standards and the monitoring the proportion of finished product where microbiological or chemical contaminants are detected on products being produced for American consumers. Additionally, sampling serves as a strong incentive for the meat, poultry and processed egg product industries to reduce the presence of pathogens on products they produce. Further, product sampling provides the regulated industries with critical information to improve current processes and focus their resources as efficiently and effectively as possible.

The Hazard Analysis and Critical Control Points (HACCP) system is an established food safety system, whereby meat and poultry establishments identify and evaluate hazards that can affect the safety of their products, institute controls necessary to prevent those hazards from occurring or keeping them within acceptable limits, monitor the performance of controls and maintain records of these practices. Microbiological and chemical residue sampling are critical components of HACCP and, as a part of FSIS' verification responsibilities, are used to help ensure that foods regulated by the Agency are safe to eat, verify that prevention efforts undertaken by a domestic establishment are successfully controlling pathogens and chemical residues and ensuring products imported from foreign countries are safe and wholesome. FSIS published the "Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems" Final Rule (61 FR 38806) in July 1996. The overarching goal of FSIS' food safety strategy and the PR/HACCP regulations is to reduce, to the maximum extent possible, the risk of foodborne illness associated with the consumption of meat and poultry products.

Current Intent and Purpose of FSIS Sampling Programs

FSIS inspects regulated establishments in a comprehensive fashion. The overall purpose of FSIS inspection and sampling is to verify that establishments maintain control of their production processes and adhere to Agency regulations, policies and performance standards, which FSIS believes helps protect the public from foodborne illnesses. Because sampling is part of FSIS' verification activities, samples are collected at regular intervals, (e.g., once a week or month) though the frequency of microbiological testing is sometimes stratified based on an establishment's production volume. FSIS' microbiological testing programs were developed to be pathogen-specific. Consequently, the outcome of a positive sample can vary with each program. For example, some FSIS sampling programs enforce the Agency's zero tolerance policy for the presence of pathogens, such as *Escherichia coli (E. coli* O157:H7) and *Listeria monocytogenes (Lm)*. Others, such as verification programs for *Salmonella* and *Campylobacter* in raw products, evaluate how well regulated establishments demonstrate process control for these pathogens. In the section below, the intent of each sampling program is briefly described. A

more complete description of the intent and purpose of each microbiological testing program, as well as chemical residue testing, are included in the following chapters.

Domestic, Federally Inspected Establishments

Microbiological

Currently, FSIS conducts microbiological sampling for four major pathogens of human health concern: *Salmonella, Campylobacter, E. coli* O157:H7[1] and *Lm.* Briefly, for *Salmonella sp.*, FSIS conducts a verification testing program per the 1996 PR/HACCP Rule to ensure that the *Salmonella* reduction performance standards are being met for the eight raw product classes, as well as a sampling program for processed egg products. For *Campylobacter*, FSIS initiated a sampling program in young chicken and turkeys in July 2011 based on new performance standards. For *E. coli* O157:H7, the objective of the verification testing program is to verify the effectiveness of the food safety system on a national level and encourage continuous industry improvement in the reduction of the pathogen in raw ground beef and other raw beef products. Finally, for ready-to-eat (RTE) meat and poultry products, the objective of the multiple regulatory testing programs is to verify the effectiveness of food safety systems in preventing the presence of *Lm* and *Salmonella* in RTE products and in the establishment's environment. In addition to these routine sampling programs, most microbiology programs have a consequential (for cause) sampling component when the production process within a regulated establishment is determined to be out of control.

Chemical Residue

FSIS sampling programs for chemical residues both in domestic and import establishments are designed to achieve the following: (1) a structured process for identifying and evaluating compounds of concern by production class; (2) the capability to analyze for compounds of concern; (3) appropriate regulatory follow-up to reports of violative tissue chemical residues; and (4) collection, statistical analysis and reporting of the results of these activities.

In-Commerce Sampling

The in-commerce sampling program is one facet of a comprehensive set of activities conducted by FSIS Compliance and Investigations Division (CID) Investigators. Microbiological sampling of FSIS-regulated products in-commerce is intended to verify that persons and firms—whose business activities involve FSIS-regulated products— prepare, store, transport, sell or offer for sale or transportation these products in compliance with the Agency's statutory and regulatory requirements.

Import Sampling Programs

In order to focus FSIS resources on imported products that may pose the greatest threat to public health, the Agency utilizes a performance-based approach to define the scope of equivalence verification audits of foreign countries and to determine the frequency of Point-Of-Entry (POE) reinspections. Consistent with domestic programs, this approach relies on previous audit findings and inspection results, as well as information regarding the product types and product volumes presented for importation into the U.S. In

[1] FSIS recently published a proposed rule in the Federal Register stating the Agency's intention to carry out verification procedures, including sampling and testing manufacturing trim and other raw ground beef components, to ensure control of both *E. coli* O157:H7 and six other serogroups of Shiga toxin-producing *E. coli* (STEC) (O26, O45, O103, O111, O121, and O145). FSIS has determined that they, as well as O157:H7, are adulterants of non-intact raw beef products and product components within the meaning of the Federal Meat Inspection Act (FMIA). http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2010-0023.pdf.

import sampling, FSIS utilizes foreign country/establishment past performance, sampling history, product type and product volume produced to assist in the design of sampling plans for *Salmonella, E. coli* O157:H7, and *Lm*. The overall purpose of FSIS import sampling is to ensure that meat, poultry and processed egg products imported into the U.S. are produced under an equivalent inspection system and are as safe as products produced domestically.

Sampling Along the Farm-to-Table Continuum

FSIS' sampling programs in establishments, in-commerce and for imported products are key components of a farm-to-table approach to food safety. This approach includes all facets of the food production process; from animal slaughter within FSIS regulated establishments, to food processing within regulated establishments, to retail establishments and home environments. FSIS seeks to have an active presence in all these venues and includes pre-harvest activities, establishment inspection, industry education at retail and consumer education in the home. For example, in domestic *E. coli* O157:H7 sampling, FSIS collects samples of beef, such as bench trim and components, as it is processed. FSIS also conducts a risk-based sample collection program in raw ground beef. If any positive samples are identified, FSIS conducts additional sampling to ensure that the establishment regains control of its processes and produces safe product. Finally, FSIS maintains an independent sampling program in-commerce for raw ground beef. While these three sampling projects were designed and are maintained separately, by sampling in these three venues—slaughter, processing, and in-commerce—FSIS seeks to verify the effectiveness of industry process controls across multiple sectors and target areas for intervention along this continuum when more attention is needed. The same principles apply to sampling for other pathogens and product classes. For example, FSIS samples in establishments on food contact and non-food contact environmental surfaces, as well as sampling for *Lm* in both non-post-lethality exposed and post-lethality exposed RTE products. As with *E. coli* O157:H7 sampling, any positive test results are followed-up with additional, intensified verification sampling to ensure that establishments identify the source of contamination and bring processes back under control. Finally, FSIS seeks to harmonize sampling programs for both domestic and imported meat, poultry and processed egg products. As such, FSIS samples for *Salmonella*, *E. coli* O157:H7 and *Lm* in imported products such as beef, processed egg products and RTE. In summary, by adopting a farm-to-table approach not only in FSIS' overall approach to food safety, but also within the Agency's sampling programs, FSIS seeks to address food safety risks along the food chain and reduce the overall number of foodborne illnesses associated with FSIS regulated products.

Relationship between FSIS Sampling and USDA/FSIS Strategic Plan Goals to Utilize a Data-Driven Approach and Reduce Foodborne Illness

In September 2010, FSIS released two reports; the *FSIS Strategic Data Analysis Plan for Domestic Inspection*[2] and *Data-Driven Inspection for Processing and Slaughter Establishments: Public Health Decision Criteria*.[3] These reports were developed to communicate FSIS' strategy for a data-driven approach to domestic inspection and describe the Agency's public health-based, data-driven decision criteria and a decision tree to select meat and poultry establishments for additional inspection activities. Further, these reports were designed to directly support FSIS' strategic goals by providing the data and analyses necessary to effectively allocate resources and measure performance. The release of this 2011

[2] Please see the following website for more information:
http://www.fsis.usda.gov/OPPDE/NACMPI/Sep2010/2010_Strategic_Data_Analysis_Plan.pdf.
[3] Please see the following website for more information:
http://www.fsis.usda.gov/OPPDE/NACMPI/Sep2010/2010_Public_Health_Decsion_Criteria_Report.pdf.

Sampling Program report continues FSIS' efforts to comprehensively identify Agency activities and consider them in light of data-driven strategic planning efforts.

Similarly, the U.S. food safety system involves multiple stakeholders along the farm-to-table continuum and includes multiple federal and state partners, regulated industries, as well as active participation from the American consumer. While FSIS recognizes that inspection and sampling at regulated slaughter and processing establishments are just two pieces of FSIS' food safety activities, the Agency believes that reducing the overall presence of harmful foodborne pathogens on products regulated by FSIS can bring about reductions in foodborne illnesses from *Salmonella*, *Campylobacter*, *E. coli* O157:H7 and *Lm* in the U.S. population. FSIS is working internally and externally with federal food safety partners to further refine our understanding of the relationship between Agency activities and foodborne illness.

Organization of Sampling Program Report

This report serves as the first of a two-part effort by FSIS to increase transparency and share information regarding the Agency's microbiological and residue sampling programs. The purpose of this report is to provide a historical grounding and a detailed description of FSIS' current sampling programs. This report contains information on how FSIS carries out the Agency's sampling programs through fiscal year 2011. Given the timeframe in which this report is being released, however, tables containing sample analysis numbers are current as of fiscal year 2010. Fiscal year 2011 sample collection and analysis numbers will be provided in the Agency's annual Sampling Program Plan, scheduled for release in the beginning of CY2012.

This report comprehensively describes the current design, statistical/policy basis and current limitations of FSIS' sampling programs. For ease of understanding and to correspond with FSIS' current organizational structure, this report is organized by the major venues in which FSIS conducts sampling; 1) Domestic, federally-inspected establishments, 2) Imports and 3) In-Commerce. FSIS also conducts outbreak investigation and sampling in response to illnesses and consumer complaints. Further, FSIS conducts two distinct types of sampling: 1) Microbiological and 2) Chemical Residues.

In general, sampling for a specific pathogen, such as *Salmonella*, is referred to in this report as "sampling program", whereas individual sampling for specific pathogens, such as HC01 for *Salmonella*, are considered "sampling projects". As such, this report will be organized first around the venue in which the sampling occurs and second, around the type of sampling program. Each major section of this report also contains information about the type of analysis FSIS conducts to determine whether or not, and to what extent, a pathogen exists on regulated product and a discussion of the volume of product produced by regulated industries, as it relates to FSIS sampling programs.

Future FSIS Sampling Program Activities

FSIS anticipates that the Agency's sampling activities will evolve over time for myriad reasons, including new and emerging public health hazards, as well as technological and methodological advancements and updates to FSIS policy. Consequently, the second part of this effort involves the development, as per the recently published FSIS Strategic Plan for 2011-2016, of a sampling program Plan that identifies fiscal year (FY) 2011 sample collection and analysis numbers, changes to the Agency's sampling activities to be implemented in FY2012 and provides summary measures for existing and emerging food safety hazards. FSIS anticipates that the plan will also be shared publicly and should be finalized by the beginning of calendar year (CY) 2012.

FSIS Public Health Information System (PHIS)

On April 11, 2011, FSIS launched its dynamic, comprehensive data analytics system called the Public Health Information System (PHIS). PHIS is a web-based application that integrates and automates FSIS' paper-based business processes into one comprehensive and fully automated data-driven inspection system. It will help facilitate the sharing of data among inspection personnel, their managers and headquarters on a daily basis. PHIS is also a powerful decision-making tool that will enable FSIS to protect public health more efficiently, effectively and rapidly than under existing systems.

As a result of implementing PHIS, many of FSIS' existing systems, such as the Performance Based Inspection System (PBIS) and, eventually, the Automated Import Information System (AIIS), will be phased out and replaced by PHIS. As such, the way in which sampling information is scheduled, shared and stored will change under PHIS. However, it is important to note that none of the fundamental elements of FSIS' sampling activities, such as the sampling frame, methodology or collection methodology will change and the transition to PHIS will not affect the day-to-day operations of pathogen verification and other FSIS sampling programs.

Definition of Terms

As this report focuses primarily on FSIS sampling programs, the reader may encounter several terms that might not be familiar. Consequently, a catalogue of technical terms utilized in this report is included in **Appendix A.**

2.0 Domestic, Regulated Establishments

Section 2.1: Microbiological Sampling Programs

2.1.1: *Salmonella*

Overview of Sampling Programs

FSIS collects *Salmonella* samples in eight raw meat and poultry product classes (*Salmonella* Pathogen Reduction Performance Standards-- project code HC01 and HC11)[4], two RTE meat and poultry products (project codes ALLRTE and RTE001) and nine processed egg products categories (project codes EM and EGGDOM). Broiler and turkey samples collected under HC11 are co-analyzed for *Campylobacter* (see Section 2.1.2). In addition, *Salmonella* testing is conducted on some raw ground beef samples collected for *E. coli* O157:H7 testing, with the *Salmonella* results recorded under project code MT43S. In the section below, the HC01, HC11, MT43S and Egg Sampling programs are reviewed. The *Salmonella* sampling program for RTE meat and poultry products (ALLRTE and RTE001) will be reviewed in the *Lm* RTE section of this report. Information on different domestic *Salmonella* sampling projects is summarized in Table 2.1.1.1.[5]

[4] Sample sets for Market Hogs, Cows/Bulls, or Steers/Heifers were not scheduled in the latter half of FY 2011.
[5] As of July 1, 2011 all broiler and turkey sets are being co-analyzed for *Campylobacter* and scheduled as HC11, not HC01.

Table 2.1.1.1 FSIS *Salmonella* Domestic Sampling Projects

Product class	*Salmonella* Sampling Projects	Number of *Salmonella* Samples Analyzed FY2010	Regulatory Purpose of Sampling Project	Type of Sampling Project
Steers/heifers[6]	HC01	6,550	Verify consistent process control	Risk Based
Cows/bulls[7]	HC01	1,688	Verify consistent process control	Risk Based
Raw Ground beef	HC01	8,982	Verify consistent process control	Risk Based
Market hogs[8]	HC01	305	Verify consistent process control	Risk Based
Broilers[9]	HC01 HC11	762	Verify consistent process control	Risk Based
Ground chicken	HC01	3,913	Verify consistent process control	Risk Based
Ground turkey	HC01	3,811	Verify consistent process control	Risk Based
Turkeys[10]	HC01 HC11	1,303	Verify consistent process control	Risk Based
Raw Ground beef	MT43S	2,957	Verify consistent process control	Random
Ready-to-eat (RTE) meat and poultry products	ALLRTE	2990	Verify adequacy of an establishment's ability to prevent microbiological contamination	Random
Ready-to-eat (RTE) meat and poultry products	RTE001	8700	Verify adequacy of an establishment's ability to prevent contamination from *Salmonella* and *Lm*	Risk Based
Egg whites with or without added ingredients	EM-31	292	Verify adequacy of a establishment's ability to prevent contamination from *Salmonella*	Random
Whole eggs/yolks with <2% added ingredients other than salt or sugar	EM-32	389	Verify adequacy of a establishment's ability to prevent contamination from *Salmonella*	Random
Whole eggs/yolks with ≥2% added ingredients other than salt or sugar	EM-33	141	Verify adequacy of a establishment's ability to prevent contamination from *Salmonella*	Random

[6] Supra footnote 4.
[7] Supra footnote 4.
[8] Supra footnote 4.
[9] No longer being scheduled for HC01 with the implementation of the new *Salmonella* and *Campylobacter* performance standards in July 2011.
[10] Supra footnote 9.

Product class	*Salmonella* Sampling Projects	Number of *Salmonella* Samples Analyzed FY2010	Regulatory Purpose of Sampling Project	Type of Sampling Project
Whole eggs/yolks with ≥2% salt or sugar added	EM-34	287	Verify adequacy of a establishment's ability to prevent contamination from *Salmonella*	Random
Dried yellow egg products	EM-35	114	Verify adequacy of a establishment's ability to prevent contamination from *Salmonella*	Random
Spray dried egg whites (with or without added ingredients)	EM-36	104	Verify adequacy of a establishment's ability to prevent contamination from *Salmonella*	Random
Pan dried egg whites	EM-37	10	Verify adequacy of a establishment's ability to prevent contamination from *Salmonella*	Random
Domestic liquid, frozen or dried egg products	EGGDOM	61	Verify adequacy of a establishment's ability to prevent contamination from *Salmonella*	Random

***Salmonella* Verification Project: HC01**

Historical Basis

In 1996, FSIS adopted the PR/HACCP final rule that instituted pathogen reduction performance standards in the major species and raw product classes.[11] At that time, there were eight classes of raw products for which FSIS had conducted nationwide baseline studies. These classes were: steers/heifers, cows/bulls, raw ground beef, broilers, market hogs, ground turkey, ground chicken and turkeys. From these baseline studies, FSIS estimated the mean prevalence of *Salmonella* in each class and then developed establishment-level performance standards to encourage all establishments to produce product whose prevalence of contamination was less than or equal to the mean prevalence for each of these classes of raw product. "Minor species," such as sheep, goats, equines, ducks, geese and guineas, were not addressed because FSIS chose to first address the most commonly consumed foods under its jurisdiction. At the time, FSIS intended to address how best to gather data and develop pathogen reduction performance standards for these other food animals at a future date.

Salmonella, regardless of serogroup/serotype, was selected as the target organism for a number of reasons: (1) it is the most common bacterial cause of foodborne illness; (2) FSIS baseline data show that *Salmonella* colonizes a variety of mammals and birds and occurs at frequencies that permit changes to be detected and monitored; (3) current methodologies can recover *Salmonella* from a variety of meat

[11] The most complete record of the original design and implementation strategy for this verification testing program is contained in the Pathogen Reduction/Hazard Analysis and Critical Control Point System final rule (61 FR 38806, July 25, 1996; see: http://www.gpo.gov/fdsys/pkg/FR-1996-07-25/pdf/96-17837.pdf. In addition, on February 17, 2005, FSIS published updated pathogen reduction performance standards for the raw classes of product that were identified as under development but not yet ready to publish in the July 25, 1996, Federal Register (see: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/02-046N.pdf). FSIS' use of baseline studies to determine performance standards was also described in a May 6th, 2002 FSIS Symposium entitled "Symposium on Pathogen Reduction: A Scientific Dialogue. Transcripts from this symposium can be found at: http://www.docstoc.com/docs/23091585/Pathogen-Reduction-A-Scientific-Dialogue---May-5-2002.

and poultry products; and (4) intervention strategies aimed at reducing fecal contamination and other sources of *Salmonella* on raw product should also be effective against other pathogens.

FSIS continues to conduct baseline studies to adjust the pathogen reduction performance standards. It is important to note that the pathogen reduction performance standards are not lot-release standards and the detection of *Salmonella* in a specific lot of raw product does not by itself result in the condemnation of that lot. The pathogen reduction performance standard policy was based on the public health judgment that reducing the percentage of carcasses with *Salmonella* would reduce the risk of foodborne illness to the public. The policy was also based on the regulatory policy judgment that establishing a clear standard for *Salmonella*, in conjunction with the implementation of PR/HACCP, would lead to significant reductions in contamination rates. At the time that the pathogen reduction performance standards were developed, there had not been a quantitative assessment of the public health impact associated with implementation.

FSIS created a verification testing project—HC01—to ensure that the *Salmonella* pathogen reduction performance standards are being met. Testing is conducted in sample sets, as described in the sampling methodology section below. The design of the pathogen reduction sample sets for raw classes of product was explicitly predicated on daily testing. When FSIS published the PR/HACCP rule, the Agency proposed requiring that establishments, not FSIS, conduct daily testing and to complete at least one sample set within a 12-month period. These design features were discussed at length at multiple public meetings, including a technical meeting in Philadelphia in which FSIS invited subject matter experts to discuss approaches to verification testing.[12] Numerous comments were received on the proposed rule specific to these design features. In response to comments, FSIS elected to conduct the daily testing for *Salmonella* to allow the Agency to have a direct measure of accountability for individual establishment control in reducing harmful bacteria in raw meat and poultry. In the implementation of the FSIS verification testing program, the Agency maintained the consecutive day sampling and 12-month completion features. FSIS designed the verification testing program in a manner to force establishments to test process control variables during a 90-day initial validation period and to maintain process control that resulted in consistently wholesome and safe product, even if changes occur in source materials or processing conditions. Consecutive day testing, with one sample collected per day, was deemed to be an appropriate timeframe to cause establishments to assess potential variability in their pathogen control program and to provide sufficient time to adjust their control program to attain compliance when the production process trended out of control early in the sample set. Daily testing for more than 50 consecutive days of production was recognized as a means for establishments to cycle through numerous source material suppliers and better reflect operational control capability over time, rather than collecting multiple samples a day, possibly all from the same source material supplier, and not demonstrate sustained control of the production process.

Under the *Salmonella* verification program as conducted from 1996 to 2006, the Agency verified that establishments were meeting a *Salmonella* standard or guideline by having FSIS inspection program personnel (IPP) collect randomly-selected product samples from randomly-selected individual establishments over the course of a defined number of sequential days of production to complete a sample set. Generally, these tests were conducted once each year for each establishment. Procedures for testing are described in Appendix E of the PR/HACCP Final Rule (61 FR 38917–38928). Although the original enforcement strategy for the *Salmonella* reduction performance standards was designed to

[12] Please see the following website for more information: http://www.gpo.gov/fdsys/pkg/FR-1998-10-07/pdf/98-26543.pdf

cause inspection to be withdrawn from an establishment after three consecutive sample set failures, a court challenge (known as the Supreme Beef case) now prevents FSIS from enforcing this provision in raw beef grinding operations, particularly when the beef is derived from carcasses that passed the Agency's pathogen reduction performance standard. As a result, FSIS modified its enforcement strategy for all classes of raw products and now uses the *Salmonella* set result as one piece of information in determining the adequacy of an establishment's food safety system.[13]

In order to address issues of resource allocation and time management, as well as provide U.S. States with "equal to" meat or poultry inspection programs, in 1997 FSIS crafted shorter *Salmonella* sample sets than were expected to be used by the Agency for State inspection programs. FSIS recognized that "equal to" State establishments typically would be classified as HACCP establishment size "very small" and that these establishments typically produce more than one class of product subject to *Salmonella* verification testing on the same day. In addition, these establishments typically processed a given class of product intermittently (e.g., weekly or seasonally). Because the minimum number of days for any sample set size was 51 days, with most sets of less than 60 days and only one set greater than 80 days, a sample set likely would not be completed within a 12-month period. Consequently, FSIS crafted shorter sample sets that were designed to achieve similar statistical confidence regarding the establishment's control of *Salmonella*.[14] Sample collection for States was updated in FY2011 to reflect the *Salmonella* and *Campylobacter* performance standards.

FSIS routinely reviews the *Salmonella* performance standards to identify gaps in the current policy and to tailor the standards to better protect the public's health. As a result, FSIS has made several changes over the years to refine the standards. One such change occurred in February 2006, when FSIS introduced a categorization system for *Salmonella* set results to address adverse trends, whereby establishments with consecutive sets with less than or equal to half of the current acceptable number of *Salmonella* positive test results in the sample set would be identified as being in Category 1.[15] Establishments with half or more, but not exceeding the acceptable number of *Salmonella* positive test results in a set, are placed in Category 2. Establishments exceeding the acceptable number of *Salmonella* positive test results in a set are placed in Category 3 and consequently fail the *Salmonella* pathogen reduction performance standard. FSIS also posted quarterly *Salmonella* sample set results on the Agency's website and provided results back to establishments immediately upon completion of each test, rather than waiting until the end of the sample set.

By January 2008, FSIS was using the new sample scheduling algorithm adopted in 2006 and scheduling approximately 75 new verification sample sets for *Salmonella* in raw classes of product each month. FSIS allocates its sampling resources within classes of raw product based on consideration of specified criteria, as provided in the *Salmonella* HC01 description below.[16,17] As a result of allocating sampling resources in a targeted manner, FSIS is able to fulfill many of the higher priority criteria, such as sampling establishments of greater concern. Now, Category 1 establishments are sampled in a period of time that may extend up to two years, whereas Category 2 establishments are scheduled at least once

[13] Please see the following website for more information: http://www.fsis.usda.gov/Fact_Sheets/FSIS_Sets_New_Procedures/index.asp.
[14] Please see the *Salmonella* (Connie Bacon) Sampling Letter for more details and sample collection requirements.
[15] Please see the following website for more information: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/04-026N.pdf.
[16] Please see the following website for more information: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2006-0034.pdf.
[17] Please see the following website for more information:
http://www.fsis.usda.gov/Science/Scheduling_Criteria_Salmonella_Sets/index.asp.

each year until the establishment's category changes. Category 3 establishments are scheduled as close to continuously as possible, until the establishment produces better results.

In May 2006, FSIS implemented a program to obtain serotype data from *Salmonella* PR/HACCP project isolates and share of serotype data with establishments in a timely manner. After FSIS laboratories report the analysis results, isolates of *Salmonella*-positive HACCP samples are serotyped at the USDA Animal and Plant Health Inspection Service's (APHIS) National Veterinary Services Laboratories (NVSL) in Ames, Iowa. In recent years, virtually all samples positive for *Salmonella* have been serotyped. Identified serotypes are communicated to establishments as soon as they are reported by APHIS to FSIS, usually within two weeks after a HACCP sample has been reported as positive. A report listing aggregate identified serotypes by year was posted in August 2007 on the FSIS website at http:// www.fsis.usda.gov/Science/ Serotypes_Profile_*Salmonella*_Isolates/ index.asp.

