Food Safety and Inspection Service's Annual Sampling Program Plan

Fiscal Year 2017

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Introduction

The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) inspects meat, poultry, and processed egg products to ensure that the food produced is safe, wholesome, and properly labeled. Verification activities serve to protect the public from foodborne hazards. A key FSIS inspection verification activity is the sampling of product for microbiological contaminants or chemical residues.

Sampling Plans

FSIS released the *Report on the Food Safety and Inspection Service Microbiological and Residue Sampling Programs* in December 2011, which identified all of FSIS' sampling programs and discussed the statistical and policy basis for the programs. FSIS has released a new sampling plan for each subsequent fiscal year (FY). These sampling plans continued FSIS' efforts to comprehensively identify the Agency's microbiological and chemical residue sampling activities and consider them in light of data-driven strategic planning efforts. The sampling plans also described FSIS' major activities related to microbiological and chemical residue sampling collectively known as analytes in domestic establishments, imports, and in-commerce facilities during the fiscal year and the Agency's overall strategy for directing its sampling resources for the following year.

This new FY2017 sampling plan seeks to accomplish the same goals, by describing FSIS' major activities related to each of the sampling programs for domestic establishments, import establishments, and in-commerce facilities in FY2016, and by describing the Agency's overall strategy for directing its sampling resources in FY2017.

Background

FSIS published a new strategic plan for FY2017-2021 which aims to strengthen FSIS sampling programs.⁴ This FY2017 Annual Sampling Plan addresses the new five year strategic plan goals, outcomes, objectives and measures. Over the next five years, FSIS will focus sampling

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¹ Please see the following website for more information: http://www.fsis.usda.gov/wps/wcm/connect/0816b926-c7ee-4c24-9222- 34ac674ec047/FSIS_Sampling_Programs_Report.pdf?MOD=AJPERES

² To review past Annual sampling plans, please see the following website for more information: http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/fsis-data-analysis-and-reporting/data-reporting

³ The term analyte refers to the target of detection in the analysis, whether it is for microbiological pathogens, chemical residues, pathology diagnoses or other various analyses.

⁴ Please see the following website for more information on the FY2017-2020 FSIS Strategic Plan: http://www.fsis.usda.gov/wps/wcm/connect/317d14d6-1759-448e-941a-de3cbff289e5/Strategic-Plan-2017-2021.pdf?MOD=AJPERES

efforts to ensure that establishments are meeting pathogen reduction performance standards, increase the percentage of country/product combinations from equivalent countries tested, increase the percentage of products from domestic establishments that are sampled, and increase the percentage of in-commerce facilities following FSIS Deli *Lm* guidelines. FSIS sampling programs will also be updated to close the gap in testing previously identified. For example, sampling will begin in poultry establishments that are religious exempt and poultry establishments that process less than 1,000 pounds of product per day (small and very small establishments), in addition to beginning sampling for minor species, and other chicken parts.

In addition to preventing illnesses, FSIS continuously looks to modernize inspection systems, policies, and the use of scientific approaches through improved reliability and access and timely collection and distribution of information; as well as modernizing scientific technique and inspection procedures FSIS plans to expand the use of Whole Genome Sequencing (WGS) for surveillance in foodborne pathogens. This expansion will also include ramping up the testing of all isolates from the Pathogen Reduction/Hazard Analysis and Critical Control Points (HACCP) sampling programs as well as outbreak sampling In addition, FSIS plans to publish establishment-specific datasets and associated information, which will allow consumers to make more informed choices, motivate individual establishments to improve performance, and lead to industry-wide improvements in food safety by providing better insights into strengths and weaknesses of different practices.

The process of scheduling, collecting, and analyzing routine domestic samples typically begins with a sampling task assigned to FSIS IPP through the Agency's Public Health Information System (PHIS). The IPP then collect and ship the samples collected to one of three FSIS testing laboratories, where the sample is tested for specified analytes. For imported product, the type of inspection verification PHIS assigns to the received product informs IPP when samples are to be collected and sent for laboratory analysis.

The FSIS laboratories perform different tests depending on the sampling project for which the sample was collected. Some sampling projects are considered routine, while others are triggered by positive test results from other projects or events and as such, are not considered routine.

All tables in this sampling plan contain the following information:

1. Number of samples which were planned to be analyzed in FY2016;⁵

⁵ The total number of samples planned to be scheduled in FY2016 was included in the FSIS Annual Sampling Program Plan. Fiscal Year 2016.

- 2. Number of samples actually analyzed in FY2016; and
- 3. Number of samples which are planned to be analyzed in FY2017.

Totals in the individual tables have been rounded. The FY2017 sampling plan is based on the number of samples anticipated to be analyzed versus scheduled. Operational abilities allow FSIS to adjust the number of samples scheduled on a monthly basis to better target the number of samples collected and analyzed.⁶

In FY2017, FSIS plans to collect and analyze approximately 101,000 routine microbiological samples (including National Antimicrobial Resistance Monitoring System for Enteric Bacteria [NARMS] cecal sampling), 14,000 chemical residue samples, and 12,000 other samples. Totals have been rounded to reflect that they are approximations. The estimates for each sampling project are based on current plans, FSIS policies, and industry practices and therefore are subject to change over the course of the fiscal year. Sections are included to describe significant changes to sampling programs or projects that occurred in FY2016 and what changes are planned for FY2017. This FY2017 Annual Sampling Plan closes the gap on a number of different products that were previously not tested which supports the Agency's FY2017 budget request. These gaps are comprised of four different slaughter classes being added to the National Residue Program (NRP) – namely bull/stag, heavy calf, formula-fed veal and nonformula-fed veal; addressing previously excepted facilities for poultry which include religious exempt and low volume establishments, sampling of minor species and other chicken parts; and testing for label verification for Antibiotic-Free, Hormone-Free, and Allergen (Soy)-Free claims.

