# Food Safety and Inspection Service's Annual Sampling Program Plan

Fiscal Year 2015

United States Department of Agriculture Food Safety and Inspection Service November 2014

# 1.0 Introduction

#### **Introduction**

The Food Safety and Inspection Service (FSIS) within the United States Department of Agriculture (USDA) inspects meat, poultry, and egg products establishments to ensure that the food produced in them is safe, wholesome, and properly labeled. The overall purpose of FSIS inspection activities is to verify that establishments meet requirements to control physical, chemical, and microbiological hazards in regulated product. Verification activities serve to protect the public from foodborne hazards. A key component of FSIS' inspection activities is the sampling of product to test for microbiological contaminants or chemical residues.

# <u>FSIS Sampling and Strategic Plan Goals to Utilize a Data-Driven Approach and Reduce</u> Foodborne Illness

In September 2010, FSIS released two reports:

- 1. FSIS Strategic Data Analysis Plan for Domestic Inspection<sup>1</sup>
- 2. Data-Driven Inspection for Processing and Slaughter Establishments: Public Health Decision Criteria.<sup>2</sup>

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, as well as 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.

FSIS also 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.<sup>3</sup> Subsequent to the release of the original report in 2011, FSIS has released a new Sampling Plan (Plan) for each fiscal year (FY).<sup>4,5,6</sup> These Plans continued FSIS' efforts to comprehensively identify the Agency's microbiological and chemical residue sampling activities and consider them in light of data-

<sup>&</sup>lt;sup>1</sup> Please see the following website for more information: http://www.fsis.usda.gov/wps/wcm/connect/84fa563e-0f5c-4df5-8e04-99a04e9ce102/2010\_Strategic\_Data\_Analysis\_Plan.pdf?MOD=AJPERES

<sup>&</sup>lt;sup>2</sup> Please see the following website for more information:

http://www.fsis.usda.gov/OPPDE/NACMPI/Sep2010/2010\_Public\_Health\_Decsion\_Criteria\_Report.pdf

<sup>&</sup>lt;sup>3</sup> Please see the following website for more information:

http://www.fsis.usda.gov/wps/wcm/connect/0816b926-c7ee-4c24-9222-

<sup>34</sup>ac674ec047/FSIS\_Sampling\_Programs\_Report.pdf?MOD=AJPERES

<sup>&</sup>lt;sup>4</sup> Please see the following website for more information:

http://www.fsis.usda.gov/wps/wcm/connect/9a484b86-583d-4e2a-aa29-

<sup>9</sup>fa208acd37d/Sampling\_Program\_Plan\_FY2012.pdf?MOD=AJPERES

<sup>&</sup>lt;sup>5</sup> Please see the following website for more information:

http://www.fsis.usda.gov/wps/wcm/connect/7f3810da-cc8f-47a7-89a1-

<sup>570438511130/</sup>Sampling\_Program\_Plan\_FY2013.pdf?MOD=AJPERES

<sup>&</sup>lt;sup>6</sup> Please see the following website for more information: http://www.fsis.usda.gov/wps/wcm/connect/62fad225-9052-47fa-9ffe-397f436dc96a/Sampling-Program-Plan-FY2014.pdf?MOD=AJPERES.

driven strategic planning efforts. The Plans also described FSIS' major activities related to microbiological and chemical residue sampling in domestic establishments, imports, and incommerce facilities during the fiscal year and the Agency's overall strategy for directing its sampling resources for the following year.

This new FY2015 Plan seeks to accomplish the same goals, by describing FSIS' major activities related to microbiological and chemical residue sampling programs for domestic establishments, imports, and in-commerce facilities in FY2014 and describing the Agency's overall strategy for directing its sampling resources in FY2015.

#### **Background**

The process of scheduling, collecting and analyzing routine domestic samples typically begins with a sampling task assigned to FSIS inspection program personnel (IPP) through the Agency's Public Health Information System (PHIS) or via paper forms mailed to the IPP. The IPP then collect and ship the samples collected to one of three FSIS testing laboratories, where the sample is tested for microbiological contaminants or chemical residues. For imported product, the types of inspection assigned to the lot by PHIS inform IPP when samples are to be collected and sent for laboratory analysis.