Additionally, in August 2007, when FSIS and the Agricultural Research Service (ARS) signed a cooperative Memorandum of Agreement for subtype data sharing, FSIS implemented a program to obtain timely access to pulsed field gel electrophoresis (PFGE) subtype data, identifying specific strains of *Salmonella* serotypes obtained from HACCP testing. Under this agreement, PFGE subtype information on *Salmonella* isolates collected by FSIS from raw meat and poultry products is matched with subtype information from isolates associated with human illness in PulseNet, a database maintained by the Centers for Disease Control and Prevention (CDC). FSIS has routine access to subtype data for all isolates maintained by ARS, in a time frame short enough to be relevant to in-establishment and public health investigations.[18]

In January 2008, FSIS chose to exclude from the *Salmonella* verification testing project schedule any slaughter establishment that processes all slaughtered carcass into RTE (e.g., cooked) product or diverts all of its raw products to another federally-inspected establishment for further processing into a RTE product. This decision is justified because FSIS conducts separate verification testing for *Salmonella* in RTE meat and poultry products via the ALLRTE and RTE001 sampling projects. If the establishment is undergoing sampling for *Salmonella*, but then elects to send all affected product to RTE, FSIS will continue to sample until the set is completed. At the end of the set, FSIS will verify that all products undergo further processing into RTE product within the establishment or in another Federal establishment. If and when such establishments again produce raw product for sale, they will be re-scheduled for *Salmonella* verification sets.

Also at that time, FSIS announced in a Federal Register Notice additional activities for low-volume ground beef operations, minor species and import samples, which have since been implemented by the Agency.[19] FSIS recognized that low-volume raw ground beef producers, which produce less than 1000 pounds of product per day, constitute a large part of the sampling frame for establishments eligible for verification sample set scheduling, though they account for a very small proportion of the raw ground beef supply. Since production of ground beef at these establishments may not occur throughout a week or month, sampling them for *Salmonella* may be extended for a year or more before a set is completed, as opposed to no more than a couple of months of sampling for higher volume establishments. To

[18] FSIS currently uses PFGE and Multiple Locus VNTR Analysis Method (MLVA) for subtyping pathogens. PFGE is considered the 'gold standard', and MLVA may help further differentiate subtypes to assist in making connections between isolates from case patients and FSIS-regulated products.

[19] Please see the following website for more information: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2006-0034.pdf.

increase efficiency, FSIS announced that samples collected at these establishments for *E. coli* O157:H7 testing would be tested for *Salmonella* as well. As a result, these establishments were removed from the *Salmonella* verification testing sample set scheduling frame. The FSIS laboratories now perform qualitative testing for the presence or absence of *Salmonella* using the same methodology, discard criteria and reporting as those in place for *Salmonella* ground beef HACCP samples, as described below. A description of this sampling project, known as MT43S, is provided below.

Most recently, on May 14, 2010, FSIS published a Federal Register Notice (75 FR 27288) in which it announced the implementation on July 1, 2011 of new performance standards for *Salmonella* and *Campylobacter* for chilled carcasses in young chicken (broiler) and turkey slaughter establishments. The new performance standards were developed in response to a charge from President Obama's Food Safety Working Group (FSWG) and based on recent FSIS Nationwide Microbiological Baseline Data Collection Programs. The standards are applied to sample sets collected and analyzed by FSIS to evaluate establishment performance with respect to requirements of the PR/HACCP Rule. These performance standards are the basis for assessing an establishment's process control for *Salmonella* and *Campylobacter* and for determining whether an establishment passes or fails a *Salmonella* or *Campylobacter* verification set. All sample sets scheduled for young chicken and turkey establishments are analyzed for both *Salmonella* and *Campylobacter* and follow-up sample sets responding to sample set failures for either organism are analyzed for both organisms.

In addition to process control, FSIS identifies the serotype, PFGE and antimicrobial susceptibility pattern of *Salmonella* isolates from each positive verification sample. FSIS uses the subtyping results to identify historical trends within the sampling data to determine whether an isolate has a historical association with human illness, and to identify clusters of patterns. Since FSIS has not established a regulatory performance standard for *Salmonella* subtypes, this information is not used to determine the status of a *Salmonella* verification set, including whether the establishment has passed or failed the set. Effective with samples sets starting in or after July 2011, *Salmonella* performance Categories 1 and 2, based on the new performance standards, are applied exclusively for FSIS internal analysis and not for web-posting purposes. FSIS posts quarterly aggregate reports showing the Category 1/2/3 distribution for each relevant product class subject to FSIS *Salmonella* testing, but does identify individual establishments.

Intent of Program

FSIS considers *Salmonella* verification testing to be a direct indicator of the effectiveness of process control. The raw pathogen performance standards program also serves a variety of other functions, including assessing establishment compliance with the performance standard, comparing industry-wide and peer-to-peer trends regarding percent positives over time, identifying serogroups of public health concern and their origins, as well as capturing pathogen isolates for PulseNet comparison and analyzing chilled product at specific points in the production process.

Type of Analysis

For each pathogen, FSIS performs different types of analysis on the sample collected. There are two possible types of analysis that the FSIS laboratories can conduct. First, FSIS laboratories can determine if the pathogen is present or absent in the sample. This is considered to be qualitative analysis. Second, FSIS laboratories can determine not only whether the pathogen is present, but also what the level of contamination is or the number of microorganisms present in the sample. This is considered to be

quantitative analysis. FSIS uses several types of quantitative analyses, including direct plating enumeration methods and the Most Probable Number (MPN) enumeration procedure, which is used to estimate the population density of viable microorganisms in a test sample.

For *Salmonella,* analysis of samples for the HC01 sampling project are qualitative, in that samples are tested for the presence or absence of *Salmonella*, rather than a count of the number of organisms in the sample. For the MT43S testing project for *Salmonella* in raw ground beef, FSIS also uses the MPN enumeration procedure to estimate the level of contamination in samples that first test positive on a qualitative screening test.

Volume Data

Yearly production volumes for raw intact beef, chicken, turkey and pork are acquired from slaughter volume data in the Electronic Animal Disposition Reporting System (eADRS) database. Volumes for ground beef production are obtained by FSIS inspectors during sampling. The inspector classifies the establishment's volume into one of four volume groups and notes monthly days of production, from which an average annual volume can be estimated. Yearly production volumes for ground chicken and turkey are obtained from the PBIS, which contains each establishment's most recent production volume for various product types over the past 30 days. Each product class has a minimum slaughter volume, under which an establishment is excluded from sampling eligibility. For example, young chicken and turkey sampling eligibility requires a minimum of 20,000 birds slaughtered per year. For livestock, a minimum of 500 animals slaughtered per year is required.

Sampling Methodology

FSIS schedules eight product classes (young chickens, young turkeys, cows/bulls, steers/heifers, market hogs, ground chicken, ground turkey and ground beef) for *Salmonella* sampling on monthly basis—see Table 2.1.1.2.[20] An establishment's compliance with the applicable pathogen reduction performance standard is evaluated by taking the indicated number of samples—generally at the rate of one or more per day— and testing each sample for *Salmonella* to determine whether the number of positive results is above the maximum acceptable for that product class. Daily testing is considered the minimal sampling necessary to detect process deviations within a realistic time frame. FSIS currently collects multiple samples from each establishment in the form of sets. FSIS verifies that establishments are meeting the *Salmonella* standards by having IPP collect product samples from individual establishments over the course of a defined number of sequential days of production to complete a sample set, as described previously. Once a sample set begins, sampling is conducted daily until the set is completed. Depending on the frequency of production, product type and availability of resources, the time for FSIS to complete a sample set ranges from two months to over a year. *Salmonella* sets are scheduled using a "risk-based" approach, where establishments with a higher rate of *Salmonella* are scheduled more frequently than establishments with lower *Salmonella* rates. In establishments that produce more than one product subject to *Salmonella* verification testing, only one product is tested at a time. Annual reports summarizing results for calendar years are available on the FSIS web site.[21] Raw products with established performance standards are carcasses of cows/bulls, steers/heifers, market hogs, broilers and turkeys.[22] Processed products with performance standards are raw ground beef, ground chicken and

[20] Supra note 6

[21] Please see the following website for more information: http://www.fsis.usda.gov/Science/Microbiology/index.asp.

[22] Supra note 6.

ground turkey. The performance standards are currently based on the prevalence of *Salmonella* as determined from FSIS' nationwide microbiological baseline studies.

Table 2.1.1.2: *Salmonella* Performance Standard Set Definitions by Product Class

Product class	Performance standard	Number of samples tested	Sampling Method	Testing Method	Maximum number of positives to achieve standard
Steers/heifers	1.0%	82	Flank, brisket, rump surface sampling- 100 cm^2 for each using one cellulose sponge hydrated with BPW[23]	MLG 4.x-enrich sponge and BPW diluent	1
Cows/bulls	2.7%	58	Flank, brisket, and rump surface sampling- 100 cm^2 for each using one cellulose sponge hydrated with BPW	MLG 4.x-enrich sponge and BPW diluent	2
Ground beef	7.5%	53	One sample per event	MLG 4.x-25 gram test portion	5
Market hogs	8.7%	55	Ham, belly, and jowl surface sampling- 100 cm^2 for each using one cellulose sponge hydrated with BPW	MLG 4.x-enrich sponge and BPW diluent	6
Broilers	7.5%	51	400 ml BPW rinsate	MLG 4.x- 30 ml test portion	5
Ground chicken	44.6%	53	One sample per event	MLG 4.x-25 gram test portion	26
Ground turkey	49.9%	53	One sample per event	MLG 4.x-25 gram test portion	29
Turkeys	1.7%	56	Back and thigh surface sampling- 50 cm^2 for each using one cellulose sponge hydrated with BPW	MLG 4.x-enrich sponge and BPW diluent	4

Constructing the Sampling Frame

The *Salmonella* HC01/HC11 project includes eight different product classes for sampling: cow/bull, steer/heifer, market hog, broilers, turkeys, ground beef, ground chicken and ground turkey.[24] Eligibility requirements for the intact raw products differ from the intact ground products. This multiple step process is described below.

[23] BPW is Buffered Peptone Water

[24] Supra note 6.

I. Establishments Producing Eligible Product

The first step in this process is to create a list of all establishments that produce sufficient volumes of eligible products.

1) Intact Raw Products

Using the eADRS, the total number of each class of eligible intact product that has been slaughtered at FSIS regulated establishments in the last 12 months is collected. Establishments that meet the minimum production volume requirements are kept in the sampling frame. The minimum requirement is as follows for each product class:

A. Cow/Bull: minimum of 500 heads/year slaughtered
B. Steer/Heifer: minimum of 500 heads/year slaughtered
C. Market Hog: minimum of 500 heads/year slaughtered
D. Broilers: minimum of 20,000 heads/year slaughtered
E. Turkeys: minimum of 20,000 heads/year slaughtered

2) Raw Ground Beef

Establishments that had samples successfully collected and analyzed under the MT43 sampling project (*E. coli* O157:H7 in raw ground beef) in the last 12 months are eligible for *Salmonella* Verification Sampling. Inspectors report the daily raw ground beef production volume every time a MT43 sample is collected, so that the mode (most frequent) response over the last 12 months can be used to determine whether an establishment meets minimum production volume requirements.[25]

A. Raw Ground Beef: minimum of 1000 pounds/day produced[26]

3) Raw Ground Poultry (Chicken and Turkey)

Salmonella Verification Sampling Program eligibility for raw ground poultry is currently limited to establishments included in the ground chicken and ground turkey baseline studies conducted in the 1990's.[27] This is because currently FSIS neither collects detailed production volume data for ground poultry, nor does the sampling program include establishments that produce "raw comminuted poultry" products.[28]

II. Active Establishments

The second step is to include only establishments that are currently listed as active in their establishment profiles. Establishments that are shut down or withdrawn from inspection are removed from eligibility, as well as establishments that are currently inactive for any reason, such as seasonal producers and temporary closure.

III. Exclusions

Next, establishments that meet certain exclusionary criteria are removed from the sampling frame. These criteria include the following:

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[25] With the implementation of PHIS, production volume data will be available in establishment profiles, which may affect how FSIS determines establishments that meet production volume requirements for raw ground product (i.e. MT43 response no longer necessary).
[26] Establishments producing less than 1,000 pounds per day are tested for *Salmonella* under the MT43S (low volume) sampling program.
[27] Please see the following website for more information: http://www.fsis.usda.gov/Science/Baseline_Data/index.asp.
[28] FSIS Notice to expand *Salmonella* Verification testing to include other raw comminuted poultry products is currently in development. This will help in increasing the number of establishments eligible for ground poultry sampling.

1) **At Establishment Level**
   A. Establishments that are currently in an ongoing set for any product are removed from the sampling frame.[29]
   B. Establishments that completed and passed a set within 30 days of the date the sets are scheduled to start collection are removed from the sampling frame. This is also known as the Category 1 exemption, where establishments are excluded from sampling for up to two years.

2) **At Establishment Product Level**
   A. Occasional producers of products are identified by responses to prior sampling requests. Establishments for which IPP returned a *Salmonella* verification sampling request form with a code 72 response (product not produced in last 30 days) within 60 days of the date the sets are being scheduled to start collection are removed from the sampling frame for that product.
   B. Establishments that perform only exempt slaughter (custom or religious slaughter) are identified by responses to prior sampling requests.[30] Establishments for which IPP returned a *Salmonella* verification sampling request form with a code 60 response (product no longer produced) within 12 months of the date the sets are being scheduled to start collection are removed from the sampling frame for that product.

Exclusion Criteria

FSIS maintains a number of additional exclusion criteria in its HC01 sampling methodology not mentioned in the exclusion section list provided above. FSIS maintains exclusion criteria for low-volume establishments. For raw ground beef, establishments that produce less than 1,000 pounds per day are excluded from *Salmonella* verification sampling, although these establishments are sampled using the MT43S program. Please see MT43S sampling section for more information on this program. Establishments which slaughter less than 20,000 birds and less than 500 animal head per year are also excluded from *Salmonella* set-based sampling. Finally, FSIS maintains product class exclusions. All production classes other than young chickens, young turkeys, ground chicken, ground turkey, cows/bulls, steer/heifers and market hog are not eligible for *Salmonella* verification sampling. For example, sheep and lambs fall under this exclusion.

FSIS Scheduling Criteria and Algorithm for the *Salmonella* HC01/HC11 for Raw Meat and Poultry[31]

Objective:

FSIS schedules up to 75 new sample sets each month for raw meat and poultry.[32] The establishments and products selected for sample sets are chosen according to a risk-based algorithm that involves sorting the list of eligible establishments and their respective products by certain criteria and selecting the top 75 from this list.[33] These priority groups are sorted in descending order of importance.[34]

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[29] If an establishment products multiple products, these products are scheduled independently; however, it will not be scheduled for more than one set at a time.

[30] Establishments that perform both exempt and non-exempt slaughter are eligible for Verification Sampling for the non-exempt products.

[31] Includes *Campylobacter* testing for broiler and turkey carcass sets begun after July 1, 2011.

[32] See Federal Register Notice of July 25, 1996 regarding the HACCP Systems Final Rule; http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/93-016F.pdf

[33] See "SOP to Identify Establishments Eligible for Inclusion in *Salmonella* and *Campylobacter* Verification Sampling Program" on FSIS website at http://www.fsis.usda.gov/Science/Microbiology/index.asp

Criteria:

I. Establishment Category or Establishment Status[35]

Establishments are initially sorted by category or status:

1) Category 3 Establishments (includes establishments with one completed set that was failing)
2) New Establishments and existing establishments with newly eligible product[36]
3) Establishments with one completed set that was passing[37]
4) Category 2 Establishments
5) Category 2T Establishments
6) Category 1 Establishments (≥660 days since last set)
7) Category 1 Establishments (365 to 659 days since last set)[38]

II. Product

Within each status category, establishments are then sorted based on product priority:

1) Broilers[39]
2) Young Turkeys[40]
3) Market Hogs[41]
4) Ground Chicken[42]
5) Ground Turkey[43]
6) Ground Beef[44]
7) Cows/Bulls[45]
8) Steers/Heifers[46]

III. Most Recent Set Result

Within each product class, priority is assigned based on the result of the most recent *Salmonella* set.

1) Failed; Exceeded Performance Standard
2) Passed; > 50% Performance Standard
3) Passed; ≤ 50% Performance Standard

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[34] This algorithm is subject to periodic intra-program review and adjustment; during natural disasters (e.g., hurricane), Category 2 establishments not currently scheduled may be scheduled.

[35] See FSIS method to categorize *Salmonella* establishments published in Federal Register Notice of January 28, 2008 (73 FR 4767-4774; http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2006-0034.htm).

[36] Includes eligible turkey slaughter establishments (carcasses) as of May 2006, and any new establishment operating for at least 90 days (to accommodate 9 CFR 304.3).

[37] These establishments, technically category 2 or 2T, are placed ahead of other category 2 and category 2T establishments.

[38] Category 1 establishments are not routinely scheduled for sampling until at least 12 months after their last set.

[39] Broiler and young turkey establishments are considered new establishments until 2 sets have been completed under the new *Salmonella/Campylobacter* performance standards, and will be targeted for expedited sampling. If an establishment fails EITHER *Salmonella* OR *Campylobacter* it will be treated as a failed set (for the purposes of scheduling only) and be scheduled for an immediate follow-up set the next month.

[40] Supra note 39.

[41] Supra note 6.

[42] If establishment is combination carcass/grinding operation, these products are scheduled independently (these establishments will have a category for each product); carcass and ground product sets will not be scheduled concurrently.

[43] Supra note 42.

[44] Supra note 42.

[45] Supra note 6.

[46] Supra note 6.

IV. Human Health Serotypes Linked to Product Class
Within each group of recent set results, the next priority is given to the number of human health serotype isolates identified in samples from an establishment's last set.[47]

V. Days Since Last Completed Set
Final priority is given to the number of days since each establishment's last completed set.

Additional Requirements:
As monthly availability permits, additional establishments may also be scheduled for *Salmonella* sample sets by request from FSIS.

As of July 1, 2011, the new *Salmonella* performance standards for broilers and young turkeys became effective. For the purposes of scheduling only, *Salmonella* categorization of establishments for these two market classes will be determined as if the standards had been in place at the time an establishment's most recent two *Salmonella* verification sets were performed, including sets performed prior to July 1, 2011.[48] Also, broiler and turkey *Salmonella* sets scheduled after July 1, 2011 are being co-analyzed for *Campylobacter*. All broiler and turkey establishments will maintain their *Salmonella* category status, but will be marked as having "newly eligible product" or "one completed set" until two sets are completed under the new testing program.[49]

Establishment categories for these poultry establishments are based on the *Salmonella* set results. However, if a establishment fails a set for either *Salmonella* or *Campylobacter*, it will be treated as a failed set (for the purposes of scheduling only) and be scheduled for immediate follow-up set the next month.

In the initial phase of implementation with regard to FSIS laboratory sampling capacity, a maximum of 16 broiler and turkey sets can be scheduled each month. Currently, the goal is to schedule the top 12 broiler establishments and the top four turkey establishments from the sorted list of eligible establishments. These target numbers are subject to quarterly review and adjustment by FSIS. The remainder of the 75 sample sets will come from other products. A discussion of FSIS' new sampling project for *Campylobacter* is included in Section 2.1.2.

Statistical or Policy Basis for Current Sampling Plan
The procedure for determining a compliance criterion to evaluate an individual establishment's performance with respect to the standard is based on an approximate 80% probability of passing the criterion, when the establishment's prevalence is equal to the performance standard percentage. Stated differently, the type 1 error rate of asserting (incorrectly) that the establishment's prevalence is greater than the performance standard is about 0.2 (20% probability of failing) when the establishment is performing at the performance standard. For a given performance standard equal to a proportion; p; the compliance criterion should be no more than m positive results in n analyzed samples comprising a sample set. Thus, m is selected such that P(m) – the probability of a random, binomially distributed variable with number parameter, n, and proportion parameter, p is less than or equal to m – is closest to

[47] Number calculated using top 20 Human Health Serotypes for most recent calendar year as reported by the CDC.
[48] See FSIS Notice 31-11 (dated 6/30/11) for information on how actual individual and aggregate set results and establishment categorizations will be reported.
[49] Once 90% of broiler and turkey establishments have 2 completed sets under the new standard, FSIS will begin putting them into categories for *Campylobacter* as well as *Salmonella*.

0.8 compared to any other value of P(m') for m' not equal to m. The other constraint is that n is a minimum of 50 samples.

Output from Sampling Results

End of Set Letters

At the completion of each *Salmonella* set, FSIS sends an "end-of-set (EOS) letter" to the sampled establishment explaining the establishment's status based on the overall set results. Each letter lists specific set factors: the number of *Salmonella* serotypes associated with human illness (high, average or low for the product class tested) and the timeframe for when the next sample set will begin at that establishment. With the new FSIS performance standards, the EOS Letter will report the establishment's *Salmonella* Category status based on the standard in effect when each reported set was started. FSIS is working with the CDC and the ARS to establish mechanisms to routinely share and compare subtyping information. As a result, when reporting sampling results, FSIS will include information on subtypes found in the sampling that are associated with human illness when that information becomes available. In the interim, the EOS letter will now include information regarding not only positive or negative test results, but also detailed serotype information for all positive *Salmonella* results. In addition, for young chicken and young turkey sets, the EOS letter will include *Campylobacter* results.

Volume-Weighted Percent Positive

From these sampling results, the volume weighted percent positive is calculated. This method gives weight to the establishment-level percent positive estimates using the volume of each product type that is produced at the sampled establishments, which is necessary to estimate the amount of contaminated product. Thus, samples testing positive for *Salmonella* from establishments that generate higher volumes of product have greater influence on the final statistic because the public health risk increases in proportion to the production volume.

Limitations of Current Sampling

1. *Risk-based Sampling*
   The current scheduling algorithm is risk-based, which is critical in positively affecting public health, but disproportionately focuses sample collection. This means that there is a large difference between well-performing establishments (Category 1) and poor, or potentially poor, ones (Category 3), in that the former might not be scheduled for sampling for a year or more, whereas the latter could be scheduled quite often. For this reason, not all establishments in the collection frame have a non-zero probability of selection each month.
2. *Product Priority*
   Establishments producing certain products are scheduled ahead of others. This prevents those establishments/products with lower priority from being sampled regularly because only a given number of sample sets can be scheduled each month. This results in data that are not representative of certain product classes. Furthermore, some product classes that have been completely excluded during certain months would not have a probability of selection for sampling for that period.
3. *Announced Sampling*
   Once a sample set begins, an establishment is aware that it will be sampled every day the product is being produced over the next few months (or longer for smaller establishments that produce less frequently), until the set is completed. This knowledge might create a bias because establishments may, intentionally or not, be more conscientious in adhering to proper sanitary procedures during

this time. This could result in an abnormally low number of positive *Salmonella* results than would occur otherwise.

4. *Sample Sets*
   Salmonella samples are scheduled in sets, which results in a high degree of clustering. That is, establishments are sampled intensively, but then not at all for a period of time. Moreover, this is problematic from a process control perspective because historical data from well-performing (Category 1) establishments does not exist. Thus, it is unknown whether these establishments are consistently maintaining low levels of *Salmonella*, or if their good performance was a temporary result of announced sampling.
5. *Production Volume*
   The major difference between the sampling data for intact and ground products is that volume information is not available at the establishment level for ground chicken or ground turkey and only a rough estimate can be determined for ground beef.
6. *Exclusion Criteria*
   As discussed above, FSIS maintains a number of different exclusion periods. For example, establishments that reach Category 1 status are not scheduled for another *Salmonella* set for up to two years. Category 2 status establishments are not scheduled for up to 100 days. These exclusion periods mean that establishments do not have a consistent probability of selection across all time periods. FSIS also maintains exclusion criteria for low-volume establishments, though these criteria also apply to FSIS baseline studies. Excluding these establishments prevents the sampling project from representing all production under FSIS jurisdiction, but allocates resources for logistical reasons.
7. *Regulatory Restrictions*
   FSIS has published the *Salmonella* Performance Standards in the Federal Register. Therefore, changes to the current project require policy changes.
8. *Seasonal Fluctuations*
   Many types of pathogenic microorganisms exhibit seasonal patterns, but FSIS verification sampling programs currently make no allowances for season fluctuations.

MT43S Sampling Project

Historical Basis

In 2008, FSIS established the MT43S sampling project so that sample collection at very low volume establishments (producing less than 1,000 pounds of product per day) would not be overly burdensome to the establishments. These establishments were already receiving regular raw ground beef sample requests under the *E. coli* O157:H7 sampling program. FSIS therefore decided to perform an additional *Salmonella* analysis under MT43S on the same sample. In this way, FSIS can effectively test for two sampling projects, without overly burdening IPP and the establishment with additional sample collection.

Type of Analysis

Samples that confirm positive are quantitatively analyzed. For example, the *Salmonella* organisms present are enumerated using the MPN procedure.[50]

[50] MPNs are only done if there is enough product left over for that analysis. Also, *E. coli* O157 MPN analysis needs trump those of *Salmonella* if there is limited product available and the sample confirms for both *E. coli* O157:H7 and *Salmonella*.

Volume Data

Ground beef production volumes under the MT43S sampling program are obtained by FSIS inspectors during the sampling process.[51, 52] The IPP classifies the establishment's volume into one of four volume groups, from which average annual ground beef volumes are estimated. The volume classes are as follows;

1) > 250,000 pounds per day,
2) 50,001 – 250,000 pounds per day,
3) 1,000 – 50,000 pounds per day, and
4) < 1,000 pounds per day.