Finally, it is important to note there may be a difference between the number of samples that were anticipated to be analyzed in FY2016 and the total number of samples actually analyzed over the same period. Some of the challenges IPP face when trying to collect all of samples accounted for in the sampling plan are the time it takes to perform the sampling task, the availability of eligible products, the number of available IPP and the overall workload of the inspectors. Depending on the resources available to the Office of Field Operations (OFO), there may be a number of sampling tasks that do not get fulfilled because of other priorities that take away time to perform these functions. In addition to OFO resources, other reasons for discrepancy include improvements made to the sampling frame throughout the year which correct lower sampling volumes, lack of production at the establishment level, and other unforeseen circumstances. These all impact IPP ability to collect samples for all sampling

⁶ FSIS targets the number of samples collected on an annual basis instead of focusing on specific collection rates as not all establishments currently being sampled under FSIS sampling projects produce every eligible product every day. In order to collect samples from infrequent producers and optimize the total number of samples collected and analyzed, FSIS adjusts the number of samples being scheduled based on the average number of samples collected throughout the sampling year.

tasks originally assigned. The same cause for discrepancy may exist moving forward for samples scheduled in FY2017.

General FY2016 Accomplishments

On February 11, 2016, FSIS announced final new pathogen reduction performance standards for *Salmonella* and *Campylobacter* in raw chicken parts and NRTE comminuted chicken and turkey products (81 FR 7287). The final rule was published on February 4, 2016.

FSIS completed its first 52-week moving window for assessing adherence to young chicken and young turkey carcass pathogen reduction performance standards. Two Federal Register notices (80 FR at 3940 and 81 FR at 7285) were published in 2015 and 2016 to inform stakeholders of FSIS' changes to performance standards in various poultry products. In particular, the notices announced that FSIS would use 52-week moving windows to determine an establishment's category for a particular pathogen and product. FSIS began testing young chicken carcasses and young turkey carcasses using the new performance standards in May 2015, and is currently posting establishment categories for *Salmonella* and *Campylobacter* on the FSIS web site⁷. FSIS plans to begin posting individual establishment categories for comminuted chicken, comminuted turkey, and chicken parts in approximately July 2017 after those performance standards have been in place for a year. FSIS may choose to post sooner based on criteria in the Federal Register notices. The Agency also began sampling raw chicken parts and NRTE comminuted chicken and turkey products on July 1 to verify adherence to the new pathogen reduction performance standards.

Switching away from sets to a moving window helps FSIS sample establishments throughout the year, allowing for better representation across all product throughout the year. The Agency posted on its website the category status for young chicken and turkey carcass sampling results⁸. Additionally, FSIS continued exploratory sampling of raw pork products for pathogens of public health concern and indicator organisms.

In an effort to create better communication with establishments regarding testing results, in

⁷ For more information on Salmonella and *Campylobacter* standards please visit: http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/salmonella-verification-testing-program

⁸ For more information on pathogen prevalence by product please visit: http://www.fsis.usda.gov/wps/wcm/connect/a63b69d1-a22a-4e60-9476-3239defd1faf/Sampling-Project-Results-Technical.pdf?MOD=AJPERES

FY2016 FSIS has begun development of Quarterly Establishment Letters. These letters will act as a replacement for the previous method, which was End-of-Set letters, and will provide support for the continuous rolling sampling windows. The information provided through the report details an establishment's performance with respect to different FSIS pathogen and residue verification testing programs. By sharing timely and comprehensive sampling results for all products sampled, FSIS expects establishments to consider the information presented in the letter as an aid in the evaluation of their process control, which will lead to potential improvements for increased food safety practices.

In FY2016, FSIS began publishing quarterly prevalence, volume weighted percent positive or percent positive calculations from sampling project results for microbiological pathogens in FSIS regulated products that are currently sampled through existing sampling projects. FSIS will provide new results each quarter using the prior 12 months of sampling data. Sampling project results calculations for microbial pathogens in raw beef, raw pork, raw chicken, raw turkey, processed egg products, as well as ready-to-eat products will be published and include the microbiological pathogen(s): *Escherichia coli* (*E. coli*) O157:H7, non-O157 STEC, *Salmonella*, *Campylobacter*, and *Listeria monocytogenes* (Lm). Depending on the data available, prevalence, volume-weighted percent positive, or percent positive will be calculated. These calculations are different than the aggregate results currently posted on the FSIS website because prevalence or volume weighted percent positive will be calculated when appropriate for these sampling project results, with these calculations being more representative of the products FSIS regulates.

FSIS is transitioning its quarterly report process to be automated. This will allow the data previously found in quarterly reports to be produced automatically each quarter. This new process will use few human resources, will be more consistent across projects, and allow FSIS to maintain a posting schedule. FSIS is preparing to publish the first set of establishment specific datasets as announced in the Federal Register on July 14, 2016 (Docket No. FSIS-2014-0032). FSIS developed this plan in response to policy documents issued by the President and the Office of Management and Budget (OMB), and to reduce the administrative burden Freedom of Information Act (FOIA) requests have placed on the Agency. Prior to publishing these datasets, FSIS is making sample datasets available. The sample datasets and corresponding data dictionaries will be found on the FSIS website. Going forward, FSIS intends to release new datasets and update existing datasets quarterly. Additional details can be found in the FSIS Establishment-Specific Data Release Strategic Plan⁹.

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⁹ For more information on the Establishment-Specific Release Strategic Plan please visit: http://www.fsis.usda.gov/wps/wcm/connect/0803f8a0-a3cc-4945-87b6-f992acdcfa9b/Establishment-Specific-Data-Plan-Final.pdf?MOD=AJPERES

During FY2016, FSIS continued collaborations with the Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), National Institutes of Health, and State agencies in furthering development of the WGS technology. In FY2016, FSIS began performing WGS on all adulterant bacterial species, including *Lm*, STEC, and *Salmonella* from RTE products. Additionally, as part of the NARMS cecal sampling program, FSIS performed WGS on *Salmonella* and *Campylobacter* isolates that exhibited resistance to one or more antimicrobial drugs in FY2016 quarters 1 and 2. In FY2016 quarter 3, FSIS began performing WGS on all *Salmonella* and *Campylobacter* isolates from the NARMS cecal testing program. WGS data for ~3,000 bacterial isolates were collaboratively shared with Federal partners in support of foodborne illness investigations and NARMS activities. In recent years, FSIS partnered with other public health and regulatory agencies in the United States to begin using WGS as part of basic foodborne pathogen surveillance and strain identification during foodborne illness outbreaks. FSIS expects that analyses of WGS data will:

- Streamline several current routine laboratory analyses to improve overall speed and
 efficiency; these analyses include pulsed-field gel electrophoresis (PFGE), antimicrobial
 susceptibility testing (AST), serotyping, and identification of known virulence
 characteristics.
- Provide improved discrimination between bacterial isolates.
- Provide additional information on pathogen known virulence attributes and resistance to antimicrobial drugs.
- Identify environmental harborage and recurrences of pathogens in FSIS regulated establishments, which can further support FSIS inspection activities, HACCP verification, and decisions regarding enforcement actions.
- Assist establishment owners and operators in developing supportable HACCP systems, taking effective corrective actions and performing adequate reassessments
 - o FSIS currently makes WGS data available to establishments by uploading the sequence information and minimal metadata about the isolates to the National Center for Biotechnology Information (NCBI), which is a publicly accessible database. In addition to serotype, PFGE, and antimicrobial resistance profile information, FSIS will make WGS identifier information available to establishments.
- Supplement current bacterial characterization methods (i.e. serotype, PFGE, Multi-locus variable number repeat analysis (MLVA)) to help differentiate food isolates within the context of outbreaks and special investigations

In FY2016, FSIS completed the Nationwide Beef and Veal Carcass Baseline Survey (BVCBS), which sampled establishments that slaughter and process beef and veal carcasses. During this survey, FSIS collected samples from the carcasses of steers, heifers, cows, bulls, stag, dairy cows, and veal at two locations in the slaughter process, immediately after hide removal (preevisceration) and at pre-chill (after all antimicrobial interventions). Information gathered from this survey allowed FSIS to determine percent positives and quantitative levels of select foodborne bacterial pathogens, such as *Salmonella* sp., *E. coli* O157:H7, six non-O157 STEC and levels of indicator bacteria, including total bacteria (aerobic plate count), generic *E. coli*, coliforms, and Enterobacteriaceae. FSIS created a report detailing the methods used in the study and results, which will be published in FY2017. Data obtained from the BVCBS are being used for estimation of the national prevalence of select pathogens; assessment of slaughter dressing procedures and process control; development of performance guidelines; and other policy considerations.

In April 2016, FSIS implemented testing on raw fish of the order Siluriformes for both domestic and import products. During the 18-month interim period, raw intact cuts of Siluriformes are being analyzed for *Salmonella*, Multiple Drug Residues, Metals, Antifungal Dyes and Speciation. By the end of September, FSIS has identified one domestic and three import lots containing drug residues or banned antifungal dyes as well as six domestic lots that tested positive for *Salmonella*.

Overview

The table below acts as a quick reference guide for microbiological analytes run on various FSIS regulated products for FY2016. For a more in-depth review, the tables in the "Sampling by Product" section contain the break out of the different analytes by product classes.

	Microbiological Analyte								
Product	Salmonella	Campylobacter	L. mono	<i>E. Coli</i> O157:H7	E. Coli Non-O157 STEC	Indicator Organisms			
Raw Beef	٧			٧	V ¹				
Raw Pork	٧					٧			
Raw Siluriformes	٧								
Raw Poultry	٧	٧							
RTE Product	٧		٧						
Eggs – Processed ²	٧		V ³						

Only domestic raw beef manufacturing trim and imported raw beef trim and other ground beef components have Non-O157 STEC testing. All other raw beef products are tested for *Salmonella* and *E. Coli O157:H7* only.

Salmonella and Campylobacter

FSIS conducts *Salmonella* testing on a broad array of products both in domestic establishments and on imported products.

- o Raw poultry
 - Chicken carcasses
 - o Turkey carcasses
 - o Chicken parts
 - o Comminuted¹⁰ chicken
 - Comminuted turkey
- o Raw ground beef and its components
 - o Raw ground beef
 - o Bench (purchased) and manufacturing trim

² In FY2017, FSIS is modernizing testing on all egg products. This update will include testing for *Listeria monocytongenes*.

³ Listeria monocytongenes is also performed as part of Shelf-Life testing for processed egg products.

¹⁰ Comminuted is defined as a product "that has been ground, mechanically separated, or hand- or mechanically deboned and further chopped, flaked, minced or otherwise processed to reduce particle size" as per 9 CFR 417.

- o Raw ground beef components other than trim
- o Raw fish
 - o Siluriformes intact cuts
- o RTE products¹¹
- o Processed egg products

In raw poultry, sampling is conducted for *Salmonella* and *Campylobacter* for young chicken and turkey carcasses; comminuted chicken and turkey; and chicken parts. In raw beef, FSIS tests for *Salmonella* on raw ground beef; bench and manufacturing trim; and components for raw ground beef in addition to raw fish, ready-to-eat meat, processed egg products, and poultry products.

Major Activities in Salmonella and Campylobacter Sampling Projects in FY2016

- 1. FSIS announced the final performance standards for comminuted chicken and turkey products and raw chicken parts in February 2016. In July 2016, FSIS began pathogen reduction performance standards verification sampling of raw chicken parts, including legs, breasts and wings, and NRTE comminuted chicken and turkey products.
- 2. FSIS assessed pathogen reduction performance for chicken and turkey carcasses on a moving window basis, and began monthly web posting of all category results.
- 3. FSIS completed the exploratory phase of the initiative (Raw Pork Products Exploratory Sampling Project [RPPESP]) for *Salmonella*, *Campylobacter*, and other analytes in comminuted, intact, and non-intact raw pork products in late November 2015. Results from this sampling have been used to develop phase two of the project, the Raw Pork Products Baseline Study (RPPBS).
- 4. The Agency began sampling domestically-produced and imported Siluriformes fish and fish products for *Salmonella* on April 15, 2016. As of September 30, 2016, FSIS has tested 46 imported samples and 46 domestic samples for *Salmonella*. At the end of FY2016, none of the import samples have been positive and we have identified six domestic samples contaminated with *Salmonella*. After observing the industry's performance throughout the transitional period, the Agency will determine the need for additional testing and for performance standards.

Changes to Salmonella and Campylobacter Sampling Projects Planned for FY2017

1. FSIS plans to propose a new performance standard for *Salmonella* in ground beef and intends to develop performance standards for beef manufacturing trimmings as well as guidance for *Salmonella* levels on beef carcasses.

¹¹ RTE products also receive *Lm* testing under the RTEPROD projects. See RTE section below for more information.