The FSIS laboratories perform different tests depending on the type of sample and 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 and so are not considered to be routine. In general, sampling for a specific pathogen, such as *Salmonella*, is referred to in this Plan as a "sampling program," whereas individual sampling projects for specific pathogens, such as HC11 for *Salmonella*, are considered a "sampling project."

All tables in this Plan contain the following information:

- 1. Number of samples that were planned to be analyzed in FY2014,8
- 2. Number of samples actually analyzed in FY2014, and
- 3. Number of samples that are planned to be analyzed in FY2015.

Totals in the individual tables have been rounded. Like the FY2014 plan, this FY2015 Plan is based on the number of samples analyzed because 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.

In FY2015, FSIS plans to collect and analyze approximately 75,000 domestic microbiological samples, 6,400 domestic chemical residue samples, 3,200 microbiological and 1,500 chemical

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<sup>&</sup>lt;sup>7</sup> FSIS uses PHIS to send sampling tasks to IPP in establishments that use PHIS (federal slaughter and processing meat and poultry establishments and import establishments). At the time that this document was published, RLm and IVT forms were still in transition from paper to electronic forms in PHIS.

<sup>&</sup>lt;sup>8</sup> The total number of samples planned to be scheduled in FY2014 was included in the *FSIS Annual Sampling Program Plan, Fiscal Year 2014*. The tables in this Plan show numbers that have been converted from the number of samples planned to be scheduled to the number of samples planned to be analyzed. Please see the following website for more information: http://www.fsis.usda.gov/wps/wcm/connect/62fad225-9052-47fa-9ffe-397f436dc96a/Sampling-Program-Plan-FY2014.pdf?MOD=AJPERES.

residue import samples, and 500 in-commerce microbiological 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 FY2014 and what changes are planned for FY2015.

Finally, it is important to note that the number of samples that were anticipated to be analyzed in FY2014 may differ from the total number of samples actually analyzed over the same period. This discrepancy occurs for a variety of reasons, including improved sampling frames due to updates to establishment profiles in PHIS (which could lead to more samples being analyzed than previously planned), emergencies, lack of production at the establishment level, and other unforeseen circumstances (which could lead to fewer samples being analyzed than previously planned). When these discrepancies occur, IPP may not be able to collect samples for all sampling tasks originally assigned. This same discrepancy may exist moving forward for samples scheduled in FY2015.

## **General FY2014 Accomplishments**

FSIS issued the *Salmonella* Action Plan (SAP), which outlined several actions FSIS will take to drive innovations that will lower *Salmonella* contamination rates, including implementing the New Poultry Inspection System (NPIS), establishing new performance standards; developing new strategies for inspection and throughout the full farm-to-table continuum; addressing all potential sources of *Salmonella*; and focusing the Agency's education and outreach tools on *Salmonella*.

FSIS assumed the performance of Pulsed field Gel Electrophoresis (PFGE) and Antibiotic Susceptibility Testing (AST) analyses formerly conducted by the Agricultural Research Service (ARS) and began conducting PFGE and AST analyses on cecal samples collected for the NARMS sampling project.

In addition to microbiological and chemical residue sampling and testing, FSIS began conducting limited, non-routine nutritional analyses of products required to bear nutrition information on their labels.

# Salmonella and Campylobacter

# **FSIS Domestic Sampling Projects**

FSIS conducts *Salmonella* and *Campylobacter* testing on a variety of products through a variety of projects. Sampling is conducted for the *Salmonella* and *Campylobacter* Pathogen Reduction Performance Standards for young chicken and turkey carcasses under the HC11 sampling project. Raw comminuted chicken and turkey are tested for both *Salmonella* and *Campylobacter* under the Not-Ready-To-Eat (NRTE) sampling project.

In FY2014, raw ground beef samples were collected under the HC01\_GB, MT43S, and MT43, sampling projects and were tested for either *Salmonella* or *E. coli* O157:H7, depending on the sampling project. In FY2015, all samples will be collected under MT43, and all samples will be tested for both *Salmonella* and *E. coli* O157:H7.