Sampling Methodology

FSIS does not schedule establishments sampled under MT43S in the regular *Salmonella* verification testing project (9 CFR 310.25(b)). Rather, these establishments are selected under the MT43 *E. coli* O157:H7 sampling project.[53] The MT43 monthly sample is randomly selected with replacement and weighted by production volume and historical test results from the frame of eligible establishments. In addition, the MT43 project limits very low volume establishments to no more than one sample per month (sampling ceiling) and each establishment must be selected at least three times per year (sampling floor). The very low volume establishments selected every month under MT43 are also selected in the same month for MT43S. These establishments produce less than 1,000 pounds of raw ground beef on an average production day. The *Salmonella* results are recorded as part of the MT43 project.

Limitations of Current Sampling

The MT43 sampling algorithm has both ceilings and floors, which impedes the ability of the weights to perform optimally. Additionally, prior notification is required, so establishments can prepare to hold product, as recommended by FSIS, pending Agency test results.

Processed Egg Products—EM 31-37

Historical Basis

FSIS carries out its food safety responsibilities with respect to processed egg products under the provisions of the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031-1056). Section 1036(a) of the Act requires egg products inspected at any official egg products establishment and found not to be adulterated and must be pasteurized before they leave the official establishment. Section 1043 delegates to the USDA Secretary of Agriculture the authority to promulgate such rules and regulations deemed necessary to carry out the purposes or provisions of the EPIA. This authority was delegated to the USDA's Under Secretary of Agriculture for Food Safety in October 1994. Under the provisions of 9 CFR 590.580, "Laboratory tests and analyses", FSIS operates a directed microbiological sampling program to verify official establishment control of *Salmonella*; the pathogen of concern when the EPIA was originally enacted in 1970. In addition, the processed egg products industry has to conduct lot acceptability testing. Establishment or private contract laboratories who analyze egg product official surveillance samples are approved and audited under the PEPRLab program[54] administered by FSIS.[55]

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[51] Volume groups were developed by a multi-disciplinary team of scientists and technical staff within the FSIS prior to 2003.

[52] With the implementation of PHIS, volume information will be obtained from the establishment profile data. For this reason, questions referring to product volume were taken off of all forms collected through PHIS.

[53] Further information on the MT43 sampling project can be found in this document under Section 2.1.4 *E. coli* O157:H7.

[54] Pasteurized Egg Product Recognized Laboratory Program (PEPRLab) at http://www.fsis.usda.gov/Science/PEPRLab_Program/index.asp.

[55] Program is administered by the Laboratory Quality Assurance Division (LQAD), Office of Public Health Science, FSIS

Processed egg product establishments are not currently operating under HACCP and only limited information about establishments is collected in PBIS. Further, compliance/non-compliance data is documented manually. In addition, processed egg product establishments are not included in the current, phased approach to PHIS implementation for meat and poultry establishments. However, FSIS processed egg product inspection is expected to be incorporated in the future into PHIS and implementation of HACCP will be considered after full implementation of PHIS for meat and poultry establishments is complete.

Volume Data

Production volume data for processed egg products is collected from establishments producing these products and submitted to FSIS on a monthly basis. Volume data on each of the seven processed egg products categories are not currently collected. Instead, summary data on the volume of whole eggs broken or received for further processing is provided by establishments. These data are further subdivided into categories of whole egg, yolks and whites. Egg processing establishments also provide volume information on the total number of ingredients added to processed egg products, the volume of liquid, frozen and dried egg products distributed in commerce and the volume of product sent to other establishments for further processing. Using this information, the total volume of processed egg products produced by each establishment can be determined. This can be further broken down into the volume of liquid, frozen and dried processed egg products produced. Using this data, establishments are placed into four volume groups, based on their annual production.[56]

Current Design of Sampling Project

There are four liquid and three dried processed egg product process categories in the domestic processed egg products sampling program—see Table 2.1.1.3. Each month, one processed egg products sample per process is collected from each establishment that produces processed eggs products.

Table 2.1.1.3: FSIS Processed Egg Products Classes

EM-31	egg whites with or without added ingredients
EM-32	whole eggs/yolks with <2% added ingredients other than salt or sugar
EM-33	whole eggs/yolks with ≥2% added ingredients other than salt or sugar
EM-34	whole eggs/yolks with ≥2% salt or sugar added
EM-35	dried yellow egg products
EM-36	spray dried egg whites (with or without added ingredients)
EM-37	pan dried egg whites
EGGDOM	Pasteurized domestic liquid, frozen or dried egg products

Frame Definition

The number of processed egg products establishments has stayed fairly consistent over the past 15 years, generally ranging from 75 to 85 active establishments. When changes are identified in the types of processed egg products that an official establishment is producing, an establishment withdraws or a new establishment comes on board, FSIS District Office and FSIS field personnel notify FSIS Headquarters staff of the changes so that the database that generates the FSIS sampling forms for egg products can be updated. Once processed egg products establishments are included in PHIS, this will be done automatically.

[56] Group 1 (≤ 5,000,000 lbs.), Group 2 (5,000,001 - 45,000,000 lbs.), Group 3 (45,000,000 - 75,000,000 lbs.), Group 4 (> 75,000,000 lbs.)

Sampling Methodology
Each month, FSIS conducts a census by sending one processed egg product sample request per process from each establishment that produces eggs products. Thus, an egg products processing establishment could be selected for collection up to seven times per month, depending on the number of production processes occurring during the month.

Collection Methodology
FSIS inspection personnel are directed to follow the instructions set forth in FSIS Directive 10,210.1, Unified Sampling Form, dated December 18, 2003. The directive lists each sampling project by number (EM31, EM32, EM33, EM34, EM35, EM36 and EM37). The directive also provides instruction to the FSIS inspector on how to collect the sample, complete the form and ship the sample. Finally, the directive provides instruction to IPP on notifying establishment management. FSIS has also developed guidance for IPP on how the establishments should be sampled under FSIS Directive 10,230.4, Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program for the *Salmonella* sampling project.

Mean Response Rate
FSIS collected 60% of all processed egg products forms that were assigned and 58% of forms scheduled by FSIS were analyzed.

Statistical or Policy Basis
Neither the sample size nor the sampling frequency for processed egg products is statistically based on a national prevalence estimate, as calculated from a baseline study. Further, there is currently no policy basis for the current sampling program. Rather, the processed egg products sampling program was historically designed to make certain that enough samples were collected and analyzed to ensure a broad understanding of contamination rates among the different types of processed egg products. Future efforts to introduce a HACCP-based processed egg products program will likely mark the development of a statistical analysis of the processed egg product data and therefore the development of a statistically-based sampling program.

Limitations of Current Sampling
Processed egg products sampling frames are not part of PBIS and no instructions have been provided to FSIS field personnel on how to update establishment profile data to incorporate processed egg products. Additionally, no baseline studies have been conducted to inform the sampling methodology. Therefore, statistics produced from the testing data are likely to be biased and have high levels of error. In September 2011, FSIS did begin the shakedown period for the Agency's Nationwide Raw Liquid Egg Microbiological Baseline Survey (RLEBS), though this baseline study will focus on pre-pasteurized egg products.[57]

<u>*Salmonella* Programs Measure of Success</u>
Each *Salmonella* sampling project has slightly different goals. However, the overall purpose of the *Salmonella* verification testing program to ensure that the pathogen reduction performance standards are being met, which ensures that the industry is maintaining process control.

[57] http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/52-11.pdf

Consequently, FSIS believes it is appropriate to measure the success of the different sampling projects in broad terms. Further, as FSIS recently implemented new performance standards for *Salmonella*,[58] adjustments to these measures may be appropriate moving forward.

As such, to measure the success of the *Salmonella* sampling projects, FSIS evaluates its efforts in terms of five key metrics:

1. Volume-weighted percent positives for *Salmonella* in eight raw product classes;
2. Estimated number of *Salmonella* foodborne illnesses associated with FSIS-regulated products;
3. Establishment categorization based on new *Salmonella* performance standards;
4. FSIS End of Set Letters; and
5. Reductions in case rates (as reported by the CDC) for the top 10 serotypes of human health concern.

Volume-Weighted Percent Positives

FSIS conducts pathogen verification testing for many of the Agency's sampling projects. FSIS uses this sampling to calculate a percent positive for many of the *Salmonella* sampling projects. FSIS believes that percent positives are a good measure of the effectiveness and success of the sampling project maintained by the Agency, with declines in percent positives potentially indicating greater control of *Salmonella* in raw product. Table 2.1.1.4 provides the production category volume-weighted percent positive rate for *Salmonella* in all raw products and on broiler chickens alone.

Table 2.1.1.4: Quarterly *Salmonella* Volume-Weighted Percent Positive Rates for All Raw Products and Broiler Carcasses Alone

Year/Quarter	Volume Weighted Percent Positive Rate (All Raw Products)	Volume Weighted Percent Positive Rate (Broilers)
FY 2009	2.74%	5.31%
FY10Q3	2.88%	5.29%
FY10Q4	2.62%	5.14%
FY11Q1	2.70%	5.22%
FY11Q2	2.58%	5.05%
FY11Q3	2.32%	5.11%

Foodborne Illness Estimates:

As FSIS' ultimate goal is to prevent foodborne illnesses from regulated products, it is important to measure reductions in foodborne illness as a result of FSIS inspections, sampling, policies and other activities. FSIS calculates a performance measure, known as the All-Illness Measure, which represents all foodborne *Salmonella*, *Lm* and *E. coli* O157:H7 illnesses from FSIS-regulated meat, poultry and processed egg product. FSIS updated the All Illness Measure in Q3, FY2011 to reflect the release of new illness burden estimates from the CDC[59] and the Healthy People 2020 goals[60], as well as to coincide with the release of the FSIS Strategic Plan for 2011-2016. Objectives for the All-Illness measure were

[58] Please see the following website for more information: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2009-0029.pdf

[59] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. Emerg Infect Dis [serial on the Internet]. 2011 Jan [*November 2011*]. http://www.cdc.gov/EID/content/17/1/7.htm

[60] Please see the following website for more information: http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=14.

set using a combination of data from published CDC FoodNet case rates and outbreak data and are aligned with Healthy People 2020 goals. For *Salmonella,* FSIS uses a rolling 12 month window of case rate data from the CDC, in addition to an attribution estimate, to estimate the total number of *Salmonella* illnesses from FSIS regulated products. Using this methodology, the illness measure is the estimate of the total annual illnesses for the fiscal year, rather than independent measures of illness for each quarter.

Performance Measure

Using the newly updated All Illness Measure data sources and methodology, FSIS set a target of 399,852 *Salmonella* illnesses associated with FSIS regulated products for Q3, FY 2011; FSIS missed that target with 472,859 estimated illnesses. However, there was an approximate 4,000 illness decline from the second quarter to the third quarter of FY2011. Figure 2.1.1.1 illustrates the quarterly targets for *Salmonella* illnesses and the estimated illnesses for the most recent four quarters.

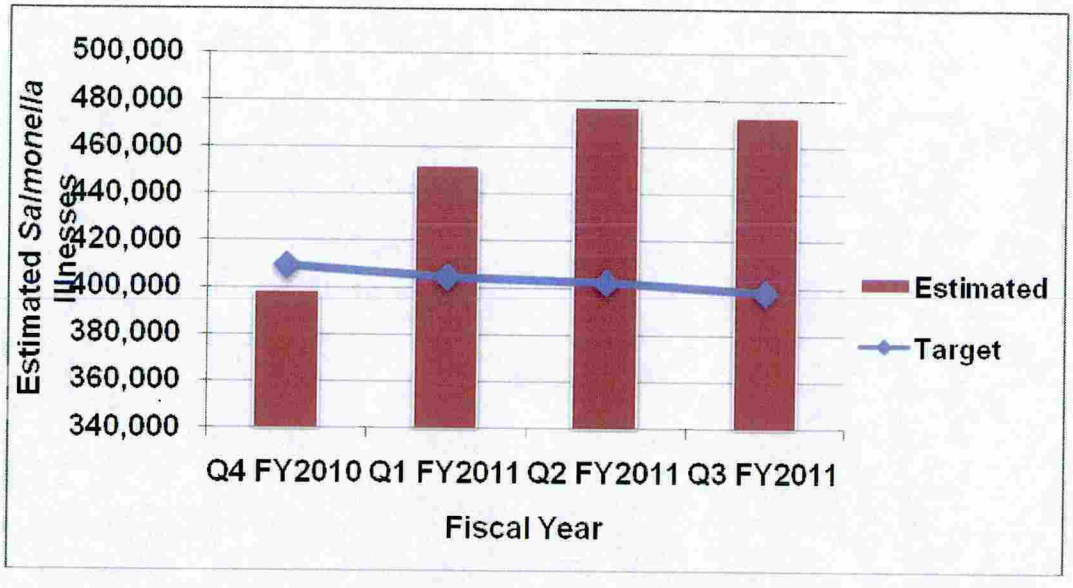

Figure 2.1.1.1: Estimated *Salmonella* illnesses associated with FSIS regulated products

Establishment Categorization

As described in this section, FSIS employs a "category" system to measure the performance of establishments producing raw products. This "Category 1" measure is publicly reported in the USDA Strategic Plan for FY2010-FY2015 and the annual USDA Performance and Accountability Report (PAR), and tracked internally at FSIS in the Quarterly Performance Report. As described above, starting in July 2011, the new *Salmonella* performance standard accepted five positive samples in a 51-sample set for young chickens and four positive samples in a 56-sample set for turkeys. *Salmonella* performance Categories 1 and 2 for young chicken and turkey establishments, based on the new performance standards, will be applied exclusively for Agency internal analysis and quarterly aggregate reporting. FSIS will track industry progress in achieving Category 1 status and achieving the new standard, with greater numbers of establishments maintaining Category 1 status conveying a public health benefit in reduced S*almonella* illnesses in the population. Finally, FSIS will web-post the names of young chicken and turkey establishments that fail the new *Salmonella* standards ("Category 3") for

their last set. This web posting will begin as sample sets scheduled for July 2011 are completed. This new standard is also a key metric in the recently published FSIS Strategic Plan for 2011-2016.

End of Set Letters

FSIS developed a set of performance measures that allow the Agency to evaluate its progress in meeting a variety of human health and other goals. These measures focus on both short-term, process-oriented goals and long-term, outcome-based FSIS goals, including reducing the burden of foodborne illness from FSIS regulated products. One of measures developed by FSIS was the "percent of slaughter establishments with an End of Set (EOS) Letter indicating a *Salmonella* serotype of human health concern was detected"—see Table 2.1.1.5. The CDC produces a list each year of the top 20 *Salmonella* serotypes (PFGE patterns) of human health concern through its PulseNet program. FSIS also uses information from the ARS VetNet program. FSIS seeks to achieve a one percent decrease annually in the percent of establishments with an EOS letter with a serotype of human health concern.

Table 2.1.1.5: FSIS Performance Measure for EOS Letters

		Objectives					Goal
		Measures					
	Baseline FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
Percent of slaughter establishments with an End of Set Letter indicating a Salmonella serotype of human health concern was detected.	37.5%	37.1%	36.8%	36.4%	36.0%	35.7%	35.3%
		31.1%					

Top Ten *Salmonella* Serotypes

In the CDC's annual FoodNet report, the Agency identifies the ten most common *Salmonella* serotypes as reported by states and localities participating in the FoodNet program.[61] FSIS also collects individual *Salmonella* subtype (serotype and PFGE pattern) results from positive samples as part of the FSIS *Salmonella* sampling program. FSIS has established the technical mechanisms to automatically populate *Salmonella* EOS Letters with this enhanced serotype information, in addition to what is currently included in EOS letters to establishments from the appropriate data tables in the FSIS data warehouse. FSIS and CDC are currently working to finalize both the data sharing agreement and the data itself. Once available, FSIS will provide establishments with this information. Additionally, once the data pathways are finalized, FSIS will provide the information to establishments and verify that they appropriately consider it when evaluating their food safety systems through the performance of a Food Safety Assessment (FSA). An FSIS Notice announcing the inclusion of this information in FSIS *Salmonella* EOS Letters has been developed and will be issued once the data pathways between FSIS and CDC have been finalized. Changes in the types of serotypes identified over time can be tracked via the annual FoodNet report.

[61] Please see the following website for more information: http://cdc.gov/foodnet/factsandfigures/2009/Table6_top10ss_09.pdf.

2.1.2 *Campylobacter*

Campylobacter Verification Project: HC11

Historical Basis

As discussed in Section 2.1.1, on May 14, 2010, FSIS published a Federal Register Notice (75 FR 27288) in which it announced the implementation on July 1, 2011 of new performance standards for *Salmonella* and *Campylobacter* for chilled carcasses in young chicken (broiler) and turkey slaughter establishments. The new performance standards were developed in response to a charge from the FSWG and based on results from the FSIS Nationwide Microbiological Baseline Data Collection Program. The standards are being applied to sample sets collected and analyzed by FSIS to evaluate establishment performance with respect to requirements of the PR/HACCP Rule. All sample sets scheduled for young chicken and turkey establishments will be analyzed for both *Campylobacter* and *Salmonella,* and follow-up sample sets responding to sample set failure for either organism will be analyzed for both organisms.

Intent of Project

FSIS considers *Campylobacter* verification testing to be a direct indicator of the effectiveness of process control. The raw pathogen reduction performance standards program for *Campylobacter* also serve, once fully established and once sampling has been conducted for an extended period of time, a variety of other functions, including assessing establishment compliance with the performance standard and comparing industry-wide and peer-to-peer trends regarding percent positive over time.

Type of Analysis

Although the *Campylobacter* performance standards are based on the positive/negative results from the quantitative test portion, the *Campylobacter* laboratory method includes both a qualitative and quantitative method that will further inform FSIS of the presence of this pathogen in regulated product.

Volume Data

Yearly production volumes for chicken and turkey are acquired from slaughter volume data in the eADRS database.

Constructing the Sampling Frame

Campylobacter verification sampling is applicable only to broiler and young turkey carcass sets scheduled to begin after July 1, 2011. Establishment categories for these poultry establishments are based on the *Salmonella* set results. However, if a establishment fails a set for either *Salmonella* or *Campylobacter* it will be treated as a failed set (for the purposes of scheduling only) and be scheduled for immediate follow-up set the next month. Additional details about the sampling criteria, exclusion criteria and sampling algorithm and frame are provided above in the *Salmonella* Section 2.1.1.

Campylobacter Programs Measure of Success

The overall purpose of the *Campylobacter* verification testing program is to ensure that the pathogen reduction performance standards are being met, which ensures that the industry is maintaining process control. Consequently, FSIS believes it is appropriate to measure the success of the different sampling project in broad terms. As FSIS recently implemented the new

performance standards for *Campylobacter*,[62] the measures of success listed below are under currently being developed and therefore adjustments to these measures may be made moving forward.

To measure the success of the *Campylobacter* sampling project, FSIS is considering evaluating its efforts in terms of three key metrics:

1. Volume-weighted percent positives for *Campylobacter*
2. Reductions in case rates (as reported by the CDC FoodNet) for *Campylobacter*
3. Estimated number of *Campylobacter* foodborne illnesses associated with FSIS-regulated products

[62] Please see the following website for more information: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2009-0029.pdf.

2.1.3: *E. coli* O157:H7 Raw Sampling Projects

Overview of Sampling Projects

FSIS maintains many *E. coli* O157:H7 sampling projects for domestic establishments. The different *E. coli* O157:H7 sampling projects are summarized in Table 2.1.3.1.

Table 2.1.3.1 FSIS *E. coli O157:H7* Sampling Projects

Product Type	*E. coli* Sampling Projects	Number of *E. coli* Analyzed samples CY2010[63]	Regulatory Purpose of Sampling Program	Type of Sampling Program
Raw ground beef	MT43	11,291	Verify zero-tolerance	Weighted Random
Follow-up testing to a raw ground beef positive	MT44	309	Verify corrective measures	Targeted Consecutive
Beef Manufacturing trim	MT50	1,274	Verify HACCP compliance	Random
Raw ground beef components other than trim	MT54	169	Verify HACCP compliance	Random
Bench trim	MT55	547	Verify HACCP compliance	Random
Follow-up testing at supplier establishments following MT43, MT44, or MT55 positive	MT52	636	Verify corrective measures	Targeted Consecutive
Follow-up testing to a MT50, MT54, MT55, or MT52 positive	MT53	125	Verify corrective measures	Targeted Consecutive

Domestic Sampling Programs (Federally inspected establishments)

Historical Basis for Sampling Raw Ground Beef

The following section provides a general overview of the historical progression of FSIS sampling for *E. coli* O157:H7. In addition to the material provided below, a timeline of FSIS activities related to *E. coli* O157:H7 can be found on the FSIS website. [64]

In 1994, FSIS announced that raw ground beef products contaminated with *E. coli* O157:H7 would be considered adulterated, unless the ground beef was processed further to destroy the pathogen. A sampling project for *E. coli* O157:H7 in raw ground beef was initiated in October 1994. The objectives of the verification testing project were to verify the effectiveness of control measures at individual grinding establishments and to stimulate industry action to reduce the presence of the pathogen in ground beef. FSIS initiated the verification testing program on raw ground beef, rather than on source materials (e.g., carcasses or beef manufacturing trimmings used to make ground beef) for a number of reasons, including that ground product was well-

[63] Please see the following website for more information: http://www.fsis.usda.gov/Science/Ecoli_Raw_Beef_Testing_Data_YTD/index.asp.

[64] Please see the following website for more information: http://www.fsis.usda.gov/PDF/Ecoli_O157_Timeline.pdf.

blended, was in the form closest to the consumer and was the product most frequently associated with foodborne illness.

The verification testing program was not statistically designed at initiation; some samples were randomly selected and others were targeted. The frame also contained retail stores and federally inspected establishments that produced raw ground beef. Random samples were scheduled at retail and federally inspected establishments. Targeted samples were scheduled at establishments identified as performing below average using Review and Assessment data,[65] PBIS performance data for sanitation, receiving, or processing deficiencies or consent orders.

Additional targeted follow-up samples were collected when a confirmed positive was detected. These samples were collected from the establishment that tested positive for *E. coli* O157:H7 and from all other establishments associated with the same corporate structure. Targeted samples were also collected from State-inspected establishments and imported ground beef products.

In February 1998, FSIS issued updated instructions for raw ground beef sampling to verify the effectiveness of controls at individual grinding establishments.[66] It was and is FSIS policy that the establishment is responsible for having a high degree of confidence that *E. coli* O157:H7 does not contaminate the production lot. Each month, FSIS randomly selected establishments, while FSIS Compliance Investigators (CI) targeted retail stores for sample collection.

At that time, FSIS based its sampling plan on information from the CDC FoodNet sentinel sites' historical data of outbreaks (e.g., geographical locations in the U. S. where public health laboratories actively collect human illness data).[67] If an establishment or a retail outlet initiated its own routine sampling program, had certification from suppliers that the product was tested, or, in the case of an inspected establishment, used in-establishment validated pathogen reduction interventions on beef carcasses, FSIS did not collect samples. When a sample tested positive for *E. coli* O157:H7, subsequent samples from new lots were collected daily until negative results were obtained in 15 consecutive samples. Additionally, if ground beef at an FSIS inspected establishment or retail outlet was associated with an outbreak of foodborne illness linked to *E. coli* O157:H7, FSIS sampled daily until 15 consecutive samples tested negative. All raw, comminuted beef products produced on the shift represented by the positive sample were subject to voluntary recall.

In 1999, FSIS further clarified in a Federal Register Notice an expanded adulteration policy, where raw beef source materials used to manufacture ground beef, as well as beef that had been handled in a way that could transfer the external surface contamination to the interior of the

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[65] From 1995-1996, FSIS had a program office called Review and Assessment. The office would visit establishments and develop review reports that could lead to suspensions in establishments where in-establishment inspection personnel had never written a PDR (a predecessor of the NR). A major focus area was establishment review triggered by high levels of fecal contamination.

[66] FSIS Directive 10,010.1 "Microbiological Testing Program for *Escherichia coli* 0157:H7 in Raw Ground Beef," February 1, 1998.

[67] The CDC FoodNet sites were used for retail sample guidance as, prior to HACCP implementation, retail stores were thought to be closest potential source of contamination for consumers. Retail samples were requested from the Compliance Offices located in or near FoodNet sites. The FoodNet site priority did not apply to Federally Inspected Establishments. Directive 10,010.1 (February 1, 1998) included the policy for inspected establishments, but the exemptions were canceled in 2002.

product, would also be considered adulterated.[68] In April 2003, FSIS announced with FSIS Notice 11-03 that it would begin testing all products that met the standard of identity in 9 C.F.R. 319.15 (a-c), which could include coarse, ground beef. Thus, if an establishment producing coarse ground beef shipped that product to another establishment that re-ground the coarse ground product into finely ground beef, FSIS would now sample the product at both establishments.

In March 2004, FSIS implemented a major revision to FSIS Directive 10,010.1, Microbiological Testing Program for *Escherichia coli* 0157:H7 in Raw Ground Beef. All establishments producing raw ground beef products, raw ground beef components or raw beef patty components were eligible for FSIS sampling for *E. coli* O157:H7. In addition, the directive provided the following instructions to FSIS field personnel:

1. Traceback procedures were to be performed to collect source supplier information after an FSIS positive test result.[69] This information was entered into a database, and suppliers identified repeatedly in the database were subject to a comprehensive FSA of the supplier;
2. Verification of process control for lots testing presumptive positive or positive for *E. coli* O157:H7 was required; and
3. Follow-up actions to an FSIS positive test result were to be implemented both at the original positive establishment and at all supplier establishments.