- 2. FSIS is planning to implement a *Salmonella* sampling program for raw chicken parts not included in the current chicken parts sampling (necks; hearts; livers; gizzards; and half and quarter carcasses).
- 3. FSIS intends to begin exploratory sampling of NRTE stuffed chicken products.
- 4. FSIS intends to begin sampling of certain minor species carcasses, such as duck, squab, ratites, goose, and lamb for *Salmonella* and *Campylobacter*.
- 5. FSIS intends to begin testing low-volume and religious-exempt poultry establishments for *Salmonella* and *Campylobacter*

E. coli O157:H7 and non-O157 Shiga toxin-producing E. coli (STEC)

FSIS maintains adulterant STEC sampling projects for domestic establishments, imported products, and raw ground beef in retail. *E. coli* O157:H7sampling is conducted in raw non-intact ground beef products and raw beef intended for raw non-intact products, and include ground beef, raw ground beef components, and beef trimmings. "Beef manufacturing trimmings" are trimmings produced from cattle slaughtered onsite. "Bench trim" is trim derived from cattle not slaughtered onsite (i.e., purchased product). In addition to *E. coli* O157:H7, six Non-O157 STEC are considered adulterants in raw beef used for production of non-intact beef products, including the following O-antigen groups: O26, O45, O103, O111, O121, and O145.

Major Activities in STEC Sampling Projects in FY2016

1. FSIS reissued FSIS Directive 10,010.1, entitled "Sampling Verification Activities for Shiga Toxin-producing *Escherichia coli* (STEC) in Raw Beef Products" (Dir. 10,010.1, Revision 4). 12

Changes Planned to STEC Sampling Projects for FY2017

- 1. FSIS plans to analyze raw pork samples collected as part of the RPPBS for STEC in order to better understand the public health risk associated with these products.
- 2. FSIS may extend non-O157 STEC sampling to raw ground beef components at slaughter establishments.

¹² http://www.fsis.usda.gov/wps/wcm/connect/c100dd64-e2e7-408a-8b27-ebb378959071/10010.1.pdf?MOD=AJPERES

Listeria monocytogenes (Lm)

FSIS conducts microbiological testing of RTE meat and poultry products for *Lm* and *Salmonella* in both domestically produced and imported RTE products as well as in domestically produced and imported processed egg products.

Routine RTE product sampling is scheduled every month under both a random sampling project and risk-based sampling project. Under the Routine Listeria monitoring (RLm) sampling program, establishments producing post lethality exposed RTE product are scheduled on a rotating basis, and samples of product, contact surfaces, and the processing environment are collected and tested for *Lm*. Intensified Verification Testing (IVT) is carried out whenever an establishment has a positive sample collected under the RLm sampling program or either one of the routine RTE sampling projects.

Major Activities in Sampling Projects for Lm and Salmonella in FY2016

- 1. FSIS began reviewing the sampling methodology for the RLm sampling project.
- 2. FSIS began reviewing the sampling methodology for the processed egg sampling projects.
- 3. FSIS modernized the processed egg sampling plan, which will eliminate EGGDOM and allow for *Lm* testing to be added to these projects.
- 4. FSIS reviewed and updated the risk factors associated with the scheduling algorithm for the RTEPROD_RAND and RTEPROD_RISK sampling projects.

Changes Planned to RTE Sampling Projects for Lm and Salmonella for FY2017

- 1. FSIS is considering implementing a follow up sampling project to begin immediately collecting product samples after a positive sampling result.
- 2. FSIS intends to implement an updated scheduling algorithm for the RTEPROD_RAND and RTEPROD_RISK sampling projects.
- 3. FSIS will continue to review the current scheduling methodology for RLm.

Chemical Residues

FSIS conducts sampling for chemical residues in regulated meat, poultry, and egg products.

Domestic sampling projects are summarized in Table 6.

Major Activities in Chemical Residue Sampling Programs in FY2016

- 1. FSIS continued Tier 2 sampling projects for sheep, goats, market swine, and old breeder turkeys.
- 2. FSIS began a KIS pilot program to get information on dairy cows and bob veal to determine if the directions for in-plant testing need to be updated.
- 3. FSIS began regulatory testing on Siluriformes for the presence of chemical residues and for species identification (speciation).
- 4. FSIS began regulatory testing for roaster swine.

Changes Planned for Chemical Residue Sampling Programs for FY2017

- 1. FSIS continues evaluation of the residue sampling projects for both domestically produced and imported further processed raw meat and poultry products as well as RTE and NRTE (combination) products.
- 2. FSIS is considering modifying directions for in-plant KIS tests. To get additional information, FSIS has finished a pilot with dairy cows and bob veal and is working on a pilot for swine classes.
- 3. FSIS is starting a Tier 2 sampling project for bulls and veal classes other than bob veal.
- 4. FSIS is continuing Tier 2 sampling projects for sheep, goats, old breeder turkeys, and market swine.

Exploratory and Baseline Studies

FSIS conducts exploratory and baseline studies to estimate the national prevalence levels of bacteria or indicator bacteria of public health concern. Each report produced after the completion of a baseline or exploratory study is a compilation of data obtained for a particular species or type of animal or product. FSIS uses this information to determine if routine sampling projects are needed and how they should be structured.

Major Activities in Exploratory and Baseline Studies in FY2016

1. FSIS completed the Nationwide Beef and Veal Carcass Microbiological Baseline Data Collection Program.

- 2. FSIS completed the RPPESP for *Salmonella*, *Campylobacter* and other analytes in comminuted, intact, and non-intact raw pork products in early FY2016. Results from this sampling have been used to develop phase two of the project, the RPPBS, which will be implemented during FY2017.
- 3. FSIS began sampling raw fish of the order Siluriformes for *Salmonella*, speciation, and chemical residues. The 18-month transitional period will run from March 1, 2016 to September 1, 2017.

Changes Planned for Exploratory and Baseline Studies in FY2017

- 1. FSIS will publish a report with the findings of the Nationwide Beef and Veal carcass Microbiological Baseline Data collection Program in FY2017.
- 2. FSIS is using the data from the RPPESP to design the second phase of FSIS' pork sampling initiative. FSIS will implement sampling for the RPPBS during FY2017.
- 3. FSIS will implement an exploratory *Salmonella* sampling program for imported raw pork products.
- 4. FSIS intends to begin testing certain minor species for Salmonella and Campylobacter.
- 5. FSIS intends to initiate an exploratory sampling project for NRTE poultry products (combination products).