The project code EM is used to identify collected samples of egg products for *Salmonella*; FSIS currently has seven project codes for routine egg sampling. *Salmonella* testing is conducted on raw beef samples under the MT project codes. In addition, samples of ready-to-eat (RTE) meat and poultry products are tested for *Salmonella* and *Listeria monocytogenes* (*Lm*) under the RTEPROD sampling program. (See Table 3 for a summary of the RTE sampling projects).

Information on the different domestic *Salmonella* and *Campylobacter* sampling projects is summarized in Table 1.

Table 1: FSIS Salmonella and Campylobacter Domestic Sampling Projects

<b>Product Class</b>	Sampling Projects	Pathogen(s)	Planned Number of Samples to Analyze in FY2014	Actual Number of Samples Analyzed in FY2014	Planned Number of Samples to Analyze in FY2015
Raw ground beef	MT43*	Salmonella	16700	15,840	12500
Raw beef trim	multiple	Salmonella	2530	1375	5600
Young Chickens**	HC11_BR	Salmonella and Campylobacter	12750	9707	3500
Turkeys**	HC11_TU	Salmonella and Campylobacter	2130	2153	400
Young Chickens**	TBD	Salmonella and Campylobacter	N/A	N/A	7200
Young Turkeys**	TBD	Salmonella and Campylobacter	N/A	N/A	3600
Chicken Parts***	TBD	Salmonella and Campylobacter	N/A	N/A	3850
Ground Chicken	HC01_GC <sup>±</sup>	Salmonella	N/A	4	N/A
Ground Turkey	HC01_GT <sup>±</sup>	Salmonella	N/A	0	N/A
Exploratory Raw Comminuted Chicken#	NRTE_EXP_CH	Salmonella and Campylobacter	5400	3140	N/A
Exploratory Raw Comminuted Turkey#	NRTE_EXP_TU	Salmonella and Campylobacter	3000	1608	N/A
Raw Comminuted Chicken#	TBD	Salmonella and Campylobacter	N/A	N/A	5400
Raw Comminuted Turkey#	TBD	Salmonella and Campylobacter	N/A	N/A	3000
Exploratory Retail Ground Pork <sup>+</sup>	PK_RETAIL_GP	Salmonella	N/A	119	0
Exploratory Raw Intact Pork <sup>+</sup>	TBD	Salmonella	1800	N/A	TBD
Exploratory Raw Non-Intact Pork <sup>+</sup>	TBD	Salmonella	N/A	N/A	TBD
Processed Egg Products	EM	Salmonella	1800	736	1600

<sup>\*</sup> In FY14, samples were collected under HC01\_GB, MT43S, and MT43. In FY15, all samples will be under MT43. \*\* FSIS intends to transition from HC11\_BR and HC11\_TU to regular monthly sampling in 2015.

- \*\*\*FSIS intends to begin sampling chicken parts in 2015.
- <sup>±</sup> HC01\_GC and HC01\_TU are used for Category 3<sup>9</sup> establishments producing ground chicken.
- <sup>+</sup> FSIS intends to start a multi-phased raw exploratory sampling project for raw pork products in FY2015.
- #FSIS intends to transition from NRTE\_EXP\_CH and NRTE\_EXP\_TU to regular monthly sampling in 2015.