In 2008, an FSIS analysis found that production volume is a better determinant of risk for *E. coli* O157:H7 than HACCP size. This analysis determined that *E. coli* O157:H7 in cattle and the incidence of foodborne illness from *E. coli* O157:H7 positive products displayed positive seasonal effects during warmer months. As a result, in January 2008, FSIS implemented risk-based sampling of raw ground beef, weighted by production volume and historical test results.[70] Under this new verification testing program, larger volume operations are tested more frequently than in the past. FSIS also implemented a change in the laboratory testing method at this time that included a single 325 gram test portion, enriched at a 4:1 ratio of enrichment broth in product as an alternative sample preparation procedure.

FSIS analytical capacity has allowed for increased sampling over time. FSIS analyzed approximately 3,000 to 7,000 samples per year from 2001 – 2003. Starting in 2005, FSIS laboratories started analyzing around 11,000 samples per year.

Historical Basis for Sampling of Products Other than Raw Ground Beef

In a January 1999 policy statement, FSIS noted that when the *E. coli* O157:H7 sampling methodology became sufficiently refined to enhance the likelihood of finding the pathogen on source materials used to make ground beef, the Agency expected to begin supplementing the verification testing project for ground beef with FSIS testing of source materials.

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[68] See: http://www.federalregister.gov/articles/1999/01/19/99-1123/beef-products-contaminated-with-escherichia-coli-o157h7.

[69] With FSIS Notice 58-10, this information is collected at the time the sample is collected.

[70] Withee J., Schlosser, W. (February 2008). Risk-based sampling for *Escherichia coli* in O157:H7 in ground beef and beef trim. USDA/FSIS/OPHS/Risk Assessment Division: http://www.fsis.usda.gov/PDF/Ecoli_Sampling_RA_Report_Feb08.pdf, accessed on November 18.

In April 2003, FSIS Directive 10,010.1 stated that head and cheek meat used for production of ground beef not treated with antimicrobial interventions could present an elevated risk for presence of *E. coli* O157:H7 and should be addressed in an establishment's HACCP plan. FSIS also stated that the Agency would soon begin testing manufacturing trimmings and carcasses to supplement the ground beef testing project, although implementation was delayed as FSIS had not developed a laboratory procedure at that time to effectively test manufacturing trimmings.

In August 2003, FSIS requested that the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) provide feedback on the Agency's baseline study design for raw ground beef components to ensure that appropriate priority was given to the different categories of product. NACMCF reordered the priority ranking of the categories provided by USDA/FSIS based on volume, the perceived contribution to the risk of illness, expert opinion on the use of the components in ground beef and processing variables, such as chilling rates during production. NACMCF recommended that FSIS reprioritize the rank order for engaging in baseline studies as follows:

1. Domestic trim and subprimals,
2. Advanced Meat Recovery (AMR),
3. Low-Temperature-Rendered Products (LTRP),
4. Imported frozen and fresh beef, and
5. Weasand, cheek, and head meat.

Domestic trim and subprimals were considered the number one priority since these components comprise the largest volume of raw materials used in ground beef and are known to contain *E. coli* O157:H7.[71]

In March 2007, FSIS began routine verification sampling of beef manufacturing trimmings intended for use in raw ground beef, hamburger or beef patty products at the slaughter establishments that produced those trimmings. Trim sampling was initiated with FSIS Notice 18-07 in March 2007 at a rate of 50 scheduled samples per week (MT50 project). This decision was partly informed by grinding establishments' claim that meat was already contaminated upon receipt by the establishment. FSIS conducted a baseline study in 2007 that showed a higher level of *E. coli* O157:H7 in tested beef manufacturing trimmings than in tested raw ground beef. Incorporating the results of the baseline study, FSIS performed a statistical analysis to determine the minimal number of samples needed to be analyzed in a year to be able to detect a 50% change in positive rates, as compared to the prevalence estimate calculated from the baseline study (under standard statistical assumptions). The evaluation concluded that an increase to approximately 3,500 analyses per year was necessary and, at the time, FSIS was sending out 2,600 sample request forms per year. However, due to budgetary constraints, this proposed change was never implemented in the MT50 project.

Starting in late 2007, FSIS made several changes to the sampling program to expand the scope of products tested for *E. coli* O157:H7. FSIS began collecting samples of raw ground beef components other than trim in December 2007 (MT54 project). FSIS also began testing trim and other raw ground beef components to enforce the policy that *E. coli* O157:H7 adulterates intact

[71] http://www.fsis.usda.gov/OPHS/NACMCF/2003/gb_base.pdf

product intended for use in raw non-intact product. Consequently, FSIS began verifying that both grinders and slaughter supplier establishments had effective controls for *E. coli* O157:H7 to incentivize suppliers and grinders to maintain effective controls for the pathogen. The frame definition for manufacturing trimmings (MT50 project) was used for this new sampling project and the sample size was calculated based on the capacity of the FSIS laboratories, which allotted 780 analyses per year. No oversampling to account for response rate was incorporated into the sample size.

Based upon research resulting from the 2007 FSIS *E. coli* Checklist,[72] the Agency decided to begin testing bench trim intended for use in raw ground beef, hamburger or beef patty products (MT55 project). Bench trim is a component of raw ground beef that is not produced at slaughter establishments. Rather, it is produced in the process of cutting down purchased carcasses, primal or subprimals into steaks or roasts. The trim produced in this process is then sold to a grinding establishment as a component of raw ground beef. Bench trim sampling began in 2009 and FSIS allocated 1,800 analyzed samples annually for this new project. No oversampling to account for response rate was incorporated into the sample size.

Type of Analysis

In general, samples for *E. coli* O157:H7 are qualitatively and quantitatively assessed for the presence of the organism. FSIS collects information on samples that confirm positive using the MPN procedure on sample reserves and this information is captured by the FSIS laboratories, though not routinely reported in public venues.

Description of the FSIS Domestic Sampling Projects for *E. coli* O157:H7

A description of each of the domestic sampling projects for *E. coli* O157:H7 follows below. Please see Appendix B for additional information on the *E. coli* O157:H7 sampling projects.

Risk-based testing of raw ground beef at domestic establishments (MT43)

Purpose

The purpose of the MT43 risk-based sampling project is to provide verification of HACCP policy and to assess, and minimize, the risk to the public's health from contaminated raw ground beef. FSIS initially implemented risk-based sampling of raw ground beef, weighted by production volume and historical test results, in January 2008.[73] The MT43 project replaced the MT03 project, which was simple random sampling of raw ground beef. The current methodology was implemented in late 2009.

Sampling Frame Definition

The frame includes establishments that meet one of the following requirements: 1) Federally inspected establishments that have the 9 CFR flag identified in their PBIS profile (per FSIS Notice 105-08, previously FSIS Notice 86-07) or report producing raw ground beef finished products in their PHIS profile and 2) Federally inspected establishments that have had an MT43

[72] Alvares, C., Lim, C., & Green, K. (August 2008). Results of checklist and reassessment of control for *Escherichia coli* in O157:H7 in beef operations. USDA/FSIS: http://www.fsis.usda.gov/PDF/Ecoli_Reassement_&_Checklist.pdf, accessed on November 18, 2010.

[73] Withee J., Schlosser, W. (February 2008). Risk-based sampling for *Escherichia coli* in O157:H7 in ground beef and beef trim. http://www.fsis.usda.gov/PDF/Ecoli_Sampling_RA_Report_Feb08.pdf.

sample collected in the last 12 months. An exclusion list is maintained to exclude establishments for special circumstances when documentation is provided by FSIS field personnel.

Average Frame Size
Generally, the frame is around 1,300 establishments. This value fluctuates monthly as new establishments become eligible and others become ineligible. Ineligibility may result from seasonal processing, closure, withdrawal of inspection, change in business practices and other reasons.

Sample Size
FSIS selects 1,300 establishments from the frame every month. The decision was not statistically based, but based upon lab capacity constraints at the time the MT03 project was initiated.

Sampling methodology
MT43 is weighted random sampling with replacement under the constraints of sampling ceiling by volume strata and annual sampling floors. See below for discussion of weights, ceilings and floors. A sampling algorithm is used, which selects the sample from the frame. The methodology was based upon the results of an FSIS analysis that identified production volume and historical test results as a significant risk factor for public health exposure.

Sampling weights
Sample selection is weighted by scaling factors to produce a probability of selection for each establishment, p_i. The scaling factor formula for n establishments has a number of inputs.

$$p_j = \frac{vs_j \cdot hs_j}{\sum_{j=1}^{n} vs_j \cdot hs_j}$$

1. Historical testing data - those establishments that have had a positive test result within the last six months are five times more likely to have a positive in the near future, so the weight for these establishments has a factor of five applied. This is referred to as the hazard score, hs_i. The hazard score is five for establishments that have had a recent positive and one for establishments without a positive test result.
2. Production volume data - those establishments that have higher estimated annual production volume are weighted more heavily. The volume weights are calculated from the four daily production volume groups, as described below, and are reported on every MT43 form or in the PBIS (and, moving forward, PHIS) establishment profile.[74] An establishment's volume group is assigned by taking the mode of all the reported groups from every form collected in the last 12 months. See Table 2.1.3.2 for details on assigning estimated annual volume by volume group. A volume score, vs_i, is then calculated that transforms the data relative to the smallest production volume.

$$vs_i = S_L + \frac{(V_i - V_4)(S_H - S_L)}{V_1 - V_4}$$

[74] Volume groups were developed by a multi-disciplinary team of scientists and technical staff within the FSIS prior to 2003. There are currently more volume groupings for MT43 sampling within PHIS, but they map exactly to the Agency's existing PBIS categories.

Table 2.1.3.2: Estimated Annual Volume by Volume Group for *E. coli* O157:H7 Sampling Projects

Assigning Estimated Annual Volume by Volume Group			
Volume Group (i)	Estimated daily volume in lbs/day	Midpoint of volume in lbs/day (V_i)	Volume Score (vs_i)
1	> 250,000*	375,000	32
2	50,001 – 250,000	150,000	13.375
3	1,000 – 50,000	25,500	3.069
4	< 1,000	500	1
* 500,000 lbs/day is assumed to be the maximum.			

3. Scaling factor constants - FSIS decided that the volume factor of the weight being allowed to function freely did not meet needs of the Agency. That is, very large volume producers were selected at too burdensome a rate and very small volume producers were selected at a rate too low to support HACCP verification. FSIS tested various scaling factors until the Agency was satisfied with the general rate of selection by production volume group. The scaling factors, $S_H = 32$ and $S_L = 1$, cause the volume scores to range from 1 to 32 rather than from 1 to 750.

Sampling ceilings

FSIS established sampling ceilings to ensure that the Agency does not over-burden very small establishments. The sampling ceilings were raised for large volume establishments in 2009 because sampling at a higher frequency in establishments that produce more volume of product results in a higher level of confidence in an estimate that is weighted by production volume.[75] Please see Table 2.1.3.3 for sampling ceilings.

Table 2.1.3.3: Sampling Ceilings for *E. coli* O157:H7 Sampling Projects

Sampling Ceilings	
Volume Group	Maximum Samples Allowed per Month
1	4 per month for large volume producers
2	3 per month for medium volume producers
3	2 per month for small volume producers
4	1 per month for very small volume producers

Sampling floors

FSIS established sampling floors to ensure that each establishment in the frame is sampled every year. The current sampling floor is three analyzed samples in 12 months.

Collection methodology

Field inspectors are to collect one pound of raw ground beef per FSIS Directive 10,010.1, Revision 3 Ch. II, III.[76]

[75] FSIS temporarily implemented sampling ceiling and sample size increases in August and September 2011 through FSIS Notice 36-11.

[76] http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10010.1Rev3.pdf

Mean response rate
Since 2006, the mean annual response rate of collected samples, as compared to printed forms, is 72%. Sample requests have a 30 day window, which means that it is likely that some establishments will be scheduled, but may not have product available within that 30 day window due to a combination of intermittent production and changing FSIS inspector patrol assignments.

Mean analyzed samples
Since 2006, FSIS laboratories have analyzed a mean of 11,482 samples per year.

Follow-up testing to a raw ground beef positive at a domestic establishment (MT44).
Purpose
An MT44 sample follows an MT43 positive. The purpose of the MT44 sampling project is to follow-up in establishments that recently had an MT43 positive, providing more frequent, targeted sampling at these establishments as a means of verifying that HACCP systems are back in control. MT44 replaced the MT04 project at the same time that MT43 replaced MT03.

Sampling Frame definition
This methodology does not define a frame because it is not a statistical sampling project. Rather, establishments that receive MT44 sample request forms are those that have recently had an MT43 positive sample.

Average frame size
This does not apply because MT44 is targeted sampling based upon MT43 results.

Sample size
For each MT43 positive at an establishment, 16 follow-up sample request forms are automatically scheduled at that establishment. In the case where the establishment produces less than a thousand pounds per day, then only eight follow-up sample request forms are collected at that establishment. The decision to collect 16 follow-up samples was made in 2008, when an FSIS analysis showed that establishments that test positive were five times more likely to receive another positive in the next 160 days than those that do not. At that time, the national average for grinders was approximately 0.17% positive in sampled lots. Under binomial distribution, 16 negative samples from 16 lots gives a 95% confidence that the establishment is less than 100 times above the national average. While FSIS performed these calculations, they were not seriously considered out of practicality as 1,750 follow-up samples over four months would need to be scheduled to verify that the establishment was at or below 0.17% positive.

Sampling methodology
Samples for the MT44 project are automatically scheduled for the establishment following an MT43 positive.

Collection methodology
Inspectors are to collect one pound of raw ground beef per FSIS Directive 10,010.1, Revision 3, Ch. II, III.

Mean response rate
Between 2006 and 2009, the mean annual response rate of collected samples, as compared to printed forms, was 56%. However, there was marked improvement in samples received for analysis starting in 2009, with a mean response rate of 83%. Also, 16 forms are sent to all establishments, but inspectors are instructed to collect only eight samples in very small volume establishments. The non-response rate may therefore be artificially inflated. Additionally, some establishments choose to stop producing raw ground beef after an MT43 positive, eliminating the possibility of follow-up sampling.

Mean analyzed samples
The annual mean of analyzed samples is 254 per year, but this value ranges from 24 samples analyzed in 2006 to 484 samples analyzed in 2009. This variation can partly be attributed to changes in the number of follow-up samples scheduled in response to a single positive. Additionally, the annual tally is based on the number of positive MT43 samples analyzed during the year.

Routine testing of manufacturing trimmings at domestic establishments (MT50)
Purpose
The intended purpose of the MT50 sampling project is to verify HACCP. The program was initiated to randomly sample establishments that produce beef manufacturing trimmings. The intention was to enhance the program at some future date to make it more risk-based and support measuring prevalence. In January 2011, FSIS published a report entitled the National Prevalence Estimate of Pathogens in Domestic Beef Manufacturing Trimmings (Trim). This report was based on data collected from a 2007 baseline study on trim. The report indicates that, from 2005-2007, the estimated national prevalence of *E. coli* O157:H7 in beef trim was 0.39%, with a 95% confidence interval between 0.05% and 0.73%. [77] Currently, the beef manufacturing trimmings verification sampling program is conducted as originally designed. Enhancements to the program are still being considered.

Sampling Frame definition
The frame includes all active, federally inspected beef and veal slaughter establishments that produce trim for use in raw ground beef and identified sister establishments. If an MT50 sampling form is returned to the laboratories with code 60 (product not produced) selected, then the establishment is excluded from the frame for 12 months. An exclusion list is maintained to exclude establishments for special circumstances when documentation is provided by FSIS field personnel.

Average frame size
Generally, the frame is around 480 establishments. This value fluctuates monthly as new establishments become eligible and others become ineligible. Ineligibility may result from seasonal processing, closure, withdrawal of inspection, change in business practices and for other reasons.

[77] Please see the following website for more information:
http://www.fsis.usda.gov/PDF/Baseline_Data_Domestic_Beef_Trimmings_Rev.pdf.

Sample size
FSIS selects between 200 and 250 establishments from the frame every month, depending upon the number of weeks in a month. Annually, this amounts to mailing 2,600 sample forms per year. This sample size is not adequate to detect practical changes from the national prevalence level as estimated by the 2007 baseline study. The choice of implementing 50 forms per week was the result of FSIS laboratory capacity at the time of implementation.

Sampling methodology
MT50 is a simple random sample without replacement.

Collection methodology
Inspectors were directed to collect an N60 sample weighing 325 grams where each piece matches a template (1" wide x 3" long x 1/8" deep) and the goal is collection of 60 pieces, per FSIS Directive 10,010.1, Revision 3, Ch. II, IV. The N60 sample is to be placed in one container and a second container is filled with small pieces. The purpose of an N60 sample is to gather a more representative sample consisting mostly of surface area, where *E. coli* O157:H7 is most likely to exist. In practical terms, however, it is nearly impossible for an inspector to collect an N60 sample that meets the number of pieces, piece dimension and total sample weight specifications. As of last year, the FSIS laboratories have redefined the analytical portion to consist of the analysis of up to 60 pieces (N60) weighing up to 715 grams (up to two 325 gram ± 32.5 gram subsamples, rather than limit the sample to 325 grams. This decision was reached after the method was validated to process a single 325 gram sample (previously it was 5-65 gram subsamples).

Mean response rate
Since 2007, the mean annual response rate for collected samples, as compared to printed forms, is 40%. The low response rate may be due to a poorly defined frame; that is, not all slaughter establishments may produce this product or they produce them infrequently. Additionally, the collection methodology is N60, which is an onerous and resource-intensive method. This may also contribute to low collection rates.

Mean analyzed samples
Since 2007, FSIS laboratories have analyzed a mean of 1,092 samples per year. The necessary number of analyzed samples to be able to estimate a change in prevalence is between 3,000 and 4,000 per year. As a result, FSIS cannot say with certainty that the results of the MT50 sampling project are statistically different from the baseline prevalence estimate.

Routine testing of domestic components to raw ground beef – other than trim – at domestic establishments (MT54)
Purpose
The intended purpose of the MT54 sampling project is to verify HACCP.

Sampling Frame definition
The frame includes establishments that meet one of the following requirements: 1) Active, federally inspected beef and veal slaughter establishments and 2) Active, federally inspected ammoniated lean finely textured beef (LFTB) producing establishments (there are six of these known to be operating in the U.S.). If an MT54 sampling form is returned to the laboratories with code 60 (product not produced) selected, then the establishment is excluded from the frame for 12 months. An exclusion list is maintained to exclude establishments for special circumstances when documentation is provided by FSIS field personnel.
Average sample frame size
Generally, the frame is around 450 establishments. This value fluctuates monthly as new establishments become eligible and others become ineligible. Ineligibility may result from seasonal processing, closure, withdrawal of inspection, change in business practices or for other reasons.

Sample size
FSIS selects between 60 and 75 establishments from the frame every month, depending upon the number of weeks in a month. Annually, this amounts to mailing 780 sample forms per year. The choice of implementing 15 forms per week was due to laboratory contracting limitations of 780 analyses per year at the time of implementation.

Sampling methodology
MT54 is a simple random sample without replacement, except for ammoniated beef establishments. The ammoniated LFTB establishments are selected with certainty every month.

Collection methodology
Inspectors are directed to collect two pounds of component product other than trim, per FSIS Directive 10,010.1, Rev. 3. How the inspector collects the sample depends upon the type of product being collected. For Advanced Meat Recovery (AMR) product and Low Temperature Rendered (LTR) product, IPP are to select randomly a sample consisting of no less than one pound, but not more than two pounds of product from a specific production lot. For other raw beef components (e.g., heart meat), IPP are to collect randomly one piece, or enough pieces, of the beef components to equal no less than one pound, but not more than two pounds of product from a specific production lot. If the component is very large, IPP are to collect an N60 sample where the goal is collection of 60 pieces, in the manner as described in Ch. II, IV. In practical terms, however, it is nearly impossible for an inspector to collect an N60 sample that meets the number of pieces, piece dimension and total sample weight specifications. As of last year, the FSIS laboratories have redefined the analytical portion to consist of the analysis of up to 60 pieces (N60) weighing up to 715 grams (up to two 325 gram ± 32.5 gram subsamples) rather than limit the sample to 325 grams. This decision was reached after the method was validated to process a single 325 gram sample (previously it was 5-65 gram subsamples).

Mean response rate
Since 2008, the mean annual response rate of collected samples, as compared to printed forms, is 27%. The low response rate may be due to a poorly defined frame; that is, not all slaughter establishments may produce this product.

Mean analyzed samples
Since 2008, FSIS laboratories have analyzed a mean of 224 samples per year.

Routine testing of bench trim at domestic establishments (MT55)
Purpose
The intended purpose of the MT55 sampling project is to verify HACCP. This sampling project was implemented in September 2009.

Sample frame definition
The frame includes all active, federally inspected beef processing establishments that produce trim from purchased product. These establishments were initially identified from a combination of PBIS extension profile data and the 2007 FSIS *E. coli* checklist responses. If an MT55 sampling form is returned to the laboratories with code 60 (product not produced) selected, then the establishment is excluded from the frame for 12 months. An exclusion list is maintained to exclude establishments for special circumstances when documentation is provided by FSIS field personnel.

Average sample frame size
Generally, the frame is around 1,100 establishments. This value fluctuates monthly as new establishments become eligible and others become ineligible. Ineligibility may result from seasonal processing, closure, withdrawal of inspection, change in business practices or for other reasons.

Sample size
FSIS selects 150 establishments from the frame every month. Annually, this amounts to mailing 1,800 sample forms per year. The decision to select 150 forms per month was due to a desire to send one form to each establishment in the original frame within the first 12 months of project implementation.

Sampling methodology
MT55 is a simple random sample without replacement.

Collection methodology
Inspectors are directed to collect an N60 sample weighting 325 grams where each piece matches the template (1" wide x 3" long x 1/8" deep) and the goal is collection of 60 pieces, per FSIS Directive 10,010.1, Revision 3, Ch. II, IV. The N60 sample is to collect 60 pieces that weigh 325 grams in one bag and to collect a second bag of small pieces. If the establishment produces trim derived from primals and subprimals resulting in large pieces, IPP are to sample the product using the N60 sampling procedures in Chapter II, IV. If the establishment produces trim derived from primals and subprimals resulting in trim too small to be sampled using the N60 sampling procedure or produces trim derived from steaks, roasts or other cuts designated for non-intact use, IPP are to collect enough pieces to equal two pounds of product for sampling. If the establishment produces both types of trim as described above, IPP are to sample only the product that can be sampled using the N60 sampling procedure. However, in practical terms, it is nearly impossible for an inspector to collect an N60 sample that meets the number of pieces, piece dimension, and total sample weight specifications. As of last year, the FSIS laboratories have

redefined the analytical portion to consist of the analysis of up to 60 pieces (N60) weighing up to 715 grams (up to two 325 gram ± 32.5 gram subsamples) rather than limit the sample to 325 gram. This decision was reached after the method was validated to process a single 325 gram sample (previously it was 5-65 gram subsamples).

Mean response rate
Since September 2009, the mean annual response rate of collected samples, as compared to printed forms, is 29%. The low response rate may be due to a poorly defined frame; that is, not all establishments in the frame may produce this product or produce them infrequently.

Mean analyzed samples
Since September 2009, FSIS laboratories have analyzed a mean of 538 samples per year.

Follow-up testing to a positive in trim or components at a domestic establishment (MT53)
Purpose
An MT53 sample follows an MT50, MT54, MT55, or MT52 positive. The purpose of the MT53 sampling project is to follow-up in establishments that recently had a trim or components positive, providing more frequent, targeted sampling at these establishments as a means to verify that HACCP systems are back in control.

Sample frame definition
This project does not define a frame because it is not a statistical sampling project. Rather, establishments that receive MT53 sample request forms are those that have recently had a trim or components positive sample.

Average sample frame size
This project does not have an average frame size because MT53 is targeted sampling based upon positive trim or component results, which can include coarse raw ground beef.

Sample size
For each positive at an establishment, 16 follow-up sample request forms are automatically scheduled at that establishment. In the case of a low-volume producing establishment, then only eight samples are collected. The decision to collect 16 follow-up samples was made in 2008, when an FSIS analysis showed that establishments that test positive were five times more likely to receive another positive in the next 160 days than those that do not. At that time, the national average for grinders was approximately 0.17% positive in sampled lots. Under binomial distribution, 16 negative samples from 16 lots gives a 95% confidence that the establishment is less than 100 times above the national average. While FSIS performed these calculations, they were not seriously considered out of practicality as 1,750 follow-up samples over four months would be needed to verify that the establishment was at or below 0.17% positive.

Sampling methodology
Samples for the MT53 project are automatically scheduled following a trim or components positive. The follow-up samples are scheduled at the same establishment with the initial positive sample.

Collection methodology
Inspectors are to collect an N60 sample weighing 325 grams, where each piece matches the template (1" wide x 3" long x 1/8" deep) and the goal is collection of 60 pieces, per FSIS Directive 10,010.1, Revision 3, Ch. II, IV. The N60 sample is to collect 60 pieces that weigh 325 grams in one bag and to collect a second bag of small pieces. If available, the product collected should be the same as the original positive. As discussed above, FSIS' laboratories have redefined the analytical portion to consist of the analysis of up to 60 pieces (N60) weighing up to 715 grams (up to two 325 gram ± 32.5 grams subsamples) rather than limit the sample to 325g. This decision was reached after the method was validated to process a single 325 gram sample (previously it was a 5-65 gram subsamples).