Other Sampling Programs

FSIS also conducts sampling in other areas, both on domestically produced and imported products. ¹³ These projects include:

- Advanced Meat Recovery (AMR) FSIS tests beef product from AMR processes to help prevent spinal cord material from entering the food supply and being misrepresented as meat.
- 2. NARMS (National Antimicrobial Resistance Monitoring System)¹⁴– is a national public health surveillance system that tracks antibiotic resistance in foodborne bacteria. NARMS monitors antimicrobial resistance among enteric bacteria from humans, retail meats, and food animals. The major bacteria currently under surveillance are *Salmonella*, *Campylobacter*, *E. coli*, and *Enterococcus*.
- 3. Foodborne Illness and Outbreak Sampling FSIS collects and analyzes food samples potentially related to human disease outbreaks. Analyses include both cultural and characterization methods such as PFGE, antimicrobial susceptibility testing, and molecular serotyping.
- 4. Food Chemistry FSIS performs other food chemistry analyses, such as moisture, protein, and fat analyses. FSIS also tests for the presence of food additives to identify mislabeling, economic fraud, and adulteration of meat, poultry, and egg products.
- 5. Species Identification FSIS conducts species verification on both imported and domestic samples.
- 6. Pathology FSIS carries out diagnostic and consultative pathology services to identify diseases, parasites, and related conditions in response to the needs of field operations.
- 7. Compliance Testing FSIS investigators collect compliance samples at in-commerce businesses on a "for-cause" basis in response to complaints, allegations, and their own observations during routine or for-cause surveillance activities.

 $\underline{http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm}$

¹³ The USDA Animal and Plant Health Inspection Service (APHIS) conducts an ongoing surveillance program for bovine spongiform encephalopathy (BSE), in which) approximately 40,000 animals are sampled each year. Under the program, either APHIS or FSIS collect samples from the cattle populations where the disease is most likely to be detected, similar to the enhanced surveillance program procedures. Laboratory analysis of collected samples is handled exclusively by APHIS. For more information about FSIS' role in sample collection for BSE, please see FSIS Directive 10,400.1, http://www.fsis.usda.gov/wps/wcm/connect/09bf6ed8-1e4b-4ef5-a3e1-fa454b116b8e/10400.1,pdf?MOD=AJPERES.

¹⁴ Additional data for NARMS can be found at the following CDC website: http://www.cdc.gov/narms/reports/
FDA website:

Major Activities in Other Sampling Programs in FY2016

- 1. FSIS conducted intensified testing of a variety of products in response to foodborne illnesses investigations and recalls. This sampling prompted investigation by the Agency for exploratory sampling of all frozen NRTE stuffed chicken products.
- 2. FSIS tested raw single ingredient ground beef product from the MT43 and MT05 projects in consumer ready packaging contain a nutritional facts panel for nutritional content which included Total Fat, Total Protein, and Sodium.

Changes Planned for Other Sampling Programs for FY 2017

1. FSIS intends to increase nutritional analysis sampling in raw ground beef.

Sampling Numbers by Product

Meat

Table 1: Raw Beef

Product Class	Sampling Project	Pathogen(s)	Planned Number of Samples to Analyze FY2016	Actual Number of Samples Analyzed in FY2016	Planned Number of Samples to Analyze in FY2017
Raw ground beef	MT43	E. coli O157:H7 & Salmonella	12,500	10,303	12,500
Raw ground beef ¹	HC01_GB	Salmonella	53	1	53
Follow-Up testing to a ground beef <i>E. coli</i> positive ²	MT44 & MT44T	E. coli O157:H7 & Salmonella	NA	95	NA
Raw ground beef components other than trim	MT64	E. coli O157:H7 & Salmonella	1,000	398	1,000
Bench trim	MT65	E. coli O157:H7 & Salmonella	2,000	1,112	2,000
Beef manufacturing trim	MT60	E. coli O157:H7, Non-O157 (STEC) & Salmonella	4,500	3,352	4,500
Follow-up testing at supplier establishments following MT43, MT44, or MT65 positive ²	MT52	E. coli O157:H7, Non-O157 (STEC) & Salmonella	NA	43	NA
Follow-up testing to an MT60, MT64, MT65, or MT52 positive ²	MT53	E. coli O157:H7, Non-O157 (STEC) & Salmonella	NA	721	NA
Raw ground beef at retail stores	MT05	E. coli O157:H7 & Salmonella	560	503	560

Product Class	Sampling Project	Pathogen(s)	Planned Number of Samples to Analyze FY2016	Actual Number of Samples Analyzed in FY2016	Planned Number of Samples to Analyze in FY2017
Follow-up testing to a MT05 sample ²	MT06	E. coli O157:H7 & Salmonella	NA	0	NA
Imported raw ground beef ³	MT08	E. coli O157:H7 & Salmonella	10	95	25
Imported trim and other raw ground beef components	MT51	E. coli O157:H7, Non- O157 (STEC) & Salmonella	850	398	900

Table 2: Raw Pork

Product Class	Sampling Project		Planned Number of Samples to Analyze FY2016	Actual Number of Samples Analyzed in FY2016	Planned Number of Samples to Analyze in FY2017
Exploratory Sampling for Pork – Comminuted ¹	EXP_PK_COM01	Salmonella & Non- O157 (STEC) & Indicator Organisms	TBD	852	1,700
Exploratory Sampling for Pork - Intact Cuts ¹	EXP_PK_ICT01	Salmonella & Non- O157 (STEC) & Indicator Organisms	TBD	588	1,400
Exploratory Sampling for Pork - Intact Other ¹	EXP_PK_IOT01	Salmonella & Indicator Organisms	TBD	309	0

¹ These samples were collected for Category 3 establishments only.

² Dependent on positive findings from other *E. coli* O157:H7 or non-O157 STEC sampling projects.

³ The number of lots of imported raw ground beef is too low to collect 100 samples.

Exploratory Sampling for Pork - Non- Intact Cuts ¹	EXP_PK_NCT01	Salmonella & Non- O157 (STEC) & Indicator Organisms	TBD	165	1,400
Exploratory Sampling for Pork - Non- Intact Other ¹	EXP_PK_NOT01	Salmonella & Indicator Organisms	TBD	134	0
Imported Pork ²	IMP_PORK	Salmonella	NA	NA	770
Pork Carcasses ³	TBD	Salmonella	0	0	TBD

¹ In FY2016, FSIS analyzed results and rebalance sample distribution to focus on specific pork products from data gathered during the Raw Pork Phase I. These project codes will change in FY2017 to reflect the change into Phase II baseline for Raw Pork.