#### Major Activities in Salmonella and Campylobacter Sampling Projects in FY2014:

- 1. FSIS issued the *Salmonella* Action Plan (SAP), which outlined several actions FSIS will take to drive innovations that will lower *Salmonella* contamination rates, including implementing the New Poultry Inspection System (NPIS), establishing new performance standards; developing new strategies for inspection and throughout the full farm-to-table continuum; addressing all potential sources of *Salmonella*; and focusing the Agency's education and outreach tools on *Salmonella*.
- 2. FSIS informed stakeholders that the Agency will be sampling raw pork products for *Salmonella*; this includes both intact and non-intact raw pork products. Results from this sampling may be used to establish performance standards in these products.
- 3. Based on the results from an exploratory sampling program for raw NRTE comminuted poultry, FSIS is developing new draft performance standards for raw comminuted chicken and turkey for *Salmonella* and *Campylobacter* and a draft *Federal Register Notice* (FRN) to announce and seek comments on the standards.
- 4. Based on the results of the FSIS baseline survey for chicken parts, FSIS is developing draft performance standards for chicken and turkey for *Salmonella* and *Campylobacter* and a draft FRN to announce and seek comments on the standards.
- 5. FSIS discontinued *Salmonella* sampling set procedures for raw ground beef products and began analyzing all raw beef samples for both STECs and *Salmonella*.
- 6. Based on the final rule for the NPIS, FSIS will modernize the Agency's poultry slaughter inspection system. FSIS anticipates the NPIS will prevent at least 5,000 illnesses from *Salmonella* and *Campylobacter* annually by focusing inspectors' duties solely on food safety.
- 7. FSIS assumed Pulsed field Gel Electrophoresis (PFGE) and Antibiotic Susceptibility Testing (AST) analyses formerly conducted by the Agricultural Research Service (ARS) and began conducting PFGE and AST analyses on cecal samples collected for the NARMS sampling project.
- 8. Developed the sampling algorithm to obtain prevalence estimates for *Salmonella* and developed the concept of the moving window for *Salmonella* sampling to achieve process control.

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<sup>&</sup>lt;sup>9</sup> Category 1 establishments have results from their two most recent completed sample sets that are at or below half of the standard. Category 2 establishments have results from their most recent completed sample set that are higher than half of the standard but do not exceed the standard. Category 3 establishments have results from their most recent completed sample set that exceed the standard for Salmonella in young chickens. Please see the following website for more information: http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/salmonella-verification-testing-program/salmonella-verification-testing-program.

# Changes to Salmonella and Campylobacter Sampling Projects Planned for FY2015:

- 1. FSIS intends to publish draft FRN on proposed performance standards for *Salmonella* and *Campylobacter* in chicken parts and raw comminuted chicken and turkey.
- 2. Initiate a new Salmonella and Campylobacter verification sampling project for chicken parts.
- 3. Implement performance standards for raw comminuted poultry.
- 4. Initiate new Salmonella sampling projects for raw pork products.
- 5. Develop a new performance standard for Salmonella in ground beef.
- 6. FSIS intends to change the current set-based sampling for ground chicken, ground turkey, and poultry carcasses to a continuous sampling model using a moving window to evaluate performance.
- 7. Implement the NPIS, which will modernize the Agency's poultry slaughter inspection system.

# Shiga Toxin-producing E. coli (STEC)

# **FSIS Domestic Sampling Projects**

FSIS maintains many adulterant Shiga toxin-producing *E. coli* (STEC) sampling projects for domestic establishments. All STEC sampling is of raw ground beef or raw beef trim. "Bench trim" is trim derived from cattle not slaughtered onsite (i.e., purchased product). "Beef manufacturing trimmings" are trimmings produced from cattle slaughtered onsite. The different STEC sampling projects are summarized in Table 2.

**Table 2: FSIS STEC Domestic Sampling Projects** 

Product Class	Sampling Projects	Pathogen(s)	Planned Number of Samples to Analyze in FY2014	Actual Number of Samples Analyzed in FY2014	Planned Number of Samples to Analyze in FY2015
Raw ground beef	MT43	E. coli O157:H7	12480	12670	12500
Follow-up testing to a raw ground beef positive*	MT44	E. coli O157:H7	N/A	110	N/A
Follow-up testing at supplier establishments following MT43, MT44, or MT55 positive*	MT52	E. coli O157:H7/ Non-O157 (STEC)	N/A	232	N/A
Follow-up testing to an MT60, MT54, MT55, or MT52 positive*	MT53	E. coli O157:H7/ Non-O157 (STEC)	N/A	511	N/A
Raw ground beef components other than trim^	MT54	E. coli O157:H7	620	540	1000
Bench trim^	MT55	E. coli O157:H7	1440	1468	2000
Beef manufacturing trim	MT60	E. coli O157:H7/ Non-O157 (STEC)	2800	3047	4200

<sup>\*</sup> Dependent on positive findings from other *E. coli* O157:H7 or non-O157 (STEC) sampling projects.