Mean response rate
Since 2008, the mean annual response rate of collected samples, as compared to printed forms, is 53%. Although 16 forms are sent to all establishments, inspectors are instructed only to collect eight samples in very small volume establishments. These forms are difficult to identify in the data structures, so they may artificially deflate the response rate. Additionally, some establishments choose to stop producing after a positive sample, so it would be impossible to collect a sample from them.

Mean analyzed samples
The annual mean of analyzed samples is 161 per year. This value is dependent upon the number of positive trim and component samples analyzed during the year.

Follow-up testing at supplier establishments following a positive in raw ground beef and bench trim (MT52)

Purpose
An MT52 sample follows a MT43, MT44, or MT55 positive. MT52 samples are also taken for the Agricultural Marketing Service (AMS) School Lunch Program and of suppliers, when raw ground beef or bench trim are recalled. The purpose of the MT52 sampling project is to follow-up at originating slaughter establishments and ammoniated LFTB following an *E. coli* O157:H7 positive, providing more frequent, targeted sampling at the implicated supplier establishments, as a means of verifying that HACCP systems are back in control.

Sample frame definition
This project does not define a frame because it is not a statistical sampling project. Rather, establishments that receive MT52 sample request forms are those that have supplied trim or components to an establishment that had a recent positive sample. Supplier establishments are identified by FSIS traceback to the originating slaughter establishments. These supplier establishments are documented and tracked in the FSIS Supplier Traceback to *E. coli* Positive System (STEPS).

Average sample frame size
This does not apply because MT52 is targeted sampling based upon positive *E. coli* O157:H7 results.

Sample size
If an originating slaughter establishment was the only supplier, or if any of the originating slaughter establishments were suppliers identified in STEPS within approximately four months (or 120 days) of the current raw ground product positive result, then 16 follow-up sample request forms are automatically scheduled at that establishment. If the establishment is a low volume producer (less than 1,000 lbs. per day), only eight follow-up samples are collected. The decision to collect 16 follow-up samples was made in 2008, when an FSIS analysis showed that establishments that test positive were five times more likely to receive another positive in the next 160 days than those that do not. At that time, the national average for grinders was approximately 0.17% positive in sampled lots. Under binomial distribution, 16 negative samples from 16 lots gives a 95% confidence that the establishment is less than 100 times above the national average. While FSIS performed these calculations, they were seriously considered out of practicality as 1,750 follow-up samples over four months would be needed to verify that the establishment was at or below 0.17% positive. If a supplier is not a sole supplier or a repeat supplier in STEPS, FSIS will request a single follow-up sample from the supplier for each component used in the positive raw ground beef product.

Sampling methodology
Samples for the MT52 project are requested following traceback investigation. The follow-up samples are scheduled at the originating slaughter suppliers or ammoniated LFTB, not at other intermediate suppliers.

Collection methodology
Inspectors are to collect an N60 sample weighing 325 grams, where each piece matches the template (1" wide x 3" long x 1/8" deep) and the goal is collection of 60 pieces, per FSIS Directive 10,010.1, Revision 3, Ch. II, IV. The N60 sample is to collect 60 pieces that weigh 325 grams in one bag and to collect a second bag of small pieces. Collection depends on the type of product being collected—see FSIS Directive 10,010.1, Revision 3. Inspectors should collect the same component identified in traceback. As discussed above, FSIS' laboratories have redefined the analytical portion to consist of the analysis of up to 60 pieces (N60) weighing up to 715 grams (up to two 325 gram ± 32.5 gram subsamples) rather than limit the sample to 325 grams. This decision was reached after the method was validated to process a single 325 gram sample (previously it was 5-65 gram subsamples).

Mean response rate
Since 2007, the mean annual response rate of collected samples, as compared to printed forms, is 77%. IPP are only to submit eight samples and mail the remaining eight follow-up forms with the last sample collected. Response rates may also be influenced by production volume of scheduled establishments.

Mean analyzed samples
The annual mean of analyzed samples is 610 per year. This value is dependent upon the number of positive *E. coli* O157:H7 samples analyzed during the year.

Limitations of Current Sampling Projects

FSIS has identified several limitations to the Agency's current sampling projects, most of which influence FSIS' ability to compute estimates.

1. *Prior Notification*
   It is possible that prior notification affects the ability of FSIS to collect representative samples. However, policy constraints require that notification be given to establishments so that they can plan for holding product until FSIS laboratory test results are to help prevent recalling product and posing a risk to the public's health. FSIS recently requested comments on a new Federal Register Notice that would change the Agency's procedures and withhold a determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received.[78]
2. *Sample Sizes for MT50, MT54, MT55 Programs*
   Precision usually improves as sample sizes increase. In addition, the precision of the estimate may provide an indicator of its reliability. That is, larger sample sizes typically lead to smaller variances. In particular, rare event sampling requires large sample sizes to obtain reasonable precision. The MT50 program detected four positive trim samples out of 1,274 analyzed samples in 2010, which gives an indication that this is rare event testing. Likewise, there were no positives out of the 169 analyzed MT54 samples in 2010 and no positives out of the 574 analyzed in MT55 samples in 2010.
3. *Representativeness of the Samples*
   For MT50, MT54 and MT55, the sample scheduling is representative of establishments. Because the sample designs do not incorporate stratification or weighting by production volume, the samples may not be adequately representative of product from each production class.
4. *Industry Testing Affecting FSIS Estimates*
   Industry test and divert practices may result in a lower percent positive estimate obtained by FSIS verification testing than would be obtained through baseline testing, because a portion of positive product would already be removed.

Recent improvements to the domestic sampling

FSIS recently stopped *E. coli* O157:H7 RTE sampling in dried/semi-dried, fermented sausages and cooked meat patties. This testing was discontinued after an analysis showed that testing over 10,000 such products for *E. coli* O157:H7 over a nine-year period yielded no positive samples. Additionally, FSIS recently shifted from five 65 gram sub sample analyses per collected sample to one 325 gram analysis for raw ground beef samples and two 325 gram sub samples for N60 samples or component samples, which should reduce the total number of analyses conducted by FSIS laboratories and release resources to conduct other analyses.

E. coli O157:H7 Measures of Success

As described above, there are several different *E. coli* O157:H7 sampling projects, each with slightly different goals. Yet, the overall purpose of the *E. coli* O157:H7 sampling projects is to provide verification of HACCP policy implementation and to assess, and minimize, the risk to public health from contaminated product.

[78] http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2005-0044.pdf

Consequently, FSIS believes it is appropriate to measure the success of the different sampling projects in broad terms, rather than focusing solely on volume-weighted percent positives in raw ground beef. As such, to measure the success of the *E. coli* O157:H7 sampling program, FSIS evaluates its efforts in terms of three key metrics:

1. Volume-weighted percent positives from FSIS' raw ground beef *E. coli* O157:H7 sampling project and unweighted percent positives from other FSIS *E. coli* O157:H7 testing projects.
2. Estimated number of *E. coli* O157:H7 foodborne illnesses associated with FSIS-regulated products.
3. Number of *E. coli* O157:H7 recalls.

Volume-Weighted Percent Positives

As described in this report, FSIS samples product regulated by the Agency to verify HACCP policy implementation and to assess, and minimize, the risk to public health from contaminated product. FSIS uses this sampling to calculate percent positives for many of the *E. coli* O157:H7 sampling projects. FSIS believes that percent positives are a good measure of the effectiveness of the individual *E. coli* O157:H7 sampling projects maintained by the Agency, with declines in percent positives indicating greater control and prevention of *E. coli* O157:H7 in finished product. Table 2.1.3.4 displays the volume-weighted percent positives from FSIS sampling of raw ground beef over time. Figure 2.1.3.1 provides unweighted percent positives for four of FSIS' major *E. coli* O157:H7 sampling projects. The reason this metric is presented is because historically, FSIS has only calculated volume weighted percent positive for the raw ground beef verification sampling project (MT43).

Table 2.1.3.4: Volume-Weighted Percent Positives from FSIS *E. coli* O157:H7 Sampling for Raw Ground Beef

Year/Quarter	Volume-Weighted Percent Positive (All FSIS MT43 Samples)
FY 2009	0.32%
FY10Q3	0.23%
FY10Q4	0.25%
FY11Q1	0.16%
FY11Q2	0.14%
FY11Q3	0.08%

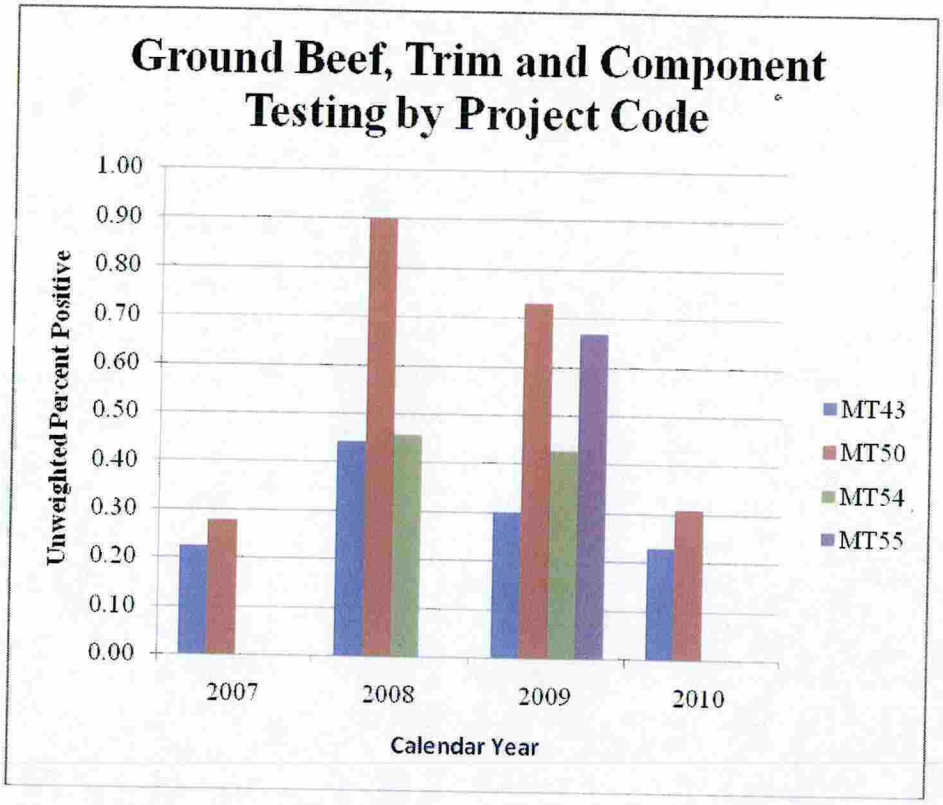

Figure 2.1.3.1: Unweighted Percent Positives for Select Group of FSIS Sampling Projects for *E. coli* O157:H7

Foodborne Illness Estimates:

As FSIS' ultimate goal is to prevent foodborne illnesses from regulated products, it is important to measure reductions in foodborne illness as a result of FSIS inspections, sampling, policies and other activities. FSIS calculates a performance measure, known as the All-Illness Measure, which represents all foodborne *Salmonella*, *Lm* and *E. coli* O157:H7 illnesses from FSIS-regulated meat, poultry and processed egg product. FSIS updated the All Illness Measure in Q3, FY2011 to reflect the release of new illness burden estimates from the CDC[79] and the Healthy People 2020 goals[80], as well as to coincide with the release of the FSIS Strategic Plan for 2011-2016. Objectives for the All-Illness measure were set using a combination of data from published CDC FoodNet case rates and outbreak data and are aligned with Healthy People 2020 goals. For *E. coli* O157:H7, FSIS uses a rolling 12 month window of case rate data from the CDC, in addition to an attribution estimate, to estimate the total number of *E. coli* O157:H7 illnesses from FSIS regulated products. Using this methodology, the illness measure is the estimate of the total annual illnesses for the fiscal year, rather than independent measures of illness for each quarter.

[79] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. Emerg Infect Dis [serial on the Internet]. 2011 Jan [*November 2011*]. http://www.cdc.gov/EID/content/17/1/7.htm.

[80] For more information please see the following website: http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=14.

Performance Measure

Using the newly updated All Illness Measure data sources and methodology, FSIS set a target of reducing the estimated *E. coli* O157:H7 illnesses associated with FSIS regulated products to 20,071 in Q3 FY 2011; FSIS achieved that target with 18,798 estimated illnesses. Figure 2.1.3.2 illustrates the quarterly targets for *E. coli* O157:H7 illnesses and the estimated illnesses for the most recent four quarters. While it is difficult to interpret these trends with a great deal of statistical certainty, this data suggests that the *E. coli* O157:H7 testing projects are effective in reducing human illness.

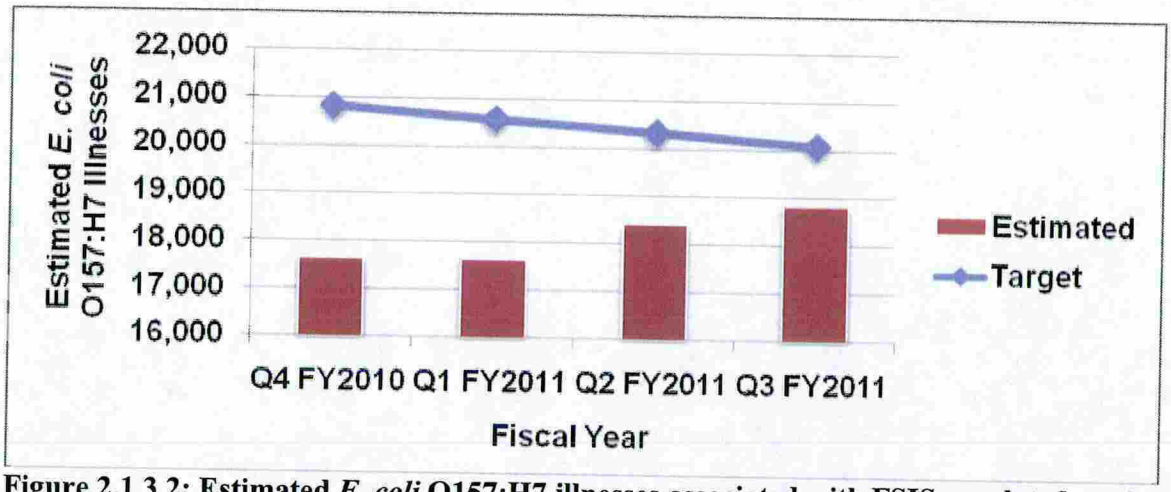

Figure 2.1.3.2: Estimated *E. coli* O157:H7 illnesses associated with FSIS regulated products

Recalls

The number of recalls FSIS supports is a good indication of the effectiveness of the *E. coli* O157:H7 sampling projects maintained by the Agency. Recalls occur when adulterated product is found in commerce. A recall is a firm's action to remove product from commerce (e.g., by manufacturers, distributors, or importers) to protect the public from adulterated or misbranded products. Although it is a firm's decision to recall product, FSIS coordinates with the firm to ensure the firm has properly identified and removed recalled product from commerce by verifying the effectiveness of the firm's recall activities. FSIS also notifies the public about product recalls.[81] In general, the discovery of a positive sample in FSIS testing should prevent contaminated product from reaching the consumer marketplace. While FSIS does not currently mandate that establishments hold product until negative test results are received, the Agency recently requested comments on a new Federal Register Notice that would change the Agency's procedures and withhold a determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received.[82]

Therefore, when firms hold product pending FSIS test results, FSIS sampling projects can prevent recalls from occurring. The possibility of recalls has prompted industry to increase its capacity and willingness to hold product while it is being tested, to institute their own test and divert programs and to ultimately contribute to the lower estimate of *E. coli* O157:H7 in the food

[81] FSIS Directive 8080.1 http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1.pdf
[82] http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2005-0044.pdf

supply. Therefore, evaluating the number of recalls due to positive *E. coli* O157:H7 results over time allow FSIS to, in part, evaluate the overall effectiveness of its policies, as Figure 2.1.3.3 demonstrates.

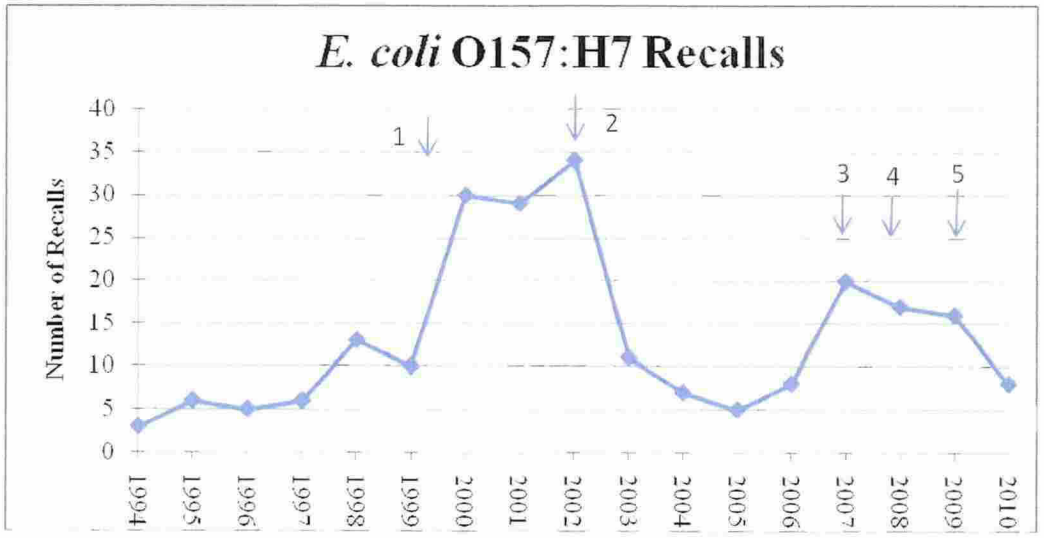

Figure 2.1.3.3: *E. coli* O157:H7 reported recalls, 1994-2010.

Key:
1996: HACCP rule published
1. 1999-2000—HACCP implementation complete
2: 2002—Industry to reassess HACCP with O157:H7 a hazard likely to occur, also industry started widespread test and divert programs
3: 2007—Started MT50 and MT54
4: 2008—Switched to risk (production volume) based sampling
5: 2009—Started MT55

2.1.4: RTE Meat and Poultry Products *(Listeria monocytogenes (Lm)* and *Salmonella)*

Overview of Sampling Projects

FSIS conducts microbiological testing of RTE meat and poultry products for *Listeria monocytogenes (Lm)* and *Salmonella.*[83] *Lm* domestic sampling projects are summarized in Table 2.1.4.1. As the projects are different, they will be described separately.

Table 2.1.4.1 FSIS RTE Domestic Sampling Projects

Product class	RTE Sampling Projects	Pathogens Tested	Number of FY2010 samples	Regulatory Purpose of Sampling Program	Type of Sampling Program
Both post-lethality exposed and non-post-lethality exposed RTE products	ALLRTE	*Lm, Salmonella*	2,990	Monitor industry performance	Random
Post-lethality exposed RTE products	RTE001	*Lm, Salmonella*	8,700	Verify non-detectable standard	Risk Based
RLm product samples	RLMPROD	*Lm*	1,960	Monitor industry performance	Risk Based
RLm food contact surface samples	RLMCONT	*Lm*	6,600	Monitor industry performance	Risk Based
RLm non-food contact environmental samples (Composited 5-sample Units; *Lm*)	RLMENVC	*Lm*	690	Monitor industry performance	Risk Based
Intensified Verification Testing (IVT) product samples	INTPROD	*Lm* or *Salmonella*	225	Response to positive ALLRTE, RTE001, RLMPROD and/or RLMCONT sample	Targeted
IVT food contact surface samples	INTCONT	*Lm* or *Salmonella*	550	Response to positive ALLRTE, RTE001, RLMPROD and/or RLMCONT sample	Targeted
IVT non-food contact environmental samples	INTENV	*Lm* or *Salmonella*	275	Response to positive ALLRTE, RTE001, RLMPROD and/or RLMCONT sample	Targeted

[83] In addition to *Lm* and *Salmonella*, testing for *E. coli* O157:H7 was performed for dry and semi-dry fermented sausages and fully cooked meat patties until April, 2011. FSIS officially announced the discontinuation of the program in a May 13, 2011 Constituent Update which can be found at: http://www.fsis.usda.gov/News_&_Events/Const_Update_051311/index.asp. This testing was discontinued after an analysis showed that testing over 10,000 such products for *E. coli* O157:H7 over a sixteen year period (1994-2011) yielded no positive samples.

Historical Basis of Sampling Programs

Lm has been implicated in illness outbreaks since the early 1980s. FSIS has conducted a regulatory microbiological testing program in RTE meat and poultry products since 1983. From 1983 until 2004, establishments were randomly selected for regulatory samples from different sub-populations or from the total population of establishments producing RTE products.[84] In 1987, FSIS increased testing for *Lm* in regulated products, including domestic cooked meat and poultry and imported cooked products.[85] In 1989, after a confirmed human listeriosis case was linked to cooked poultry, FSIS identified *Lm* as an adulterant subject to recall if found in commerce.[86] After the implementation of PR/HACCP regulations in 1996,[87] FSIS organized *Lm* testing around the four HACCP processes of; 1) fully cooked, not shelf stable products, 2) heat-treated, shelf stable products, 3) not heat-treated, shelf stable products and 4) products with secondary inhibitors that are not shelf stable. In addition to the material provided below, a timeline of FSIS activities related to *Lm* can be found on the Agency's website.[88]

FSIS began random testing of RTE product samples in the 1990s, while risk-based testing of RTE products for *Lm* began in 2005. Since the inception of the *Lm* verification testing program for RTE meat and poultry products, FSIS has also sampled packaged RTE products for the presence of *Salmonella*.

Type of Analysis

All samples collected for analysis in the RTE product testing projects are evaluated using qualitative and quantitative methods. In 2006, FSIS initiated MPN analysis of positive RTE food products identified during follow-up testing.

Volume Data

Production volume data for the ALLRTE and RTE0001 sampling projects are obtained in two ways:

1. For all establishments with post-lethality exposure (RTE001 and R*Lm* sampling projects), volume information was provided on an annual basis using FSIS Form 10,240-1, as required under Federal Regulation 9 CFR 430. This form contained the establishment's annual production volume of post-lethality exposed RTE meat and poultry products for each control Alternative[89] in each of nine product categories.[90]
2. For RTE establishments that produce RTE products with no post-lethality exposure (which are a part of the ALLRTE sampling projects), volume information is provided on a voluntary basis.[91]

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[84] Please see the following website for more information: http://www.fsis.usda.gov/Science/Micro_Testing_RTE/index.asp.
[85] Federal Register, Volume 52, No. 47, March 11, 1987.
[86] Federal Register Volume 54, No. 98, Tuesday May 23, 1989.
[87] Pathogen Reduction/Hazard Analysis and Critical Control Point System final rule (61 FR 38806, July 25, 1996).
[88] Please see the following website for more information: http://www.fsis.usda.gov/PDF/Lm_Timeline.pdf
[89] For Alternative 1, the establishment uses a post-lethality treatment for its product and an antimicrobial agent or process that suppresses or limits of growth of *Lm*. For Alternative 2, the establishment uses either a post-lethality treatment for product (choice 1) or an antimicrobial agent or process that suppresses or limits the growth of *Lm* (choice 2). For Alternative 3 the establishment uses a sanitation program that controls *Lm* contamination in the processing environment and on the product.
[90] This form was discontinued as of September 30th, 2011. Moving forward, this information will be collected through PHIS.
[91] This volume information will be collected in PHIS once it has been fully implemented.

Thus, approximately 90% of establishments in the ALLRTE sampling project have volume information available from the RTE001 sampling project, the exceptions (prior to PHIS) being those establishments with no post-lethality exposure.

Current Design of Sampling Plans

FSIS conducts regulatory microbiological testing of RTE meat and poultry products for two microorganisms: *Lm* and *Salmonella*. Currently, there are three verification testing projects for the detection of *Lm* contamination: ALLRTE, RTE001 and RLm. ALLRTE and RTE001 product samples also are concurrently tested for *Salmonella*. Intensified Verification Testing (IVT) is conducted in establishments with positive ALLRTE, RTE001, and RLMPROD and/or RLMCONT (product and food contact surface) samples.

In general, all sampling projects for *Lm* in post-lethality exposed RTE products rely on 9 CFR 430.4 "Control of *Listeria monocytogenes* in post-lethality exposed ready-to-eat products", published on June 6, 2003 (68 FR 34207). Other relevant regulations/directives/notices for each sampling program are listed after each program description.

Description of the FSIS RTE Domestic Sampling Projects for *Lm* and/or *Salmonella*

A description of each domestic sampling project for RTE meat and poultry products, food contact surfaces and non-food contact environmental surfaces follows below.

ALLRTE

Purpose

The ALLRTE sampling project began in January 2004 and was designed to obtain random samples across all RTE products and across all establishments producing a RTE product, regardless of risk or product type. The ALLRTE sampling program is structured with the intent of verifying compliance with zero tolerance for *Lm* in RTE products. Products are sampled for *Lm* and *Salmonella*. Both post-lethality exposed and non-post-lethality exposed products are tested. Currently, samples are randomly selected by FSIS.

The following FSIS policy relates to ALLRTE: FSIS Directive 10,240.4 Revision 2 "Verification Procedures for Consumer Safety Inspectors for the *Listeria monocytogenes* (*Lm*) Regulation and *Lm* Sampling Program", dated February 3, 2009.