² In FY2017, FSIS is considering to start sampling imported raw pork products

³ FSIS stopped routinely sampling carcasses in FY2011 because the positive pathogen rate was low, and the potential public health benefit did not justify the expenditure of the necessary Agency resources to perform the sampling. The Agency decided to reallocate those resources to sampling procedures that would yield a more effective public health benefit. However, if a need arises, based on positive sample results or other events, FSIS can and will conduct *Salmonella* sampling in carcasses.

Table 3: Raw Fish

Product Class	Sampling Project	Analyses			Planned Number of Samples to Analyze in FY2017
Raw fish of the order Siluriformes	EXP_FI_MIC01	Salmonella	TBD	28	200
	RES_FI ¹	Chemical residues and Speciation	TBD	55	200
	IMPFISH_MI	Salmonella	TBD	42	100
Imported Raw fish of the order Siluriformes	IMPFISH_CH_E ² & IMPFISH_CH_W ³	Chemical residues and Speciation	TBD	84	100

¹ Chemical Residues Testing Includes: Multiresidues, Metals, Antifungal Dyes, Pesticides, and Nitrofurans
² Chemical Residues Testing Includes: Multiresidues, Metals, and Antifungal Dyes
³ Chemical Residues Testing Includes: Pesticides and Nitrofurans

Table 4: Raw Poultry

Product Class	Sampling Project	Pathogen(s)	Planned Number of Samples to Analyze FY2016		Planned Number of Samples to Analyze in FY2017
Young Chickens	HC_CH_CARC01	Salmonella, Campylobacter & Indicator Organisms	12,000	7,562	12,500
Sampling for Ground and Other Comminuted Chicken (not Mechanically Separated)	HC_CH_COM01	Salmonella, Campylobacter & Indicator Organisms	4,000	1,069	5,000
Exploratory Sampling for Mechanically Separated Chicken	EXP_CH_MSK01	Salmonella, Campylobacter & Indicator Organisms	150	85	150
Chicken Parts – Legs, Breasts, Wings	HC_CPT_LBW01	Salmonella, Campylobacter & Indicator Organisms	8,000	5,470	8,500
Chicken Parts – Other Parts	EXP_CPT_OT01	Salmonella, Campylobacter & Indicator Organisms	NA	NA	360
Chicken Parts – Quarters, Halves	EXP_CPT_QH01	Salmonella, Campylobacter & Indicator Organisms	NA	NA	120
Turkeys	HC_TU_CARC01	Salmonella, Campylobacter & 2,500 1,571 Indicator Organisms		1,571	3,000
Sampling for Ground and Other Comminuted Turkey (not Mechanically Separated)	HC_TU_COM01	Salmonella, Campylobacter & Indicator Organisms	1,500	765	2,000

Product Class	Sampling Project	Pathogen(s)			Planned Number of Samples to Analyze in FY2017
Exploratory Sampling for Mechanically Separated Turkey	EXP_TU_MSK01	Salmonella, Campylobacter & Indicator Organisms	150	82	150
Imported Raw Intact Chicken and Turkey	IMP_POULTRY	Salmonella, Campylobacter & Indicator Organisms	800	635	800
Minor Species ²	TBD	Salmonella, Campylobacter & Indicator Organisms	NA	NA	1,800
Religious exempt establishments ³	HC_CH_CARC01 HC_TU_CARC01	Salmonella, Campylobacter & Indicator Organisms	NA	NA	50
Establishments <1000lbs/day ³	HC_CH_CARC01 HC_TU_CARC01 HC_CPT_LBW01 HC_CH_COM01 HC_TU_COM01	Salmonella, Campylobacter & Indicator Organisms	NA	NA	50
Follow-up Sampling for Chicken Parts, Comminuted Chicken and Turkey ⁴	F_CPT_LBW01 F_CH_COM01 F_TU_COM01	Salmonella, Campylobacter & Indicator Organisms	NA	NA	NA

¹ FSIS will begin sampling of other chicken parts along with quarters/halves in FY2017.

² FSIS is considering an exploratory sampling program for minor species.

³ Religious exempt and <1000lbs/day establishments will be included as part of the projects listed respectively. They were included separately to indicate that testing will begin for those types of establishments in FY2017.

⁴ Dependent on findings from other *Salmonella and Campylobacter* projects.

Ready-to-Eat, NRTE and Egg Products

Table 5: RTE, NRTE and Egg Products

Product Class	Sampling Project	Pathogen(s)	Planned Number of Samples to Analyze FY2016	Actual Number of Samples Analyzed in FY2016	Planned Number of Samples to Analyze in FY2017
Both post lethality-exposed and non-post lethality-exposed RTE products	RTEPROD_Rand	Lm & Salmonella	4,400	3,702	7,400
Post lethality-exposed RTE products	RTEPROD_Risk	Lm & Salmonella	10,400	9,920	7,400
RLm product samples (Composited 5-sample Units)	RLMPRODC	Lm	690	534	690
RLm food contact surface samples	RLMCONT	Lm	6,880	5,292	6,880
RLm non-food contact environmental samples (Composited 5-sample Units)	RLMENVC	Lm	690	537	690
Intensified Verification Testing (IVT) product samples ¹	INTPROD	Lm or Salmonella	NA	708	NA
IVT food contact surface samples ¹	INTCONT	Lm or Salmonella	NA	1,361	NA
IVT non-food contact environmental samples ¹	INTENV	Lm or Salmonella	NA	803	NA
Imported intact RTE product	IMVRTE	Lm & Salmonella	2,200	2,785	2,200
Follow up testing to imported RTE product	FLISTERIA	Lm	NA	97	NA

Product Class	Sampling Project	Pathogen(s)	Planned Number of Samples to Analyze FY2016	Actual Number of Samples Analyzed in FY2016	Planned Number of Samples to Analyze in FY2017
Follow up testing to imported RTE product	FRTESALMONEL	Salmonella	NA	15	NA
Processed Egg Products ²	EM31-EM37	Lm & Salmonella	1,600	1,454	1,600
Collector-generated egg product testing ²	EGGDOM	Lm	NA	0	NA
Pasteurized imported liquid, frozen or dried egg products ²	EGGIMP	Lm & Salmonella	80	170	125
Not-Ready-to-Eat (NRTE) products ³	TBD	Salmonella & Campylobacter	NA	NA	2,200

Chemical Residues

Table 6: Chemical Residues

Product Class	Sampling Project	Planned Number of Samples to Analyze FY2016	Actual Number of Samples Analyzed in FY2016	Planned Number of Samples to Analyze in FY2017	
Beef Cows	NRP_BC	712	578	712	
Bob Veal	NRP_BV	356	496	356	
Dairy Cows	NRP_DC	712	610	712	
Heifers	NRP_HF	356	337	356	
Steer	NRP_ST	356	311	356	

¹ Dependent on positive findings from RTEPROD_RAND, RTEPROD_RISK, and RLm sampling projects
² EGGDOM will be retired in FY2017 during the Egg Modernization program. This program also includes adding *Listeria monocytongenes* testing to the EM projects.