<sup>^</sup> The sampling project codes for bench trim and raw ground beef components other than trim will change when the statistical design changes are implemented (when the next revision of FSIS Directive 10,010.1 publishes). The new codes will be MT65 for bench trim and MT64 for the raw ground beef components other than trim program.

#### Major Activities in STEC Sampling Projects in FY2014:

- 1. FSIS computed national prevalence estimates of *E. coli* O157:H7 in raw ground beef for FY2007 FY2013 using data from the MT43 sampling project. This research will be made available on the FSIS website in 2014 and supports the analysis FSIS has already done on prevalence estimation, which is posted on the FSIS website.<sup>10</sup>
- 2. FSIS began a beef and veal carcass baseline survey (See "Other Sampling Programs").
- 3. FSIS began collecting data to support prevalence estimation of *E. coli* O157:H7 and other STEC in beef manufacturing trimmings.
- 4. FSIS announced in an FRN new procedures that will allow the Agency to trace contaminated ground beef and bench trim back to its source more quickly, remove it from commerce, and find the root cause of the incident to prevent it from recurring. FSIS also announced new recall procedures if the establishment was the sole supplier of beef trim for ground beef product.
- 5. FSIS proposed in an FRN requiring that all makers of raw ground beef products keep records in order to further protect consumers by ensuring retailers can trace sources of ground meats.
- 6. FSIS announced updated guidance on pre-harvest management controls and intervention options for reducing STEC shedding in cattle.
- 7. FSIS conducted a risk assessment associated with grinding of boxed beef and store-generated bench trim in retail establishments.

#### Changes Planned to STEC Sampling Projects for FY2015:

- 1. FSIS will implement its redesigned bench trim and non-trim components sampling projects to improve detection of *E. coli* O157:H7 in regulated product using a data-driven approach; the new sampling design is nationally representative and comparable to the existing MT60 and MT43 sampling designs.
- 2. FSIS plans to publish a *Federal Register Notice* announcing the proposed HACCP 2.0 rule and availability of associated beef slaughter guidance.
- 3. FSIS plans to address recommendations made by the Agency Strategic Performance Working Group (SPWG) especially those relating to sanitary dressing procedures.
- 4. FSIS plans to publish the completed analysis on the estimated costs and benefits associated with the implementation of its non-O157 STEC testing on beef manufacturing trimmings and the costs and benefits associated with the potential expansion of its non-O157 STEC testing to ground beef and ground beef components other than beef manufacturing trimmings.
- 5. FSIS plans to reissue FSIS Directive 10,010.1, "Verification Activities for Escherichia coli O157:H7 in Raw Beef Products".

<sup>&</sup>lt;sup>10</sup> For more information, please see the following website: http://www.fsis.usda.gov/wps/wcm/connect/56b2ccbd-ad57-4311-b6df-289822d28115/Prevalence\_Estimates\_Report.pdf?MOD=AJPERES.

# Listeria monocytogenes (Lm) and Salmonella in Ready-to-Eat (RTE) Products

# **FSIS Domestic Sampling Projects**

FSIS conducts microbiological testing of RTE meat and poultry products for *Lm* and *Salmonella*. RTE domestic sampling projects are summarized in Table 3.

Routine product sampling is scheduled every month under the RTEPROD sampling project. For an RTEPROD\_RISK sampling task, only post lethality-exposed product is sampled, and samples are selected based on risk. For an RTEPROD\_RAND sampling task, both post lethality-exposed and non-post lethality-exposed samples are collected, and a randomly selected product is sampled.

Under RLm, establishments producing 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 RLm or RTEPROD.