Any RTE products testing positive for *Lm* and *Salmonella* are considered to be adulterated and subject to regulatory control. FSIS recommends that establishments hold product pending FSIS confirmed test results so that adulterated products are not sold into commerce. If an establishment releases a product into commerce that later confirms positive *Lm* or *Salmonella*, FSIS recommends a recall to remove the product from commerce and requires the establishments to rework, re-cook or condemn the product in a manner validated to destroy the adulterant. As discussed above, FSIS recently requested comments on a new Federal Register Notice that would change the Agency's procedures and withhold a determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received.[92]

[92] Please see the following website for more information: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2005-0044.pdf.

Frame Definition, Frame Size, and Sample Size
The ALLRTE frame contains approximately 2,400 active RTE establishments under Federal or Talmadge/Aiken (T/A) inspection authority,[93] based on information available in PBIS. This value can fluctuate as new establishments become eligible and others become ineligible. Ineligibility may result from seasonal processing, closure, withdrawal of inspection or change in business practices. A total of 85 samples per week (4,420 per year) are selected from the frame, with the goal of each establishment being selected at least once per year, with a number of establishments being selected twice or more annually.

Several establishments were excluded from the ALLRTE sampling project prior to 2009 because they produced excepted products, which include oils, shortening, lard, margarine, lard margarine, pork skins, pork rinds, dried soup bases and mixtures of rendered animal fats and products labeled "for further processing," among other products.[94] FSIS Directive 10,240.4, Revision 2 removed the exceptions for these products (excluding products for further processing) from the ALLRTE sampling project. However, FSIS Notice 10-10 stated that "oils, shortening, lard, margarine, lard margarine, and mixtures of rendered animal fats are not to be collected for sampling under the ALLRTE or RTE001 sampling projects because there is no validated method for testing these products for *Lm.*"[95] FSIS will continue to sample popped pork skins, pork rinds, dried soup bases, concentrated (high salt content) soup mixes, and pickled pig's feet under both RTE sampling projects. Because there is not enough information on which specific products are produced at a given establishment at any given time, it is not possible to automatically exclude establishments that produce such products from sample scheduling algorithms. However, FSIS anticipates that this issue will be addressed through full PHIS implementation.

Sampling Methodology
On a monthly basis, FSIS randomly selects the samples from the frame using simple random selection. The sample size is 85 per week. Establishments that have already been sampled once within a fiscal year are removed from the frame and then reinstated on a cyclic basis. Samples are selected so that all RTE establishments, regardless of HACCP size, production volume or process design have an equal chance of being sampled each fiscal year (e.g., no weighting is applied during sample selection).

Collection Methodology
Two pounds of product in its final packaged form are collected at the establishment and sent to FSIS laboratories for testing.

Response Rate
In fiscal year 2010, an average of 66% of scheduled ALLRTE samples were collected and analyzed for both *Lm* and *Salmonella.*

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[93] Talmadge-Aiken establishments, formally known as Federal-State Cooperative Inspection Plants, are the approximately 250 meat and poultry establishments in 10 states where USDA has contracted with state agency inspectors to conduct federal inspection activities. Even though state employees conduct the inspections in these establishments, they are considered to be under federal rather than state inspection Talmadge-Aiken (7 U.S.C. 450)
[94] FSIS Directive 10,210.1, Amendment 6
[95] Please see the following website for more information: http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/10-10.pdf.

RTE001

Purpose

The RTE001 sampling project is a risk-based verification testing project, implemented in January 2005. This sampling project is used primarily to verify that establishments producing post-lethality exposed meat and poultry products are controlling *Lm* and are in compliance with the zero tolerance requirements of 9 CFR 430. In this project, products are sampled for both *Lm* and *Salmonella.* This project is also used to calculate volume-adjusted percent positives for *Lm.*

The following FSIS policy relates to the RTE001 sampling project: FSIS Directive 10,240.4 Revision 2.

Any RTE products testing positive for *Lm* or *Salmonella* are considered to be adulterated and subject to regulatory control. Currently, FSIS recommends that establishments hold product pending FSIS confirmed test results so that adulterated products are not sold into commerce. If an establishment releases product into commerce that later confirms positive for *Lm* or *Salmonella,* then FSIS recommends a recall to remove the product from commerce and requires the establishment to otherwise rework, re-cook or condemn the product in a manner validated to destroy the adulterant. As discussed above, FSIS recently requested comments on a new Federal Register Notice that would change the Agency's procedures and withhold a determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received.[96]

Frame Definition, Frame Size, and Sample Size

The RTE001 frame contains about 2,170 active RTE establishments with post-lethality exposure under Federal or T/A inspection authority, based on information available in PBIS. This value can fluctuate as new establishments become eligible and others become ineligible. Ineligibility may result from seasonal processing, closure, withdrawal of inspection and change in business practices, among other possibilities. A total of 200 samples per week (10,400 per year) are selected from the frame.

Sampling Methodology

Establishments are identified for sampling based on a risk-ranking algorithm, which takes into account the *Lm* control Alternative,[97] the production volume, the type of product produced and the sampling history. An establishment is selected from the frame as little as once per year to, at most, once per month, depending on its position in the risk-ranking algorithm.

Collection Methodology

Two pounds of product in its final, packaged form are collected at the establishment, with higher risk products given priority for collection. The order of risk for the various types of products is provided in FSIS Directive 10,240.4, Revision 2. The current list of product types used for risk-ranking purposes is as follows:

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[96] Please see the following website for more information: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2005-0044.pdf.

[97] Control Alternative refers to any one of four procedures used to prevent (control) the growth of *Lm* in post-lethality exposed RTE products. See footnote 89 for a complete description of the Alternatives.

1) Deli-meats that are sliced in the federal establishment,
2) Deli-meats shipped whole from the federal establishment (this does not include cook-in-bag products; only those exposed post-lethality),
3) Hotdog Products,
4) Deli salads, pâtés, and meat spreads,
5) Fully cooked type products (other than cooked products in 1-4 above),
6) Fermented products,
7) Dried products,
8) Salt-cured products, and
9) Products labeled as "Keep Frozen".

Response Rate
In fiscal year 2010, the percent of RTE001 samples that were collected and analyzed for both *Lm* and *Salmonella* averaged 83%.

RLm
Purpose
The RLm sampling project, implemented in April 2006, is a routine, risk-based sampling project, which consists of food contact samples, non-food contact environmental samples, and product samples taken during the production of RTE meat and poultry products exposed to the post-lethality environment. Samples are analyzed only for *Lm* and are taken during the same day of production. In conducting the RLm project, FSIS assesses the compliance of establishments with regulation 9 CFR 430 regarding the control of *Lm* in post-lethality exposed RTE production areas and ensures that RTE products are safe for consumption at the end of the production process.

RLm sampling, done in conjunction with an FSA, provides an in-depth evaluation of the effectiveness of the food safety practices employed by an establishment. The ability to use the product, contact and environmental data collected from the establishments can help identify possible risk factors that could be associated with positive results.

The following FSIS policy relates to the RLm sampling project: FSIS Directive 10,240.5 Revision 2.

Frame Definition, Frame Size, and Sample Size
The RLm frame is identical to that of RTE001. It contains about 2,170 active RTE establishments with post-lethality exposure under Federal or T/A inspection authority, based on information available in PBIS. This value can fluctuate as new establishments become eligible and others become ineligible. Ineligibility may result from seasonal processing, closure, withdrawal of inspection and change in business practices, among other possibilities. In 2009, FSIS policy was to require an RLm/FSA in every establishment with post-lethality exposure at least once every four years. Pursuant to an Office of the Inspector General (OIG) mandate, starting in August 2009, a sample size of 45 establishments per month (540 per year) is selected from the frame.

Sampling Methodology

RLm establishments are selected from the frame using the FSA prioritization model, which takes into account FSIS' public health decision criteria,[98] control alternative and type of product produced. The RLm project consists of the following three concurrent sampling projects:

1. RLMPROD—routine, risk-based testing of intact RTE food product samples throughout the selected production shift; three samples are collected per sampling unit.
2. RLMCONT— routine, risk-based testing of surfaces that have direct contact with RTE products in the RTE production area (e.g., conveyor belts, storage racks, slicer blades, loaders and table tops).
3. RLMENVC—routine, risk-based testing of environmental (non-food contact) surfaces in the RTE production areas (e.g., floors, drains, walls and floor mats). Starting in August 2009, environmental samples were composited at the testing labs.

Collection Methodology

Microbiological samples are collected as units. A unit consists of 10 food contact surface swabs (RLMCONT), five environmental swabs, which are later composited at the testing laboratories (RLMENVC), and three intact product samples (RLMPROD). In establishments that use brine chillers, the FSIS Enforcement Investigations and Analysis Officers (EAIO) collect a sample of brine from each line using a brine chiller. Brine samples could be either RLMENVR (environmental/not composited) if the product package is impermeable or RLMCONT if the product package is permeable. The number of units per establishment is based on HACCP size. FSIS collects three sample units from large HACCP establishments, two sample units from small establishments and one sample unit from very small establishments.[99]

Response Rate

In fiscal year 2010, the average response rate for RLm samples (combined RLMPROD, RLMCONT and RLMENVR/RLMENVC units) was 93%.

Intensified Verification Testing (IVT)

Purpose

IVT is a follow-up, targeted sampling project, where FSIS tests product, food contact surfaces, and environmental surfaces for either *Salmonella* or *Lm.* An IVT is initiated after an establishment has either a positive *Salmonella* or *Lm* result in either finished product (ALLRTE, RTE001 and RLMPROD) or on a food contact surface (RLMCONT). An IVT can also be initiated at the discretion of an FSIS District Manager, in response to continuing sanitation non-compliances at the establishment. The IVT is performed after the establishment has taken corrective and preventative measures in response to FSIS' findings. As described above for the RLm program, in an IVT, FSIS collects samples in units. As with RLm, IVTs are performed with a FSA to provide an in-depth evaluation of food safety systems at the establishment. However, the FSA is conducted for-cause, rather than being routine in nature. A maximum of five units in a given establishment are considered per IVT.

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[98] FSIS' Public Health Decision Criteria can be found at: http://www.fsis.usda.gov/OPPDE/NACMPI/Sep2010/2010_Public_Health_Decsion_Criteria_Report.pdf.

[99] HACCP Establishment Sizes are as follows: Large; 500 or more employees, Small: 10-499 employees, and Very Small: < 10 employees and annual sales >2.5 million.

The following FSIS policy relates to the IVT sampling project: FSIS Directive 10,300.1 "Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for *Listeria monocytogenes*," dated February 3, 2009, which provides instructions for performing an IVT.

Frame Definition, Frame Size, and Sample Size
There is no sampling frame for IVT, as it is dependent on a positive *Lm* or *Salmonella* ALLRTE, RTE001, RLMPROD and/or RLMCONT sample from a given establishment.

Sampling Methodology
IVTs are scheduled in accordance with FSA prioritization criteria from FSIS Directive 10,200.1, with all establishments with *Lm* or *Salmonella*-positive ALLRTE, RTE001, RLMPROD and RLMCONT samples requiring an IVT. The FSIS districts have 30 days in which to schedule the IVT.

Collection Methodology
As described above for the RLm project, IVT microbiological samples are collected in units. A sampling unit for *Lm* consists of ten food contact surface samples, five environmental samples and three product samples per RTE processing line in operation on the day of sampling, whereas a unit for *Salmonella* consists of eight food contact surface samples, five environmental samples and five product samples per processing line. If the establishment uses a brine chiller, FSIS will also collect one brine sample per line from the brine chiller.

Response Rate
In fiscal year 2010, the IVT response rates in response to *Lm*- and/or *Salmonella*-positive ALLRTE and RTE001 samples were 100% and 71%, respectively. IVT for positive RLMPROD and/or RLMCONT samples was not implemented until October 2009 with the issuance of FSIS Notice 62-09. The RLm response rate was 56% for the fiscal year.

Limitations of Current Sampling Programs
FSIS has identified several limitations to the current *Lm* sampling projects; namely sampling rates not being met for specific establishments, sampling frequency, project overlaps, sampling biases, volume-weighted percent positive results and regulatory considerations. These issues will be discussed in detail below.

1. *Sampling Rates for Establishments*
One objective of the ALLRTE and RTE001 sampling projects is to sample every RTE establishment (ALLRTE) and every RTE establishment with post-lethality exposure (RTE001) at least once each year. In FY 2011, virtually all of the approximately 2,400 active RTE producing establishments were scheduled for collection in one of the three RTE verification testing projects (ALLRTE, RTE001 and/or RLm). However, not every establishment is sampled annually and a small number of establishments were not sampled at all between 2005 and the present. The reasons for this are varied. In the case of ALLRTE, some establishments produce products such as popped pork skins, which were previously exempt from testing. In other instances, an establishment may be producing seasonally and could not be scheduled during a period of

production. As of October 2011, approximately 98% of all RTE establishments were sampled at least once over the calendar year.

2. *Sampling Frequency*
For ALLRTE, the random monthly sampling of scheduled RTE product producing establishments, plus the inclusion of all establishments in the sampling frame, may permit a comparative annual *Lm* positive rate in FSIS inspected establishments for an aggregate of the RTE products collected. Because the specific product to be collected is determined by IPP, specific products may be either over or under-sampled in relation to national production. For RTE001, higher risk establishments are scheduled more frequently. Accordingly, positive rates may vary as a function of the samples collected and tested from the scheduled establishments, resulting in a different measure of aggregate positive rates.

3. *Project Overlaps*
FSIS acknowledges that the RTE001 and ALLRTE projects exhibit a high degree of overlap due to independent scheduling. As the ALLRTE is independent of RTE001, sampling results are not currently combined, even though a single establishment may be sampled in both projects in a given month. However, sampling of the same establishment in the ALLRTE and RTE001 projects in the same month often results in only the risk-based (RTE001) sample being collected, which can cause a non-response bias.[100]

4. *Sampling Biases*
RTE001 data are biased towards high-risk products based on the program structure. There may be a similar, though less pronounced bias in the ALLRTE data, as historical instructions to the field allowed for sampling of higher-risk products in ALLRTE. Regardless, for both ALLRTE and RTE001, no mechanism exists for truly randomizing what products are collected at a given establishment over time. These issues may arise from such factors as samples not being collected, lack of random product selection at the establishment level and lack of randomness in sample selection from the frame (see also project overlaps above).

5. *Volume-Weighted Percent Positive Results*
The ALLRTE and RTE001 percent positive numbers were standard FSIS performance measures for the Agency's annual Performance and Accountability Report (PAR) for *Lm* until 2008; these have subsequently been replaced by volume-weighted positive rates. Such rates attempt to take into account the proportion of national volume represented by an individual sample, but do not adjust for missing establishments, missing, over or under-represented products or sampling bias not related to the design of the project.

6. *Regulatory Considerations*
RTE projects were developed as a result of regulatory activities. Consequently, changes to the current projects may require reissuance of existing policies or issuance of new policies.

[100] FSIS has attempted to reduce this bias by issuing instructions for the ALLRTE sampling program in Directive 10240.4 stating that "Consumer Safety Inspectors (CSIs) should make every effort to sample all the RTE products produced at an establishment by rotating through the products when CSIs receive sample request forms."

_Lm_ Sampling Program Measures of Success

There are several different *Lm* sampling projects, each with slightly different goals. Yet, the overall purpose of *Lm* sampling program is structured with the intent of verifying compliance with zero tolerance for *Lm* and *Salmonella* in RTE products.

Consequently, FSIS believes it is appropriate to measure the success of the different sampling projects in broad terms, rather than focusing solely on volume-adjusted percent positive rates. As such, to measure the success of the *Lm* sampling projects, FSIS evaluates its efforts in terms of three key metrics;

1. Volume-weighted percent positives from *Lm* sampling projects,
2. Estimated number of *Lm* foodborne illnesses associated with FSIS-regulated products, and
3. Number of *Lm* recalls.

Percent Positive Rates

FSIS conducts pathogen verification testing for the Agency's sampling programs. As described in this report, FSIS samples product regulated by the Agency to verify HACCP policy and to assess, and minimize, the risk to public health from contaminated product. FSIS uses this sampling to calculate a positive rate for many of the *Lm* sampling projects. FSIS believes that positive rates are a good measure of the effectiveness or success of the *Lm* sampling projects maintained by the Agency, with declines in percent positives potentially indicating greater control and prevention of *Lm* in RTE and meat and poultry products.

Table 2.1.4.2 provides the production category volume-weighted percent positive rate for the RTE001 project and the ALLRTE project.

Table 2.1.4.2: Quarterly Volume-Weighted Percent Positive Rates for *Lm* Sampling Projects

Year/Quarter	Volume-Weighted Percent Positive (ALLRTE)	Volume-Weighted Percent Positive (RTE001)
FY 2009	0.10%	0.24%
FY10Q3	0.01%	0.18%
FY10Q4	0.00%	0.10%
FY11Q1	0.00%	0.10%
FY11Q2	0.03%	0.14%
FY11Q3	0.04%	0.14%

Foodborne Illness Estimates:

As FSIS' ultimate goal is to prevent foodborne illnesses from regulated products, it is important to measure reductions in foodborne illness as a result of FSIS inspections, sampling, policies and other activities. FSIS calculates a performance measure, known as the All-Illness Measure, which represents all foodborne *Salmonella*, *Lm* and *E. coli* O157:H7 illnesses from FSIS-regulated meat, poultry and processed egg product. FSIS updated the All Illness Measure in Q3,

FY2011 to reflect the release of new illness burden estimates from the CDC[101] and the Healthy People 2020 goals[102], as well as to coincide with the release of the FSIS Strategic Plan for 2011-2016. Objectives for the All-Illness measure were set using a combination of data from published CDC FoodNet case rates and outbreak data and are aligned with Healthy People 2020 goals. For *Lm,* FSIS uses a rolling 12 month window of case rate data from the CDC, in addition to an attribution estimate, to estimate the total number of *Lm* illnesses from FSIS regulated products. Using this methodology, the illness measure is the estimate of the total annual illnesses for the fiscal year, rather than independent measures of illness for each quarter.

Performance Measure

Using the newly updated All Illness Measure data sources and methodology, FSIS set a target of reducing the estimated *Lm* illnesses associated with FSIS regulated products to 866 in Q3 FY2011; FSIS achieved that target with 718 estimated illnesses. Figure 2.1.4.1 illustrates the quarterly targets for *Lm* illnesses and the estimated illnesses for FY2010 and FY2011.

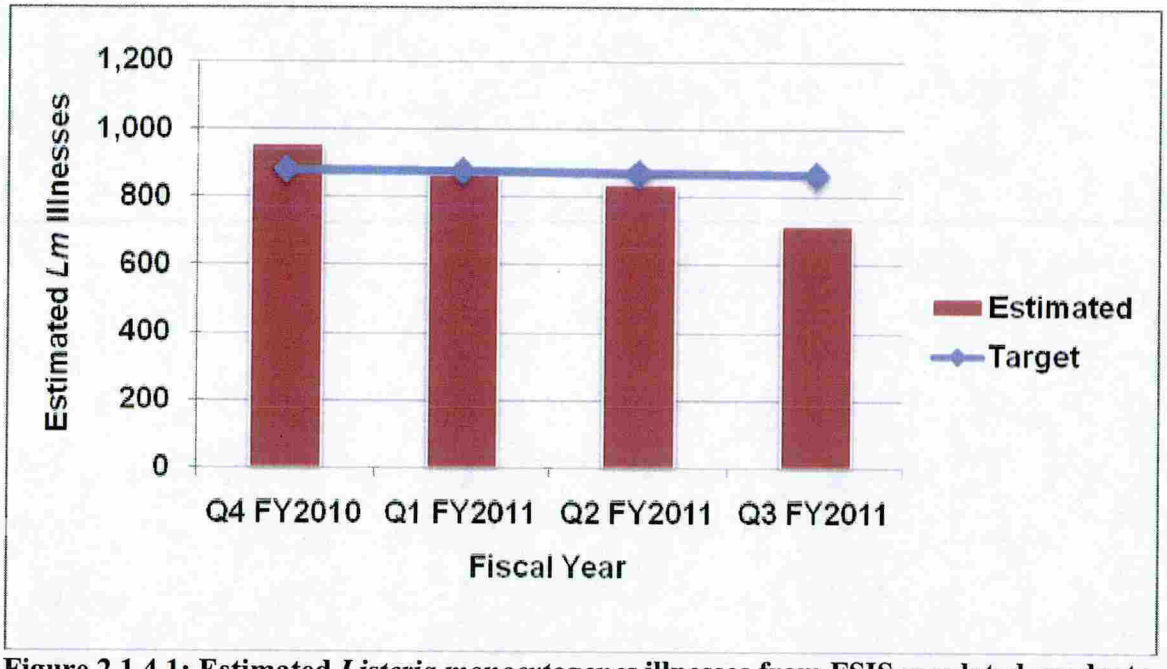

Figure 2.1.4.1: Estimated *Listeria monocytogenes* illnesses from FSIS regulated products

Recalls

The number of recalls FSIS supports is a good indication of the effectiveness or success of the *Lm* sampling projects maintained by the Agency. Recalls occur when a FSIS regulated product is found in commerce. A recall is a firm's action to remove product from commerce (e.g., by manufacturers, distributors or importers) to protect the public from consuming adulterated or misbranded products. Although it is a firm's decision to recall product, FSIS coordinates with the firm to ensure it has properly identified and removed recalled product from commerce by

[101] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. Emerg Infect Dis [serial on the Internet]. 2011 Jan [*November 2011*]. http://www.cdc.gov/EID/content/17/1/7.htm

[102] Please see the following website for more information: http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=14.

verifying the effectiveness of the firm's recall activities. FSIS also notifies the public about product recalls.[103] In general, the discovery of a positive sample in FSIS testing prevents contaminated product from reaching the consumer marketplace. Consequently, FSIS sampling programs can prevent recalls from occurring. Additionally, FSIS recently announced a new Federal Register Notice to encourage establishments to hold product while testing is underway to prevent contaminated product from reaching the marketplace. Further, evaluating the number of recalls over time allows FSIS to evaluate, in part, the effectiveness of its policies, as Figure 2.1.4.2 demonstrates.

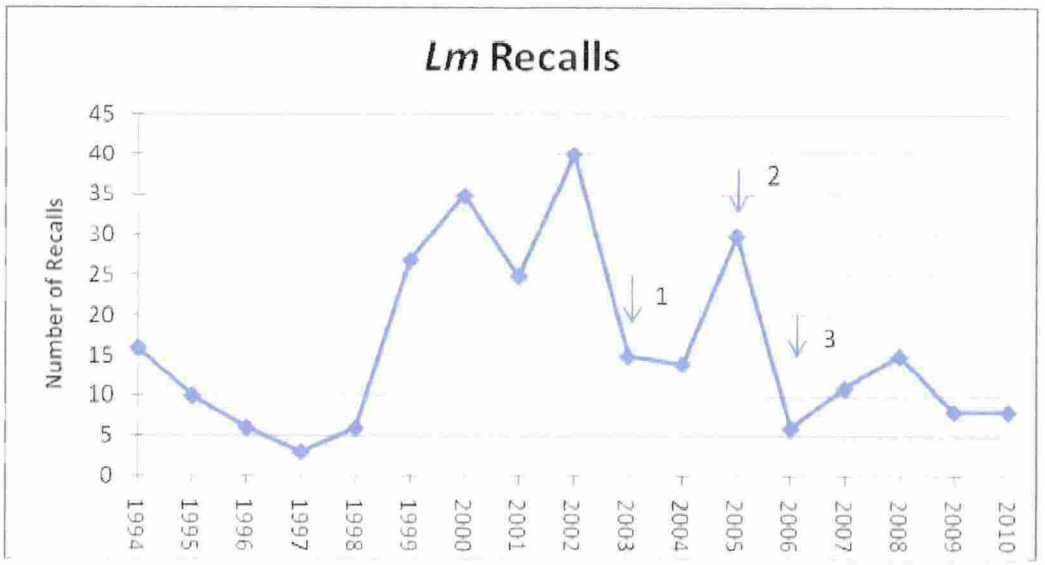

Figure 2.1.4.2: Reported FSIS recalls for Products Contaminated with *Lm*, 1994-2010.

[103] FSIS Directive 8080.1, Revision 6. http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1.pdf

Section 2.2: FSIS Microbiological Baseline Data Collection

In 1992, FSIS began a concerted effort to identify the microbiological profile of various classes of inspected raw meat and poultry carcasses and ground product. The purpose was to use the data to establish both pathogen reduction performance standards (for carcasses and ground product) and process control performance criteria (for carcasses). The pathogen reduction performance standards were intended to spur industry to control the presence of pathogens of public health concern, particularly *Salmonella*. The process control performance criteria were designed to reflect the prevalence and levels of contamination of *E. coli* (Biotype 1) on carcasses, as an indicator of process control for fecal contamination. In designing the baselines, FSIS intended to capture microbiological profile data for microorganisms of varying degrees of public health concern, and organisms or groups of organisms of value as indicators of general hygiene or process control. In addition, FSIS stated its expectation to repeat the baseline studies over time to document changes. Although microbiological data were collected by FSIS prior to 1992, these earlier efforts were not conducted as part of anticipated rulemaking. A more complete description of the various microbiological baseline data collection efforts and their design considerations can be found in the preambles to the proposed and final rules associated with the PR/HACCP system rulemaking effort.[104]

The carcass baselines, conducted periodically, were specifically designed to identify nationwide changes in the prevalence of *Salmonella,* expressed as a percentage of contaminated carcasses. Enough samples were taken to describe the annual distribution of test results and to account for possible seasonal variation, as well as provide for missing samples and incomplete data. These baselines were targeted at the major classes of livestock and poultry slaughtered, comprising approximately 95 percent of all livestock slaughtered, and approximately 99 percent of domestic birds slaughtered. The carcass baselines were originally designated as data collection "programs" because of the scope and length of time for the data collection effort, generally comprising at least one year. By contrast, the ground product baselines were originally designated as data collection "surveys." The surveys reflected the prevalence of *Salmonella* (expressed as a percentage of positive samples) as a snapshot over a short period of time, generally limited to a six month data collection effort. In the preamble to the PR/HACCP final rule, FSIS referred to both data collection efforts, collectively, as FSIS baseline surveys.