³ FSIS plans to bring on-line testing for NRTE products. This type of testing could occur over several different sampling projects.

Product Class	Sampling Project	Planned Number of Samples to Analyze FY2016	Actual Number of Samples Analyzed in FY2016	Planned Number of Samples to Analyze in FY2017
Sows	NRP_MS	712	590	712
Market Swine	NRP_SW	712	625	712
Young Chicken	NRP_YC	712	634	712
Young Turkey	NRP_YT	712	569	712
Sheep	NRP_SH	356	254	150
Goats	NRP_GO	356	281	150
Old Breeder Turkeys (Mature Turkeys)	NRP_OBT	90	81	100
Roaster Swine	NRP_RS	300	277	300
National Residue Program State Residues ¹	Various	700	454	700
Bulls/Stags	NRP_BS	NA	NA	100
Veal other than bob veal	NRP_HC, NRP_FFV, NRP_NFFV	NA	NA	100
KIS™ Test	KIS	NA	163,457	NA
KIS™ Test – Laboratory Confirmation ²	KIS	NA	3,027	NA
Collector Generated Residues	Various	NA	118	NA
Import Residue	Various	3,000	2,298	3,000

¹ FSIS schedules and analyzes samples for states using PHIS. Those samples are spread across the same species that FSIS samples at federally inspected establishments at the rate of 88 per year.

² FSIS in-plant inspection personnel send positive KIS tests to FSIS laboratories for confirmation.

Table 7: Chemical Residues Tested by Production Class

Tier 1: Pro					Product	oduction Class			Tier 2: Production Class						
Methods	Beef Cows	Dairy Cows	Steers	Heifers	Bob Veal	Market Swine	Market Sows	Young Chicken	Young Turkey	Goats	Sheep	Non-Bob Veal	Bull	Mature Turkey	Roster Swine
Multi-class	٧	٧	٧	٧	٧	٧	٧	٧	٧	٧	٧	٧	٧	٧	٧
Aminoglycoside	٧	٧	٧	٧	٧	٧	٧	٧	٧			٧	٧		٧
Pesticides	٧	٧	٧	٧	٧	٧	٧	٧	٧	٧	٧		٧		
Metals	٧	٧	٧	٧	٧	٧	٧	٧	٧				٧	٧	
B-agonists	٧	٧	٧	٧	٧	٧						٧			
Carbadox															٧
Hormones	٧	٧	٧	٧	٧										
Avermectins	٧	٧	٧	٧	٧	٧	٧			٧	٧				
Arsenic	٧	٧	٧	٧	٧	٧	٧	٧	٧	٧	٧				
Nitrofurans								٧	٧					٧	

Other

Table 8: All Other Program Areas

		Planned Number of Samples to Analyze	Samples Analyzed	Planned Number of Samples to Analyze
Sampling Project	Sampling Project	FY2016	in FY2016	in FY2017
Advanced Meat Recovery (AMR) – Beef ¹	AMR01	150	99	150
Import AMR Beef ¹	IMPAMRBEEF	10	14	10
Follow-up testing to a AMR01 Beef Sample 1,2	FAMR01	NA	28	NA
AMR Pork ³	TBD	TBD	TBD	TBD
National Antimicrobial Resistance Monitoring System for Enteric Bacteria	NARMS	5,400	4,522	6,400
NARMS/Residue Sampling on Cull Dairy ¹²	TBD	NA	NA	TBD
Foodborne Illness and Outbreak Sampling 4,5	Various	3,000	1,030	7,000
Label Verification for Nutrient Content - Raw Ground Beef ⁶	NUTR_GB & EXP_LV_NUTR	240	123	200
Label Verification – Allergens ⁷	EXP_LV_SOY	100	NA	200
Label Verification – Antibiotic Free ⁷	EXP_LV_ABX	200	NA	400
Label Verification – Hormone Free ⁷	EXP_LV_HORM	100	NA	200
Species Identification - Collector Generated	SPECID	NA	24	NA
Import Species Identification 8	IMPSPECIESID	250	141	250
Food Chemistry - Collector Generated ⁹	FOODCHEM	NA	2	NA
Compliance Testing 4,10	COMPLIAN	NA	36	NA

Sampling Project		Samples to Analyze		Planned Number of Samples to Analyze in FY2017
Pathology - Collector Generated 4, 11	Various	NA	4,686	NA
Import Abnormal Container	IMPABNCONT & ABNCONT	NA	1	NA

¹ FSIS conducts a sampling project in regulated establishments for AMR processes to help prevent beef spinal cord material from entering the food supply and being misrepresented as meat. If an AMR sample is positive, additional samples are assigned to the establishment in PHIS through the FAMR01 sampling. FSIS is considering expanding the beef AMR program to include calcium and iron.

² Dependent on positive findings from the AMR01 sampling project.

³ FSIS is considering implementing an AMR pork program.

⁴ Samples for these projects are not planned in advance, but rather are collector-generated in the field based on inspector findings or other circumstances. This number is a baseline of 2,000 plus the follow-up sampling from projected numbers.

⁵ FSIS collects and analyzes food samples potentially related to human disease outbreaks. Analyses include cultural and molecular methods such as polymerase chain reaction (PCR), PFGE, antimicrobial susceptibility testing and molecular serotyping to identify and further characterize organisms in outbreak samples

⁶ FSIS is changing over programs from an Exploratory to a Label Verification project in FY2017.