Table 3: FSIS Domestic Ready-to-Eat (RTE) Sampling Projects for Listeria monocytogenes (Lm) and Salmonella

Product Class	Sampling Projects	Pathogen(s)	Planned Number of Samples to Analyze in FY2014	Actual Number of Samples Analyzed in FY2014	Planned Number of Samples to Analyze in FY2015
Both post lethality-exposed and non- post lethality-exposed RTE products	RTEPROD_RAND	Lm and Salmonella	4400	3424	4400
Post lethality-exposed RTE products	RTEPROD_RISK	Lm and Salmonella	10400	10060	10400
RLm product samples (Composited 5-sample Units)	RLMPRODC	Lm	690	510	690
RLm food contact surface samples	RLMCONT	Lm	6880	5072	6880
RLm non-food contact environmental samples (Composited 5-sample Units)	RLMENVC	Lm	690	516	690
Intensified Verification Testing (IVT) product samples*	INTPROD	Lm or Salmonella	N/A	698	N/A
IVT food contact surface samples*	INTCONT	Lm or Salmonella	N/A	1390	N/A
IVT non-food contact environmental samples*	INTENV	Lm or Salmonella	N/A	741	N/A

<sup>\*</sup>Dependent on positive findings from RTEPROD\_RAND, RTEPROD\_RISK, and RLm sampling projects.

# Major Activities in RTE Sampling Projects for Lm and Salmonella in FY2014:

1. FSIS combined its random ALLRTE and risk-based RTE001 product sampling projects into the RTEPROD project code. The RTEPROD sampling project uses two project identification codes: RTEPROD\_RAND for product samples selected randomly and RTEPROD\_RISK for post-lethality exposed product samples selected based on risk.

# Changes Planned to RTE Sampling Projects for Lm and Salmonella for FY2015:

- 1. FSIS intends to review the Agency's RTE sampling projects and may propose changes to sampling projects based on repeat positives at particular establishments or trends found in particular establishment types (e.g., small establishments).
- 2. FSIS intends to review and update the risk factors associated with the scheduling algorithm for the RTEPROD\_RAND and RTEPROD\_RISK sampling projects.
- 3. FSIS intends to review the current scheduling methodology for RLm.

#### **Chemical Residues**

# **FSIS Domestic Sampling Projects**

FSIS conducts sampling for chemical residues in regulated meat, poultry and egg products. Domestic sampling projects are summarized in Table 4.

**Table 4: FSIS Domestic Sampling Projects for Chemical Residues** 

Sampling Project+	Sampling Project Code	Planned Number of Samples to Analyze in FY2014	Actual Number of Samples Analyzed in FY2014	Planned Number of Samples to Analyze in FY2015
National Residue Program (NRP) <sup>11</sup> (Tier 1)	NRP (animal)	5700*	5571	5700
National Residue Program State Residues <sup>12</sup>	NRP (animal) S	700*	202	700
EU <sup>13</sup>	EU	N/A	326	N/A
KIS™ Test-Field	KIS	N/A	^210086	N/A
KIS <sup>TM</sup> Test –Lab	KIS	N/A	4883	N/A
Dairy Cows with Mastitis and negative KIS test (Tier 2)	N/A	260	275	N/A
Sheep (Tier 2)	NRP_SH	150	161	150
Goats (Tier 2)	NRP_GO	150	146	150

<sup>\*</sup> The NRP consists of a combination of state and federal sampling. The combined 6400 samples are split between federal and state.

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<sup>+</sup> FSIS conducted exploratory testing of turkey products for semicarbazide (SEM) in 2014 in response to questions that arose about long-term exposure of poultry meat to antimicrobial treatments.

<sup>&</sup>lt;sup>11</sup> FSIS maintains three tiers of sampling for the NRP. The three-tiered system is as follows: Tier 1: scheduled sampling (collected as a part of exposure assessment activities), Tier 2: targeted sampling at the production or compound class level, and Tier 3: targeted sampling at the herd/flock or compound class level. FSIS conducts testing in nine production classes: beef cow, bob yeal, dairy cow, steer, heifer, market hog, sow, young chickens, and young turkeys.