From the FSIS baseline surveys, the prevalence for *Salmonella* was used for setting the qualitative pathogen reduction performance standards. However, for the process control performance criteria, a statistical procedure known as a "3-class attributes sampling plan" applied in a moving window was used. Consequently, the "m" and "M" criteria were set at the closest power of 10 to the actual numbers estimated for the 80th and 98th percentiles from the FSIS baseline surveys. These criteria are quantitative (colonies per square centimeter of carcass surface area).

The data generated from FSIS baseline surveys continue to be used to set pathogen reduction performance standards, and to inform design of FSIS regulatory testing programs, as well as in guidance to industry related to effective process control. Since the time that the PR/HACCP final rule was implemented, FSIS has also used FSIS baseline survey data in risk assessments to predict the public health impact of risk mitigation strategies. During the most recent poultry

[104] 60 FR Federal Register 6774, February 3, 1995, and 61 Federal Register 38806, July 25, 1996.

carcass baseline surveys, a method for isolating *Campylobacter* was developed and validated and has since been adopted by the agency. Some of the commodities for which baseline surveys have been conducted since the original FSIS baseline surveys supporting the PR/HACCP final rule include: beef trim, young chicken carcasses and young turkey carcasses. The most recent FSIS baseline surveys underway include market hogs and chicken parts. A second FSIS baseline survey of unpasteurized liquid egg product is underway with the intent of using the data to establish lethality performance standards for pasteurized egg product.

Section 2.3 Chemical Residues

Overview of Sampling Projects

FSIS conducts testing for chemical residues in regulated meat, poultry and processed egg products. Domestic sampling projects are summarized in Table 2.3.1.

Table 2.3.1: Residue Sampling Projects

Residue Sampling Projects	Number of Residue Analyzed samples FY2010	Regulatory Purpose of Sampling Program
Routine-NRP[1]	14,929	Chemical Residue Exposure Assessment-Random
KIS™ Test-Field	157,524	Targeted
KIS™ Test –Lab[2]	8,041	Targeted
FAST-Field	47,676	Targeted
FAST-Lab	291	Targeted

1. National Residue Program samples for meat, poultry and processed egg products, as well as residue monitoring and inspector generated samples.
2. Verification/confirmation sampling conducted by the FSIS Laboratories. Includes confirmatory KIS™ tests on field positives.

Background Information

Since 1967, FSIS has administered the United States National Residue Program (NRP). FSIS collects samples of raw meat, poultry and processed egg products, as well as imported product and analyzes the samples at one of the three FSIS laboratories. The NRP is designed to detect contamination of meat, poultry and processed egg products with residual veterinary drugs, pesticides and heavy metals. Under this program, FSIS inspectors sample meat, poultry and processed egg products in slaughter and processing establishments for chemical residues and compare, when applicable, the results with tolerances established by the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) to prevent adulterated meat, poultry and processed egg products from entering into commerce. The NRP is an interagency program operating under a 1984 Memorandum of Understanding. There are three interagency workgroups that coordinate residue sampling operations: 1) the Interagency Residue

Control Group (IRCG), 2) the Surveillance Advisory Team (SAT), and most recently, 3) the Senior Executive Council (SEC).

The IRCG meets about once a month to discuss all pertinent residue testing issues and is attended by chemical residue subject matter experts from the USDA (FSIS, AMS and ARS), FDA and EPA. The SAT meets once a year and identifies the priority public health residues of concern. FSIS then develops specific sampling plans, which guide the allocation of FSIS' laboratory and inspection resources. In response to a 2010 OIG recommendation to have a process for elevating issues and resolving broader policy issues, the SEC was formed to ensure that senior level management meet regularly to resolve long-standing chemical residue issues.

Each year, FSIS publishes the "National Residue Program Scheduled Sampling Plans" (the Blue Book) as a means of informing stakeholders about the sampling program and "National Residue Program Data" (the Red Book) as a means of reporting the results of the Agency's NRP testing. The Blue Book provides a description of the principles and methods used to design the sampling plans for the NRP and summarizes the planned domestic and import sampling plans on a calendar year basis. The Red Book presents details on the testing results of the various NRP sampling projects conducted throughout the calendar year. The Blue Book also includes a summary of adjustments to the previous year's NRP. [105] Taken together, these books provide a comprehensive view of the program and the analyses of the data.

An important component of the NRP is to provide verification of chemical residue control in HACCP systems. As part of the HACCP regulation, slaughter and production establishments are required to identify all chemical residue hazards that are reasonably likely to occur and develop systems that prevent, eliminate or minimize these hazards. A vigilant chemical residue prevention program is essential to ensure the prudent use of veterinary drugs and pesticides in food animals and is a complement to the NRP.

A violation occurs when a FSIS laboratory detects the presence of a chemical compound or a given compound level in excess of an established tolerance or action level in a sample. FSIS shares violation findings with FDA through the Residue Violation Information System (RVIS). To assist FDA in investigating producers at an on-farm level, FSIS obtains the names of producers and other parties involved in offering the animals for sale. FSIS informs producers through certified letters that a product from their animal tested positive for violative chemical residues and that they will be considered repeat violators if associated with more than one violation. FSIS also maintains Residue Repeat Violator Lists for FSIS field personnel, establishments and livestock markets to help identify producers with more than one residue violation in the last 12 months either in the same establishment or different establishments.[106]

Intent of Sampling Program

The NRP is designed to: 1) provide a structured process for identifying and evaluating chemical compounds of concern in food animals; 2) analyze chemical compounds of concern; 3) collect

[105] Information on the National Residue Program can be obtained from the FSIS website at: http://www.fsis.usda.gov/Science/Chemistry/index.asp#nrp.

[106] Please see the following website for more information: http://www.fsis.usda.gov/science/chemistry/index.asp.

and report results and 4) provide appropriate regulatory follow-up when violative levels of chemical residues are found.

Current Design of Sampling Program

Domestic chemical residue sampling consists of scheduled and inspector-generated sampling. Scheduled sampling plans consist of random sampling of tissue from food animals that have passed ante-mortem inspection. The development of scheduled sampling plans is a process that proceeds in the following manner: 1) determine which compounds are of food safety concern; 2) use algorithms to rank the selected compounds; 3) pair these compounds with appropriate production classes and 4) establish number of samples to be collected. The annual SAT provides an interagency forum to discuss prioritization of chemical hazards, as well as to determine the compound/production class pairs to be sampled. Inspectors receive the scheduled requests for sampling from FSIS headquarters.

Inspector-generated sampling is conducted by in-establishment Public Health Veterinarians (PHVs) or a designated and trained IPP. If the PHV/IPP believes an animal may contain violative levels of chemical tissue in any of its edible tissues, the inspector may use his/her own judgment in collecting a sample, including guidance from FSIS Directives 10,800.1 and 10,220.3. When an inspector-generated sample is collected, a residue quick test (Kidney Inhibition Screen (KIS)™ test or Fast Antimicrobial Screen Test (FAST)) is performed on tissue collected from the suspect animal. If the KIS™ or FAST is positive, muscle, liver and kidney tissue from the positive animal is sent to the FSIS laboratory and the carcass is held pending confirmation from the laboratory. If a carcass or parts of the carcass is found to contain violative levels of chemical residues, the carcass, parts or both are condemned.

Objectives of Sampling

The NRP consists of two different types of projects. First, the FSIS chemical residue control projects seek to: 1) Monitor the occurrence of meat, poultry and processed egg products contaminated with chemical residues; 2) Document the use, non-use or misuse of certain compounds and 3) Maintain equivalency status with international trading partners. Second, the NRP conducts exploratory assessments, which seek to determine the identity and the concentrations of a particular chemical residue that may be in meat, poultry and processed egg products, such as melamine in baby food or dioxin in chicken products.

Statistical or Policy Basis for Current Sampling Programs

The FSIS domestic scheduled sampling program consists of random sampling of tissue from food animals that have passed ante-mortem inspection. Since 2006, FSIS has selected 300 samples for each compound/production class pair to provide a 95 percent assurance that with zero violations in the samples, the violation rate in the entire population for a particular chemical or chemical compound is less than one percent. If one or more violations are found in the 300 samples for each compound/production class pair, then the violation rate is one percent or more.

Description of the FSIS Residue Sampling Projects

Fast Antimicrobial Screen Test (FAST)

Historical Basis

When FSIS suspects, based on herd history or ante-mortem or post-mortem examination, that animals may have illegal levels of antimicrobial drug residues, the Agency conducts an in-

establishment screening test to determine whether IPP will need to submit a sample to an FSIS laboratory for further testing. The FAST is one of the biological screening tests used for the detection of antimicrobial residues in animal tissues. FAST has been validated for use in testing swine and cattle for antimicrobial residue levels and is performed by a veterinarian or a designated food inspector in a slaughtering establishment. FAST is an adaptation of the antimicrobial screening test that was used in FSIS laboratories for many years. FAST replaced the Swab Test on Premises (STOP) in-establishment screen for testing in livestock, including sheep, goat and horses.

Purpose/Intent of the Project
FAST is an in-establishment screen performed by in-establishment personnel as part of a targeted testing project. FAST testing is necessary in problematic slaughter classes or subpopulations of these classes (those with a high prevalence of antimicrobial residue violations) and helps to detect carcasses with violative antimicrobial residues so they cannot enter the food supply. It is also used to more closely monitor producers and others who are known historically to have marketed animals with violative concentrations of antimicrobial residues. Further, the FAST is used to determine whether establishment noncompliances have been corrected and to verify the performance of an establishment's HACCP system in preventing or eliminating chemical (residue) hazards.

Statistical or Policy Basis
Targeted testing in establishments allows FSIS to verify that establishments have adequate residue control projects. FSIS IPP are instructed to perform in-establishment screening when they suspect animals (ante-mortem inspection) or carcasses (post-mortem inspection) have violative levels of chemical residues in their tissues. FSIS Directive 10,220.3 provides a list of pathologies and conditions warranting sampling and retention for in-establishment testing. As this screen is intended to target animals suspected of having violative residue levels and testing is at the discretion of field personnel, the FAST project is not statistically based.

Limitations of Sampling
FAST materials are no longer being produced, and FSIS laboratories are maintaining supplies until the Agency has completely phased in the KIS™ Test.

Functionally, FAST will screen for approximately 20 antibiotics and is not as sensitive for many of these drugs as the KIS™ Test, which is described below. For example, FAST does not detect Non-Steroidal Anti-Inflammatory Drugs (NSAIDS), a common class of pharmaceuticals used in cattle.

Kidney Inhibition Screen (KIS™) Test
Historical Basis
In mid-2007, the only company supplying the FAST kits discontinued its contract with FSIS. FSIS thus had to seek other options to continue in-establishment screening for residues and selected the KIS™ test produced by Charm Sciences, Inc. A pilot trial was successfully completed in six bovine establishments simulating real-life situations and the FSIS Midwest laboratory confirmation validated this new test. The Charm KIS™ Test is an antibiotic detection test for kidney tissue and the principle of detection is microbial inhibition. Bacteria, cultured in

agar with purple pH indicator media and kidney extract, generate acid that produces a yellow color. In the presence of antibiotic, the bacterial growth is inhibited, and the test remains blue/purple. KIS™ Test screening was implemented in the highest slaughter volume cattle establishments in July 2009 and expanded to cover all bovine slaughter establishments in 2010.

Purpose/Intent of the Project
The KIS™ Test is an in-establishment screen performed by IPP as part of a targeted testing program. KIS™ testing is necessary in problematic slaughter classes or subpopulations of these classes (those with a high prevalence of antimicrobial residue violations) and helps to detect carcasses with violative antimicrobial residues so they cannot enter the food supply. It is also used to more closely monitor producers and others who are known historically to have marketed animals with violative concentrations of antimicrobial residues. Further, KIS™ testing can be used to determine whether establishment noncompliances have been corrected and to verify the performance of an establishment's HACCP system in preventing, eliminating or minimizing chemical (residue) hazards.

Statistical or Policy Basis
Targeted testing in establishments is a means for FSIS to verify that establishments have adequate residue control projects. FSIS field personnel are instructed to perform in-establishment screening when they suspect animals (ante-mortem inspection) or carcasses (post-mortem inspection) to have violative levels of chemical residues in tissues. Directive 10,220.3 provides a list of pathologies and conditions warranting sampling and retention for in-establishment testing.[107] As in-establishment field screen tests are intended to target animals suspected of having violative residue levels and testing is at the discretion of field personnel, the KIS™ testing program is not statistically based.

Limitations of Sampling
Similar to the FAST sampling program, the KIS™ program does not screen for NSAIDS.

Overall Limitation of Current Residue Sampling
The current algorithm for the annual sampling plan has been unchanged for approximately ten years and contains variables (measured qualitatively) that may no longer be appropriate measures for prioritizing hazards. In addition, the scheduling algorithm is a "one size fits all" strategy that determines the number of samples collected, regardless of product class/compound pairing, geographical area or seasonal trends. In an attempt to reduce oversampling issues, several ad hoc rules have been created to manage the scheduling algorithm, which reduces the random nature of the program. Finally, there are continual complaints that the NRP is a resource intensive sampling program that provides FSIS with minimal information on the true chemical residue burden in Agency regulated products and is structured in such a manner that the program is slow to respond to emerging residue issues.

[107] FSIS is in the process of revising Directive 10,220.3 to incorporate the implementation of KIS™ testing.

3.0 Imports

Section 3.1: Microbiological Sampling Programs

Overview of Sampling Programs

The U.S. imports over three billion pounds of meat, poultry and egg products annually.[108] All shipments of meat and poultry and processed egg products that enter the U.S. must be presented to an FSIS inspector at one of the approximately 130 official FSIS import facilities located at major ocean ports and land border crossings. One hundred percent of imported product entering the U.S. is reinspected by FSIS at the point-of-entry (POE) for that product and every shipment is examined for proper documentation and box count, general condition, labeling and transportation damage.

In addition to these POE verifications, FSIS performs random reinspections on shipments of meat, poultry and processed egg products. The POE random reinspection activities include physical product examinations, condition-of-container reinspections and laboratory testing (e.g., microbiological sampling, food chemistry analysis, species verification and chemical residue testing). This process is assisted by FSIS' Automated Import Inspection System (AIIS), a centralized computer database that generates and stores reinspection results. Acceptable products are marked as "Inspected and Passed" and released into U.S. commerce. Non-compliant products are marked as "Refused Entry" and prohibited from entering U.S. commerce. More intensive reinspection is automatically applied to subsequent product shipments from a foreign establishment that produces products failing reinspection.

FSIS' POE verifications and reinspections involve evaluation of products that have first been inspected under an equivalent food safety system established by the exporting country. Thus, FSIS' POE activities are intended to monitor the effectiveness of exporting countries' inspection systems and overall food safety programs. Reinspections are one component of FSIS' comprehensive quality assurance/quality control process designed to ensure the equivalence of exporting country' food safety systems.

Sections 3.1, 3.2, and 3.3 describe FSIS' POE pathogen testing programs. Section 3.4 describes FSIS' chemical residue testing in imported regulated products.

[108] Please see the following website for more inforamation: http://www.fsis.usda.gov/factsheets/importing_meat_poultry_egg_products/index.ASP.

3.1.1: *Salmonella*

FSIS maintains a formal sampling project for *Salmonella* in imported processed egg products. This program is described in Table 3.1.1.1 below. FSIS also tests for *Salmonella* in RTE products as part of the IMVRTE program—this project is described in Section 3.3.

Table 3.1.1.1: FSIS Sampling for *Salmonella* in Imported Product

Product Type/Class	Sampling Project	Total Number of Samples Analyzed (Failures)	Average Number of Samples Collected Per Establishment	Number of Establishments Included in Sampling Population	Regulatory Purpose of Sampling Program	Type of Sampling Program
Pasteurized imported liquid, frozen or dried products (POE Sampling)	EGGIMP	74 (0)	Not Applicable	Not Applicable	Component of FSIS' on-going equivalence verification program	Performance -Based

EGGIMP—Processed Egg Products

Historical Basis and Overview:

The imported processed egg products sampling program is a carry-over from when the AMS administered the program. Up until October 1, 2006, whenever a lot of pasteurized dried, liquid or frozen egg product was presented for import reinspection, a product examination and a *Salmonella* sample were assigned. After that date, a policy decision was made that processed egg products examinations would be consistent with the meat and poultry testing requirements.

Volume Data

Import volumes (number of lots presented for reinspection and presented net weights) are reported and tracked by exporting country, foreign establishment, species, process category and process sub-category within AIIS. When PHIS is implemented, process subcategories will be expanded and replaced with product category and product group. FSIS compiles this information and utilizes it in determining sample sizes for the various import sampling programs.

Statistical or Policy Basis

The current processed egg product sampling project utilizes the same approach that FSIS uses to determine the required number of product examinations to be performed in imported meat and poultry products. Under this program, the number of product examinations performed annually is based on the number of lots of product imported annually. When the meat and poultry procedures were implemented for processed egg products, a product examination and a *Salmonella* sample were randomly assigned in advance of the processed egg products shipment arrival at a FSIS regulated import facility. Thus, this was the beginning of "Skipped" lot sampling in imported processed egg products.

Sample Sizes

Annual sample sizes for the various import reinspection programs are based on the average number of lots presented in the previous two years and the country history by each eligible country for the applicable species/process category combination.

Limitations of Current Sampling

Currently, imported processed egg product sampling is not a part of the AIIS and is not based on a statistical methodology specifically related to processed egg products food safety.

3.1.2: *E. coli* O157:H7

There are two primary *E. coli* O157:H7 sampling projects for imported products;

1) Raw ground beef (MT08)
2) Raw, non-intact beef (MT51)

Please see Table 3.1.2.1 for more details.

Table 3.1.2.1: FSIS *E.* coli O157:H7 Sampling Projects for Imported Products

Product Type/Class	Sampling Project	Total Number of Samples Analyzed (Failures)	Average Number of Samples Collected Per Establishment	Number of Establishments Included in Sampling Population	Regulatory Purpose of Sampling Program	Type of Sampling Program
Imported raw ground beef (POE Sampling)	MT08	23 (1)	Not Applicable	Not Applicable	Component of FSIS' on-going equivalence verification program	Performance-Based
Trim and other raw ground beef components (POE Sampling)	MT51	695 (2)	Not Applicable	Not Applicable	Component of FSIS' on-going equivalence verification program	Performance-Based

Ground Beef (MT08)

Current Design

The current sampling project is based on a desired number of *Normal* level samples to be assigned and analyzed over a given calendar year for each country. The samples are divided and allocated based on the amount of raw ground beef/veal product the country has exported to the U.S. over the past 24 months. This approach results in approximately 25 samples scheduled annually for MT08, a number that was calculated by FSIS in 2008. Because of the small number of lots of raw ground beef imported annually, this number has remained approximately static.

When the FSIS identifies a foreign establishment as a "Multi-source" positive *E. coli* O157:H7 supplier in STEPS, FSIS management places the foreign establishment on *Increased* inspection. Foreign establishments may also be placed on *Increased* inspection as a result of a management decision triggered by other concerns, such as failure to present.[109] Under *Increased* inspection, the AIIS is programmed to assign samples for *E. coli* O157:H7 to a minimum of the next 15 consecutive lots of applicable beef/veal product. If all samples are negative, the *Increased* level is removed from the AIIS and sampling returns to *Normal.*

Similarly, when a foreign establishment or country is identified during a U.S. audit as having issues, FSIS may place the country or establishment on *Increased* inspection. The sampling rate is determined by FSIS. The *Increased* level is removed when the objective has been met, or by management decision and sampling returns to *Normal.*

When a positive *E. coli* O157:H7 sample is reported, the AIIS is programmed to place the foreign establishment that produced the product on an *Intensified* level of inspection. This means that, at a minimum, the next 15 consecutive lots of raw ground beef/veal and 15 times the weight of the failed lot are assigned *E. coli* O157:H7 sampling. If all samples are negative, the *Intensified* level is removed from the AIIS and sampling returns to *Normal.*

Limitations of Current Sampling

The statistical power of the MT08 project is limited by the small number of lots of raw ground beef imported into the U.S. annually.

Non-Intact Beef (MT51)

Current Design

The project is based on a desired number of *Normal* level samples to be assigned and analyzed over a given calendar year for each country. The samples are divided up and allocated based on the amount of beef/veal trimmings a country has exported to the U.S. over the past 24 months. This resulted in 356 samples annually, a number calculated by FSIS in 2008. This sample size remained approximately static in 2009 and 2010. In 2011, the number of normal samples scheduled to be collected was increased to reflect the large number of lots of non-intact beef presented for reinspection at U.S. POE.

Beginning CY2010, because the AIIS was incapable of assigning only to beef/veal, a decision was made to pro-rate the samples by import region and have them assigned. Based on the

[109] Failure-to-Present (FTP) is when product has not been presented to the FSIS inspector for an AIIS assignment and enters commerce. Failure to present for FSIS inspection may result in penalties.

number of lots presented in the past, a set number of samples were provided to each import region to assign throughout the year for each country. Import regions were given time periods in which they should sample based on number of positive samples and where the producing country is located geographically. When FSIS identifies a foreign grinding establishment as a "multi-source" supplier of *E. coli* O157:H7 positive beef/veal, FSIS management will place the foreign establishment on *Increased* inspection.

The designation of a "multi-source" or "sole-source" positive *E. coli* O157:H7 supplier notification result is reported in STEPS. The AIIS is programmed to assign samples for *E. coli* O157:H7 to a minimum of the next 15 consecutive lots for a "multi-source" supplier notification of applicable beef/veal product. In the case of a "sole-source" supplier notification, the next 15 consecutive lots of applicable beef/veal product and 15 times the weight of the lot (if known) are sampled. If all samples are negative, the *Increased level* is removed from the AIIS and sampling returns to *Normal*.

FSIS conducts periodic audits of those countries certified to export meat, poultry and processed egg products to the U.S. The audits focus on ensuring that the country maintains a food safety system equivalent to that of the U.S.. Audit findings that result in a food safety concern, such as inadequate government oversight, will be brought to FSIS headquarters attention. Based on the health risks associated with the food products and the nature of the failure, FSIS management may decide to place the country or establishment on *Increased* inspection for the product exported by that country.

When a positive sample is reported, the AIIS is programmed to place the foreign establishment that produced the product on an *Intensified* level of inspection. This means that, at a minimum, the next 15 consecutive lots of applicable beef/veal product and 15 times the weight of the failed lot are assigned *E. coli* O157:H7 sampling. If all samples are negative, the *Intensified* level is removed from the AIIS and sampling returns to *Normal*.

Statistical or Policy Basis
The current *E. coli* O157:H7 import sampling project is based on the number of positive samples.

Limitations of Current Sampling
The current MT51 sampling project relies on implementation by the FSIS field supervisors to ensure that amenable product subcategories (e.g., boneless cuts) are sampled at the correct intervals. As a result, the MT51 project is more time-consuming to administer and monitor than the import sampling projects, such as MT08, that are fully implemented through the AIIS.

3.1.3 RTE Meat and Poultry Products

Overview of Sampling Programs

FSIS maintains one sampling project for RTE products from importing countries. This project is listed below in Table 3.1.3.1 and described in more detail below.

Table 3.1.3.1: FSIS RTE Sampling for Imported Products, FY 2010

Pathogen	Product Type/Class	Sampling Project	Total Number of Samples Analyzed (Failures)	Average Number of Samples Collected Per Establishment	Number of Establishments Included in Sampling Population	Regulatory Purpose of Sampling Program	Type of Sampling Program
Salmonella* and *Lm	Imported Intact RTE Product	IMVRTE (POE Sampling)	4,512 (3)	Not Applicable	Not Applicable	Component of FSIS' on-going equivalence verification program	Performance-Based

IMVRTE—Imported Intact RTE Product

Current Design

The current project is based on a desired number of *Normal* level samples to be assigned and analyzed over a given calendar year. The samples are divided up and allocated based on the amount of RTE product a country has exported to the U.S. over the past 24 months, and then further subdivided and allocated by HACCP process category to each country. Consequently, approximately 3,000 total samples should be analyzed, as calculated by FSIS in 2008. Based on the way the AIIS is programmed for the import RTE sampling (IMVRTE) project, the AIIS assigns analyses for both *Lm* and *Salmonella* for a given sample unit. This results in more than 6,000 sample analyses for *Lm* and *Salmonella.* However, this number is beyond FSIS' current capacity. Therefore, the sampling target was reduced to approximately 1,500 to 2,000 samples annually and each sample submitted to the lab is analyzed for the applicable pathogens.