⁷ FSIS is bringing on-line several other Label Verification programs in FY2017 which were originally scheduled to begin in FY2016.

⁸ Species sampling occurs for 1 out of every 48 lots re-inspected by FSIS.

⁹ FSIS performs food chemistry analyses such as moisture, protein, fat and testing for the presence of food additives to identify mislabeling, economic fraud, and adulteration of meat, poultry, and egg products

¹⁰ FSIS investigators collect compliance samples at in-commerce businesses on a "for-cause" basis in response to complaints, allegations, and their own observations during routine or for-cause surveillance activities.

¹¹ FSIS carries out diagnostic and consultative pathology services to identify diseases, parasites and related conditions in response to the needs of field operations.

¹² FSIS plans to begin sampling on a combined NARMS and Residue testing project in FY2017. This project gathers data to determine if there is a link between antimicrobial resistance and drug use in animals.

Test and Analyte Numbers for Products by Discipline

FSIS continuously seeks out ways to improve sampling procedures and testing of the products collected. One way this increased efficiency is demonstrated is through the amount of testing performed on one sampling collection event. The following tables detail the numbers of analyses and corresponding number of analytes performed on the total number samples for a product group (e.g. beef, poultry, RTE) by discipline. Data is based off proposed number of samples and which analyses were performed during that specific fiscal year. The term analyses (tests) refer to the methodology used on a sample, while the term analyte refers to each individual, reportable item tested in the method. For example one MT60 sample will be tested for *Salmonella*, *E. coli* O157:H7 and Non-O157 STEC. This would result in 3 separate analyses for the sample. However, since the Non-O157 STEC method looks at 6 different species of *E. coli* then the number of analytes tested for would be 8, six from the STEC analysis, 1 from the *E. coli* O157:H7 analysis and 1 from *Salmonella*.

Microbiology

Table 9: Number of Analyses (Tests) performed by FSIS Microbiology

		FY2015	FY2016	Planned for FY2017	Difference (FY2017- FY2016)
	Raw Beef	63,192	89,280	76,680	-12,600 ¹
	Raw Pork	0	3,600	15,840	12,240
	Raw Poultry	46,104	32,328	69,048	36,720
6	Raw Fish	204	300	300	0
Products	RTE	34,032	34,032	34,032	0
Proc	RLm	8,280	16,560	16,560	0
	NRTE	0	0	4,416	4,416
	Eggs	1,680	1,680	3,456	1,776
	NARMS	10,800	10,800	12,816	2,016

	FY2015	FY2016	Planned for FY2017	Difference (FY2017- FY2016)
Total Analyses Per year ²	164,292	188,580	233,148	44,568

¹ The number of raw beef analyses is greater in FY2016 due to the Beef Veal Carcass Baseline.

2 The total number of analyses does not include the any additional tests resulting from further characterization done on isolates.

Table 10: Number of Analytes tested for in Microbiology

		FY2015	FY2016	Planned for FY2017	Difference (FY2017- FY2016)
	Raw Beef	113,592	149,904	141,480	-8,424 ¹
	Raw Pork	0	10,800	58,080	47,280
	Raw Poultry	46,104	32,328	138,096	105,768
	Raw Fish	204	300	300	0
Si	RTE	34,032	34,032	34,032	0
Products	RLm	8,280	16,560	16,560	0
Pro	NRTE	0	0	4,416	4,416
	Eggs	1,680	1,680	3,456	1,848
	NARMS	10,800	10,800	12,816	2,016
	Total Analytes Per year ²	214,692	256,332	409,236	152,904

¹ The number of raw beef analyses is greater in FY2016 due to the Beef Veal Carcass Baseline.

² The total analytes do not include the analytes from further characterization testing performed on isolates.

Residues

Table 11: Number of Analyses (Tests) performed by Chemistry

		1. Number of Analys	FY2015	FY2016	Planned for FY2017	Difference (FY2017 – FY2016)
		Beef Cows	4,000	3,560	3,560	0
		Bob Veal	4,000	1,780	1,780	0
		Dairy Cows	4,000	3,560	3,560	0
		Heifers	2,000	1,780	1,780	0
	Tier I	Steer	2,000	1,780	1,780	0
	F	Sows	4,000	3,560	3,560	0
		Market Swine	4,000	3,560	3,560	0
		Young Chicken	2,800	2,492	2,492	0
ass		Young Turkey	2,800	2,492	2,492	0
Product Class		Sheep	1,050	1,246	525	-721
onpo		Goats	1,050	1,246	525	-721
Pro		Mature Turkey	200	270	300	30
		Roaster Swine	0	900	900	0
	_	Bulls/Stags	0	0	400	400
	Tier II	Veal - Other	0	0	300	300
	-	Fish	0	1,500	1,500	0
		State NRP	0	0	0	
		Import Residue	0	0	0	-
		KIS	8,000	8,000	8,000	0
	То	tal Analyses Per year	39,900	37,726	37,014	-712

¹ The analyses vary for import and State testing depending on what was selected by IPP.

Table 12: Number of Analytes tested for by Chemistry

		z. Namber of Analys	FY2015	FY2016	FY2017	Difference (FY2017 – FY2016)
		Beef Cows	92,000	119,972	119,972	0
		Bob Veal	92,000	59,986	59,986	0
		Dairy Cows	92,000	119,972	119,972	0
		Heifers	46,000	59,986	59,986	0
	Tier I	Steer	46,000	59,986	59,986	0
	Ë	Sows	88,400	116,768	116,768	0
		Market Swine	90,800	118,548	118,548	0
		Young Chicken	86,800	116,056	116,056	0
ass		Young Turkey	86,800	116,056	116,056	0
Product Class		Sheep	30,600	52,154	23,325	-28,829
quc		Goats	30,600	52,154	23,325	-28,829
Pro		Mature Turkey	6,150	8,820	10,650	1,830
		Roaster Swine	0	31,950	31,950	0
	_	Bulls/Stags	0	0	16,150	16,150
	Tier II	Veal - Other	0	0	10,850	10,850
	-	Fish	0	44,250	44,250	0
		State NRP	0	0	0	-
		Import Residue	0	0	0	-
		KIS	248,000	424,000	424,000	0
	То	tal Analytes Per year	1,036,150	1,500,658	1,471,830	-28,828

¹ The analyses vary for import and State testing depending on what was selected by IPP.