<sup>12</sup> State meat and poultry inspection programs that are equivalent to FSIS must conduct residue testing in accordance with current FSIS policies. FSIS assigns

<sup>&</sup>lt;sup>12</sup> State meat and poultry inspection programs that are equivalent to FSIS must conduct residue testing in accordance with current FSIS policies. FSIS assigns residue samples to states using PHIS as part of the NRP.

<sup>&</sup>lt;sup>13</sup> FSIS routinely schedules and collects residue samples from meat and poultry products for products exported to the European Union (EU). These samples, however, are analyzed by an outside contract laboratory, not FSIS.

^ KIS<sup>TM</sup> samples are not scheduled in advance by FSIS; rather they are collected at the discretion of field inspectors and therefore the total number of samples collected and analyzed by FSIS may change markedly from year to year. Please see 2014 Blue Book for more information about the animal classes and methods for which FSIS tests in its National Residue Program.<sup>14</sup>

# Major Activities in Chemical Residue Sampling Programs in FY2014

- 1. FSIS finished an exploratory sampling project requested by the Food and Drug Administration (FDA) (MASTITIS\_DC), applying the in-laboratory multi-residue method (MRM) to collect samples from dairy cows that appeared to have mastitis, but yielded negative KIS<sup>TM</sup> tests.
- 2. Issued the National Residue Program for Meat, Poultry, and Egg Products: 2014 Residue Sampling Plans ("Blue Book"), which provides a summary of the scheduled domestic and imported meat, poultry, and processed egg product sampling plans. <sup>15</sup>
- 3. Began two Tier 2 sampling projects; one for sheep and one for goats. Each project was allocated 150 samples, and 20 sampling tasks per month were assigned

# Changes Planned for Chemical Residue Sampling Programs for FY2015:

- 1. FSIS intends to begin a Tier 2 NRP sampling project for Mature Turkeys, evaluating samples by using the MRM and metals methods
- 2. FSIS will routinely begin using the new hormone method for beef muscle.

<sup>&</sup>lt;sup>14</sup> For more information, please see the following website: http://www.fsis.usda.gov/wps/wcm/connect/533beea8-1bcf-468e-a13b-531232b2af2f/2014-Blue-Book.pdf?MOD=AJPERES.

<sup>&</sup>lt;sup>15</sup> For more information, please see the following website: http://www.fsis.usda.gov/wps/wcm/connect/533beea8-1bcf-468e-a13b-531232b2af2f/2014-Blue-Book.pdf?MOD=AJPERES.

# **Imports**

FSIS maintains a number of different sampling projects for meat, poultry, and egg products imported into the United States. The FSIS sampling project (EGGIMP) for imported egg products tests only for *Salmonella*. There are two primary STEC and *Salmonella* sampling projects for imported beef products: 1) Raw ground beef (MT08) and 2) Trim and other raw ground beef components (MT51); each has a follow-up sampling project in the case of a positive sample (FMT08 and FMT51). FSIS also maintains one verification sampling project (IMVRTE) for *Lm* and *Salmonella* in RTE products from importing countries. Finally, FSIS maintains a chemical residue sampling project for imported product. See Table 6 for more information on the sampling projects.

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<sup>&</sup>lt;sup>16</sup> During FY2014, FSIS transitioned from using separate follow up sampling project codes for MT08 and MT51, which eliminated the need for manual entry of the level of reinspection. Post-transition, follow-ups were conducted under the original sampling project code using the "Intensified" level of reinspection.