When a foreign establishment or country is identified as having issues during a U.S. audit or by some other means, FSIS management may place the country or establishment on *Increased* inspection. The sampling rate is determined by FSIS management, in accordance with guidelines developed by the Agency, and monitored to ensure that the specific management objective is met. The *Increased* level is removed when the defined management objective has been met, or by management decision, and sampling returns to *Normal.*

When a positive sample is reported, the AIIS is programmed to place the foreign establishment that produced the product on an *Intensified* level of inspection. This means that, at a minimum, the next 15 consecutive lots or 15 times the weight of the failed lot are assigned sampling in the same HACCP process category for the pathogen that tested positive. If all samples are negative, the *Intensified* level is removed from the AIIS and sampling returns to *Normal.*

Limitations of Current Sampling

Increased sampling is manual, and comes with the same difficulties *Intensified* sampling does, namely that while targeting is a good practice, it is not always one hundred percent accurate.

Additionally, product sampling following a positive is limited to the same process category. Consequently, other products may be produced in the same area/line, but under a different HACCP process, which means that *Intensified* sampling does not take it into account.

Imports Measures of Success

POE reinspections, including pathogen and residue testing, are one component of a comprehensive, ongoing verification process designed to ensure equivalence of exporting countries' food safety systems. POE reinspections help to ensure that imported FSIS-regulated products are safe and wholesome by supporting FSIS' overall equivalence program through:

- Identifying shipments that do not meet FSIS requirements and refusing entry of these products into the U.S.
- Providing detailed information to support FSIS' equivalence verification audit programs.
- Providing detailed information to support FSIS' performance-based sampling programs.
- Providing detailed information to support the NRP.

In addition, POE reinspection findings are used to identify foreign establishments warranting *increased/intensified* reinspection, such as more frequent reinspection of subsequent shipments following presentation of a shipment that failed reinspection.

To measure the success of the import sampling programs, FSIS evaluates its efforts in terms of four key operational metrics, as described in Table 3.1. Operational measures are included here as it is not currently possible to estimate the number of foodborne illnesses that come from imported products, as the number of samples collected do not warrant a measure of prevalence and the CDC does not differentiate illnesses acquired from eating contaminated imported food, as opposed to domestically produced food.

Table 3.1: Measures of Success for FSIS Import Sampling Program

	Measure		Goal
Operational Performance Measure	**FY 2009**	**FY 2010[110]**	**FY 2015**
Percent of AIIS assigned *E. coli* samples that are collected.	> 99 %	>98%	95 %
Percent of AIIS assigned *E. coli* samples that are not analyzed due to inspector error.	< 1%	<1%	5 %
Percent of AIIS assigned *E. coli* foreign establishment-follow-up samples (e.g., establishment under intensified inspection status) that are collected.	100 %	100%	95 %
Percent of AIIS assigned *E. coli* foreign establishment-follow-up samples (e.g., establishment under intensified inspection status) that are not analyzed due to inspector error.	[none]	<5%	5 %

[110] The performance measure is calculated by using a 12 month rolling window, so the measure reflects the most recent 12 months of data up to and including the current year.

Section 3.2: Chemical Residues

Overview:

Imported meat, poultry and processed egg products are sampled at U.S. POE to detect chemical residues as part of a POE reinspection. POE reinspection is a monitoring program conducted to verify the equivalence of inspection systems in exporting countries. The chemical residue sampling program is one of several Types of Inspection (TOI) conducted during FSIS reinspection of imported products. The following are the three levels of chemical residue reinspection:

- Normal sampling, defined as random sampling from a lot;
- Increased sampling, defined as above the normal sampling as the result of an FSIS management decision; and
- Intensified sampling, defined as occurring when a previous sample for a TOI failed to meet U.S. requirements.

For both normal and increased sampling, the importer may choose to retain the lot pending the laboratory results, but it is not required. However, the lot is subject to recall if it is not retained and is found to contain violative levels of chemical residue. For *Intensified* sampling, the lot must be retained pending laboratory results. The data obtained from laboratory analyses are entered into the AIIS.

Fresh and Processed

Current Design

The current program is based on a desired number of *Normal* level samples to be assigned and analyzed by compound over a given calendar year for each country, product (fresh or processed) and species. When the import volume of a particular product class is less than one percent of the total amount of meat, poultry and processed egg products imported, then eight samples are assigned to each country. The sample numbers come from the NRP SAT and are programmed into the AIIS. Please see Table 3.2.1 for fresh and processed samples analyzed in FY2010.

Residue Sampling	Total Number of Samples Analyzed	Regulatory Purpose of Sampling Program
Fresh and Processed	3,408	Component of FSIS' on-going equivalence verification program

Table 3.2.1: FSIS Residue Sampling for Imported Products, FY 2010

Statistical or Policy Basis

The allocation of samples under the import program is based on several factors including: country of origin, product type, volume imported and chemical tested. The FSIS NRP Blue Book provides the algorithms used to prioritize reinspection sampling.

Limitations of Current Sampling

The current sampling program is based primarily on compounds known to be used domestically, and may exclude compounds of concern in the foreign country or compounds which exporting countries may use, but are prohibited for use in the United States. FSIS is currently evaluating its protocol for prioritizing hazards from chemical exposure, which may impact both domestically produced products, as well as those imported.

4.0 In-Commerce Activities

Overview

FSIS Compliance Investigators (CI) conduct surveillance to protect the health and welfare of consumers by ensuring that meat, poultry and processed 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 POE and U.S. 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 report.

Current Design of Sampling Plan

FSIS has the following sampling projects currently in place at retail:

1) *E. coli* O157:H7 testing in raw ground beef at businesses operating under a retail exemption (MT05).
2) Follow-up testing for *E. coli* O157:H7 in raw ground beef products (MT06) scheduled only when an MT05 sample tests positive.

Table 4.1: FSIS *E. coli* O157:H7 Sampling Projects for In-Commerce Surveillance

Products	Sampling Projects	Number of *E. coli* O157:H7 samples analyzed in CY2010	Regulatory Purpose of Sampling Program	Type of Sampling Program
Raw ground beef at retail stores	MT05	905	Verify compliance with regulatory standard	Targeted
Follow-up testing to a MT05 sample	MT06	0	Verify corrective measure	Targeted, Consecutive

Objectives of Retail Sampling:

Retail sampling is an important part of FSIS' overall *E. coli* O157:H7 sampling activities. The retail sampling program addresses several objectives for FSIS:

1. Helps ensure hazard controls at retailers are adequate to prevent product from becoming adulterated.

Statutory provisions requiring inspection do not apply to the types of operations traditionally and usually conducted at retail stores. However, FSIS' adulteration and misbranding provisions do apply to exempt retail businesses. Retailers have the potential to adulterate product in the absence of adequate hazard controls. FSIS testing of retail samples for *E. coli* O157:H7 gives the Agency additional assurances that products are not being adulterated at retail facilities operating under a retail exemption.

2. Encourages industry to adopt complete and accurate product tracing systems for food.

   Retail facilities should consistently maintain adequate records concerning suppliers of source material for raw ground beef products, as required by regulations and the Federal Meat Inspection Act (FMIA). With regard to investigations associated with raw ground beef consumption, product lot coding, production date and beef manufacturing establishment information are required to successfully conduct product traceback.

   In many circumstances, however, investigators are provided with only purchase information, such as date and location of purchase or type of ground beef. FSIS CI then must rely heavily on grinding records kept in retail stores, meat markets and other operations to gather the information needed to undertake traceback actions. Unfortunately, CI frequently find these grinding records to be incomplete or inaccurate, thereby delaying or preventing the traceback of potentially adulterated products, which could result in additional illnesses.

   When FSIS collects samples of raw ground beef from retail businesses, the Agency collects the relevant information using the FSIS Form 8010-1, Retail Ground Beef Sampling Worksheet, which is used if an *E. coli* O157:H7 positive finding is later identified. FSIS has stated it expects retail facilities to consistently maintain complete and adequate records, as required by the regulations (9 CFR part 320) and the Section 202 of the FMIA (21 U.S.C. 601 *et seq.*).

3. Encourage industry to conduct testing programs for *E. coli* O157:H7.

   FSIS considers product sampling to be one of several activities conducted to verify supplier claims and the effectiveness of hazard controls at retail facilities. Since the adoption of the FSIS *E. coli* O157:H7 testing program, many grinders and suppliers of raw ground beef components have instituted programs to routinely test their raw ground beef products or raw materials used in raw ground beef products for *E. coli* O157:H7.

4. Serves as an indicator of the overall trend of the presence of *E. coli* O157:H7 in raw ground beef.

   Although FSIS views results from verification samples from Federal establishments as the best indicator of the overall trend of the presence of *E. coli* O157:H7 in raw ground beef, the test results from retail sampling gives the Agency another indicator of trends in the presence of *E. coli* O157:H7 in raw ground beef products.

MT05 and MT06—Raw Ground Beef at Retail

Historical Basis and Background Information

Although most microbiological samples are collected at federally inspected establishments, FSIS collects samples from retail stores in accordance with criteria listed in FSIS Directive 8010.1, Rev. 2, Methodology for Conducting In-Commerce Surveillance Activities, dated June 25, 2008. "Retailers" are one of more than a dozen business types in the FSIS In-Commerce Surveillance System (ICS) and constitute about 60% of businesses in the system. FSIS samples at retail when: 1) the retail store produces raw ground beef using whole muscle or trimmings from a cutting/boning operation conducted at the store, 2) the retail store does not maintain records of raw beef suppliers or records documenting clear and accurate grinding logs or 3) the retail store is not cleaning and sanitizing the grinder between the use of different source materials.

Retail samples are not scheduled from an existing list of businesses producing raw ground beef. Rather, CI are instructed to collect a one-pound sample of raw ground beef for *E. coli* O157:H7 testing at every retail business they visit for a surveillance review, if the business has raw ground beef it prepared under the retail exemption and the business meets one of the criteria listed above. Whether a raw ground beef sample will be collected depends on what the CI observes during a surveillance review at a retail business.

Of the approximately 29,000 surveillance activities that FSIS has conducted since October 1, 2008, over one-third (about 11,000) were performed at retailers and 2,627 ground beef samples were collected by the Agency. In FY 2011, CI collected 1,280 verification samples at retail businesses. Of the retail samples collected since October 1, 2008, 0.11% tested positive for *E. coli* O157:H7.

In September 2011, as a result of a formal review of FSIS in-commerce activities by the National Academies of Science (NAS), the Agency shifted retailers from Tier 2 to Tier 3 facilities, making them lower priority for Agency surveillance.[111,112] Tier 3 businesses are surveilled only "for cause."[113] Therefore, while the number of retail surveillances FSIS will likely perform "for cause" next year and in future years is unknown, it is unlikely to be high enough to generate comparable numbers of retail ground beef samples. Indeed, it is possible that the number of samples collected will be fewer than one hundred each year.

Statistical or Policy Basis

Approximately 75,000 retail businesses grind beef in the U.S. The MT05 sampling project for *E. coli* O157:H7 in raw ground beef at retail venues was started in 1994 to monitor compliance with regulatory standards and continues with that intent today. Neither the MT05 nor the MT06 projects are conducted using a random method. Rather, they are targeted sampling projects to verify corrective actions that have been conducted as a result of a previous positive test and are therefore not statistically based. Present targeting criteria for sample selection are described in

[111] Please see the following website for more information: http://www.nap.edu/openbook.php?record_id=12786.

[112] Please see the following website for more information: http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/53-11.pdf.

[113] Tier 1 and Tier 2 businesses, generally, have significant inherent hazards, handle large volumes of meat, poultry, and egg products, and receive minimal scrutiny by other regulatory authorities and accordingly are considered higher priority by FSIS. Tier 3 businesses, on the other hand, generally receive significant scrutiny from other regulatory authorities and therefore are considered lower priority by FSIS.

FSIS Directive 8010.1. There is no set, required sample collection frequency or sample size, though the sample size is generally one pound. Samples are collected by a CI when a retail business meets at least one of the criteria described in FSIS Directive 8010.1. The number of samples collected and the percent positive have varied widely over time. Collection criteria also have varied over time. These issues, and other concerns regarding the representativeness of samples, make it inappropriate to extrapolate findings to all products sold at retail. Starting in October 2011, the sampling program was modified to collect a purposive sample of approximately 460 samples per year to provide a 99% probability of detecting one or more positive samples, if the actual percent positive rate reaches as high as 1%, with 90% probability of detecting one or more positives if the true percent positive is 0.5%. If every FSIS CI collects approximately one sample quarterly, this will produce about 460 samples per year, distributed evenly through the year and around the country.

Not all retailers produce ground beef and not all of those produce it under the conditions specified in Appendix 1 of Directive 8010.1. Historically, FSIS CI has collected ground beef for *E. coli* O157:H7 testing during one out of four retail surveillances. However, CI will have to surveil- *on average*- only three retailers to identify a retailer eligible for sampling. Nationally, this would mean about 1,380 surveillances to generate about 460 samples. While this constitutes about 14% of FSIS' surveillances, these surveillances would be "for cause."

Limitation of Current Sampling

Past sampling objectives and strategies cannot be confirmed, but appear to vary. However, the present sampling strategy as outlined in Directive 8010.1 would result in samples that would not accurately represent the prevalence of *E. coli* O157:H7 in raw ground beef processed at retail. FSIS collects ground beef for testing from a very small proportion of retail businesses processing ground beef and virtually none are collected on a non-risk basis. Without further understanding of the situation, it would be difficult to compare yearly results from the retail program, with results from Federal establishments, or to all ground beef in-commerce.

In-Commerce Measures of Success

Though the in-commerce *E. coli* O157:H7 sampling program differs in purpose and intent from the Federal establishment sampling programs, the overall purpose of the program is to assess, and minimize, the risk to public health from contaminated product. As such, to measure the success of the *E. coli* O157:H7 sampling projects, FSIS can evaluate its efforts in terms of the percent positives from the in-commerce *E. coli* O157:H7 sampling program.

Percent Positives

FSIS believes that percent positives are a good measure of the effectiveness of the *E. coli* O157:H7 individual sampling projects maintained by the Agency, with declines in percent positives indicating greater control and prevention of *E. coli* O157:H7 in finished product. In FY 2011, CI collected 1,280 samples. Of these samples, only 0.08% tested positive for *E. coli* O157:H7.

5.0 Foodborne Illness Investigation and Consumer Complaint Sampling Programs

Domestic Programs

Current Design of Sampling Program

FSIS regulated products are collected during foodborne illness and consumer complaint investigations.

Statistical or Policy Basis for Current Sampling Plan

A foodborne illness investigation is defined as an investigation of the possible association between human illnesses and FSIS-regulated product that includes epidemiologic, laboratory and environmental assessments. Foodborne illness investigations are conducted as described in FSIS Directive 8080.3 and internal Standard Operating Procedures (SOPs). A consumer complaint is any complaint reported to FSIS that is initiated by or on behalf of a consumer and that is directly related to a meat, poultry or processed egg product. Consumer complaint investigations are conducted as described in FSIS Directive 5610.1 and internal SOPs.

Purpose of Program

During the course of foodborne illness and consumer complaint investigations, previously opened (non-intact) products consumed by case-patients (e.g., individuals identified by an illness investigation) or complainants may become available for investigative sampling and analysis by FSIS. Similarly coded intact products may be collected directly from the identified individuals at a point of purchase or at the producing establishment. These samples can provide the best opportunity for detecting foodborne hazards, including microbial pathogens, extraneous materials and chemicals. The data obtained from outbreak and consumer complaint sampling supplements available epidemiologic and environmental findings and assists with determining the type and extent of product contamination. Collectively, the information provides rapid results for timely and informed risk management decisions.

Sampling Frame Definition

To determine whether to sample and test potentially implicated products, FSIS investigators consider the following questions:

1. Do the epidemiologic investigation data, including the reported food history, support a link between the illness or other described hazard and FSIS-regulated product?
2. Do the laboratory findings support a link between the illness or other described hazard and FSIS-regulated product?
3. Does the environmental assessment support a link between the illness or other described hazard and FSIS-regulated product?
4. Is there product available to test that meets FSIS criteria for product identity, chain of custody and product handling? If not, are there reasons for testing product that may not meet all of these criteria?
5. Has product already been tested by a non-FSIS laboratory with reliable methodology?[114]
6. Can testing be carried out by or in association with FSIS?

[114] See FSIS Directive 10,000.1 Policy On Use Of Results From Non-FSIS Laboratories.

To determine whether to sample and test a non-intact product, FSIS investigators consider the following questions:

1. Was the non-intact product directly handled by the case-patient or complainant?
2. Was the non-intact product stored properly to avoid cross-contamination and temperature abuse?
3. Are packaging materials and product labels that identify the non-intact product available? If not, was traceback successful in determining the product identity?

Sampling size and methodology

After determining whether to collect an investigative sample, FSIS drafts a sampling plan that takes into account the product available for sampling and the available laboratory resources and capacity. Potential sampling plans are described below:

1. ***When a limited amount of product is available*** (e.g., if a few packages and lots are available for sampling):
    a. FSIS may request that all intact packages be submitted to the FSIS laboratory.
2. ***When an un-manageable number of product packages are available***:
    a. FSIS will provide guidance on sampling procedures consistent with available resources. FSIS has identified the following procedures when a unmanageable number of packages are available:
        i. ***Sampling by perceived relative risk***. If evidence indicates that product of one lot/code is more suspect than another potentially implicated lot/code, FSIS may propose to stratify and allocate random sampling either proportionally or in tiers. For example, the FSIS laboratory determines it can analyze 50 samples per day. Lot A product appears to be of greater risk or concern compared to Lot B, but there is some reason to believe that the latter lot may be at risk as well. Both production lots are identified and under regulatory control. If the priority for the investigation is to determine status for both lots as quickly as possible, FSIS may propose weighted stratified sampling for each lot. For example, 30 samples from Lot A and 20 from Lot B.
        ii. ***Sequential sampling over time***. If time is available for multiple analyses, FSIS may propose sequential sampling over time. For example, 50 samples of Lot A may be analyzed initially and an additional 50 samples may be analyzed at a later date, as resources allow.
        iii. ***Sampling by relative volume***. For sampling product from one or more lots or consignments of different size, FSIS may propose proportional random sampling by total volume. For example, Consignment A is 500 pounds, B is 1500 pounds and C is 3000 pounds. For 50 total sample analyses, 5, 15 and 30 samples for Consignments A, B and C, respectively, would be selected.

Sampling Weights, Ceilings, and Floors

Not applicable to foodborne illness and consumer complaint investigation related sampling.

Collection methodology

If product sampling and testing is warranted, FSIS will follow procedures in FSIS Directive 8080.3, Section IX or FSIS Directive 5610.1. FSIS staff would be directed to collect product samples using Domestic Laboratory Report Form 10,000-2 to document chain of custody, as described in FSIS Directive 8010.3 and to use sample seals as described in FSIS Directive 7355.1. Samples are delivered to an FSIS Field Service Laboratory or another laboratory with available capacity and expertise. Results from foodborne illness and consumer complaint investigation related sampling is reported by email to FSIS management and other designated recipients, but are not reported through Biological Information Transfer and E-mail System (BITES) and Laboratory Electronic Application for Results Notification (LEARN). Results are also available in the FSIS Laboratory Information Management Systems (LIMS). Non-microbial test results are reported through the Consumer Compliant Monitoring System II (CCMS II).

Mean Response Rate, Mean Analyzed Sample, and Percent Positive Rate for Samples Analyzed

Not applicable to foodborne illness and consumer complaint investigation related sampling.

Limitations of Current Sampling

- Testing should be performed within the context of available resources
- Testing cannot guarantee that a sampled lot is free from targeted hazard(s).
- Foodborne illness and consumer complaint investigation related testing is often performed outside the scope of the ISO 17025[115] accreditation maintained by the FSIS laboratory system.
- FSIS laboratories may not have the expertise or capacity to test for certain analytes.[116]
- In some situations, FSIS may arrange for outbreak samples to be tested by other laboratories, such as FDA-Center for Food Safety and Applied Nutrition (CFSAN), ARS, the Food Emergency Response Network (FERN) or state laboratories of agriculture.

[115] ISO/IEC 17025 is the main standard used by testing and calibration laboratories.

[116] A summary of routine FSIS laboratory analyses is available at http://dchqintra/learn/docfile/analyses.htm.

6.0 Appendices

Appendix A: Definition of Terms

Data Warehouse: FSIS collects numerous types of data from a variety of different sources. This data is stored in an electronic "warehouse," known as the FSIS Data Warehouse (DW).

Exclusion Criteria: Exclusion criteria are the standards FSIS uses to determine whether an establishment should be included in the sampling frame. For example, establishments that produce a very low volume of product may be excluded from the sampling frame. Therefore, producing low volume is the exclusion criterion.

Percent Positive: The percentage of positive samples is expressed as a percentage, determined as the number of positive samples for the pathogen per the total number of samples tested, multiplied by 100. The expected value of this percentage in this document is called "the percent positive."[117]

Performance Based Sampling: A sampling plan in which establishments are sampled at a greater or lesser frequency based on their performance. For example, establishments that have fewer positive pathogen test results might be considered to be high performers and are therefore sampled less frequently than establishments that have more positive pathogen test results.

Random Sampling: A random sample is one chosen by a method involving an unpredictable component. Random sampling can also refer to taking a number of independent observations from the same probability distribution, without involving any real population.

Replacement: When a sampling unit is drawn from a finite population and is returned to that population, after its characteristic(s) have been recorded, but before the next unit is drawn, the sampling is said to be "with replacement." In the contrary case, the sampling is "without replacement." A different usage occurs in sample surveys when samples are taken on successive occasions. If the same members are used for successive samples there is said to be no replacement; but if some members are retained and others are replaced by new individuals there is said to be "partial replacement".[118]

Risk Based Sampling: A sampling plan in which establishments are sampled at a greater or lesser frequency based on the risk the establishment poses. For example, establishments that have fewer positive pathogen test results might be considered to be low risk and are therefore sampled less frequently than establishments that have more positive pathogen test results.

Sampling Frame[119]: Sampling frame is the actual set of units from which a sample has been drawn. In the case of a simple random sample, all units from the sampling frame have an equal chance to be drawn and to occur in the sample. In the ideal case, the sampling frame should coincide with the population of interest.

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[117] Please see the following website for more information: http://www.fsis.usda.gov/PDF/Draft_Guidelines_Sampling_Beef_Trimmings_Ecoli.pdf.

[118] Please see the following website for more information: http://stats.oecd.org/glossary/detail.asp?ID=3835.

[119] Please see the following website for more information: www.statistics.com.

Sample Size: The sample size of a statistical sample is the number of observations that constitute it. It is typically denoted *n*, a positive integer. The sample size is an important feature of any empirical study in which the goal is to make inferences about a population from a sample. In practice, the sample size used in a study is determined based on the cost of data collection, and the need to have sufficient statistical power. In a census, data are collected on the entire population; hence the sample size is equal to the population size. Larger sample sizes lead to increased precision when estimating unknown parameters. For example, to know the proportion of cattle that is infected with a pathogen, a more accurate estimate of this proportion will result from a sample of 200, rather than 100 cattle.

Sample Ceiling: The maximum number of samples in a sampling frame.

Sample Floor: The minimum number of samples in a sampling frame.

Time Series: A time series is a set of regular, time-ordered observations of a quantitative characteristic of an individual or collective phenomenon taken at successive, in most cases equidistant, periods/points of time. Breaks in statistical time series occur when there is a change in the standards for defining and observing a variable over time. Such changes may the result of a single change or the combination of multiple changes at any one point in time of observation of the variable.[120] For example, changes to the way in which the *E. coli* O157:H7 sampling frame is constructed over time disrupts the time series and makes it difficult to compare results from year to year.

[120] Please see the following website for more information: http://stats.oecd.org/glossary/search.asp.

Appendix B: *E. coli* O157:H7 Sampling Program Description and Features

Project Code	Purpose	Frame Definition	Average Frame Size	Sample Size	Sampling Method	Collection Method	Sampling Weights	Sampling Ceilings/Floors	Sampling Frequency	Mean Response Rate	Mean Samples Analyzed
MT43	Verification of HACCP and assess risk to public health	Federally inspected beef grinding estab.	1300	1300 per month (15600 per year)	Weighted random sampling with replacement	1 lb of raw ground beef	Production volume and historical test results	Ceilings: 4/ month for large volume producers, 3/month for medium, 2/month for small volume, and 1/month for very small Floor: 3 analyzed samples per year per estab.	1 lb sample of raw ground beef	72% collected	11,482 samples per year
MT44	Follow-up to MT43 positives	Federally inspected beef grinding estab.	NA	16 (or 8) follow-up samples per MT43 positive	Targeted sampling	1 lb of raw ground beef				56% collected	254 samples per year

MT50	To track rate of O157:H7 in manufact. trimmings over time as compared to the 2007 prevalence estimate.	Federally inspected beef and veal slaughter estab.	480	50 per week (2600 per year)	Simple random sampling without replacement	N60 sample weighting 325 g			40% collected		1092 samples per year
MT53	Follow-up to positive trim or component sample	Federally inspected slaughter estab.	NA	16 (or 8) follow-up samples/ initial positive	Targeted sampling	N60 sample weighing 325 g or 2 lbs of component				52% collected	161 samples per year
MT54	Verification of HACCP	Federally inspected beef slaughter, veal slaughter, and ammoniated beef estab.	450	15 per week (780 per year)	Simple random sampling without replacement	2 lb collection				27% collected	224 samples per year
MT55	Verification of HACCP	Federally inspected estab. (non-slaughter)	1100	150 per month (1800 per year)	Simple random sampling without replacement	N60 sample weighting 325 g				29% collected	538 samples per year
MT52	Follow-up at suppliers to positive sample	Federally slaughter inspected estab.	N/A	1 sample at each supplier if there are multiple suppliers OR 16 (or 8) samples if there is only one supplier	Targeted sampling	N60 sample weighing 325 g or 2 lbs of component				77% collected	610 samples per year