**Table 6: FSIS Import Sampling Projects** 

Product Class/Sampling Project	Sampling Project Codes	Pathogen/ Chemical Residue/ Chemistry	Planned Number of Samples to Analyze in FY2014	Actual Number of Samples Analyzed in FY2014	Planned Number of Samples to Analyze in FY2015
Pasteurized imported liquid, frozen or dried egg products	EGGIMP	Salmonella	80	9	80
Imported raw ground beef	MT08	E. coli O157:H7/ Salmonella	10	11	100
Follow up testing to an imported raw ground beef positive	FMT08	E. coli O157:H7/ Salmonella	N/A	0	N/A
Imported trim and other raw ground beef components	MT51	E. coli O157:H7/ Non-O157 (STEC)/ Salmonella	850	632	850
Follow up testing to an imported trim or components positive	FMT51	E. coli O157:H7/ Non-O157 (STEC)/ Salmonella	N/A	26	N/A
Imported intact RTE product	IMVRTE	Lm and Salmonella	2200	3332	2200
Follow up testing to imported intact RTE product	FLISTERIA	Lm	N/A	32	N/A
Follow up testing to imported Intact RTE Product	FRTESALMONEL	Salmonella	N/A	30	N/A
Imported Fresh and Processed Product	Residue	Residue	1550	2106	1550
Import Species Identification	IMPSPECIESID	N/A	Varies*	543	Varies*

<sup>\*</sup>Species sampling occurs for 1 out of every 48 lots reinspected by FSIS.

# Major Activities in Import Sampling Projects in FY2014

1. On May 16, 2014, FSIS announced in the FRN (Docket No FSIS-2012-0038) that imported (and domestic) raw beef samples collected for routine and follow-up sampling projects for STEC also will be analyzed for *Salmonella*. For imported product, this additional testing was fully implemented by the end of FY2014.

# Major Changes Planned for Import Sampling Projects for FY2015:

- 1. FSIS intends to begin analyzing for *Salmonella* in imported raw broiler and turkey carcasses, NRTE comminuted chicken and turkey products, and raw chicken parts in FY2015.
- 2. FSIS is working to eliminate manual procedures currently required for yearly revisions to import project sampling rates for laboratory and other types of inspection within PHIS. As per the design of the PHIS imports module and to achieve the planned yearly number of analyzed samples, automated sampling rates initially will be set on a calendar year basis and adjusted monthly per actual laboratory analyses completed to date.

# **In-Commerce**

FSIS has the following sampling projects at retail:

- 1) E. coli O157:H7 testing in raw ground beef collected at businesses operating under a retail exemption (MT05).
- 2) As of June 29, 2014, retail raw beef samples collected for MT05 were analyzed also for Salmonella.
- 3) Follow-up testing for *E. coli* O157:H7 in raw ground beef products (MT06) scheduled only when an MT05 sample tests positive for *E. coli* O157:H7.

In-commerce sampling projects are summarized in Table 7.

Table 7: FSIS E. coli O157:H7 Sampling Projects for In-Commerce Surveillance

Product Class	Sampling Projects	Pathogen	Planned Number of Samples to Analyze in FY2014	Actual Number of Samples Analyzed in FY2014	Planned Number of Samples to Analyze in FY2015
Raw ground beef at retail stores	MT05	E. coli O157:H7	460	550	460
Raw ground beef at retail stores	MT05	Salmonella	N/A	139	460
Follow-up testing to a MT05			As required as		As required as
sample*	MT06	E. coli O157:H7	follow-up	0	follow-up

<sup>\*</sup> Dependent on positive findings from the MT05 sampling project.

### Major Activities in In-Commerce Sampling Projects in FY2014

1. FSIS collected and analyzed approximately 550 retail MT05 samples; none of the samples tested positive, so no MT06 samples were collected. FSIS monitors retail sampling each quarter to ensure that samples are collected throughout the year and are geographically representative of retail ground beef sales.

# Changes Planned for In-Commerce Sampling Projects for FY2015:

1. FSIS will continue to monitor the number of MT05 retail samples that test positive for *E. coli* O157:H7 and respond appropriately to events that suggest a trend detrimental to public health.

# **Other Sampling Programs**

FSIS also conducts sampling in other areas <sup>17</sup>:

- 1. Fish in the order of Siluriformes
  - a. Fish and products from fish in the order of Siluriformes will not be under FSIS jurisdiction until the effective date of the final rule. Please see Table 8 for information on FSIS' current thinking on the Agency's proposed sampling program. Additionally, FSIS anticipates that the Chemical Residue Multi Residue Method will be extended to Siluriformes.

Table 8: Draft Proposed FSIS Siluriformes Slaughter/Processing Sampling Scheme

Product Class	Sampling Projects	Planned Number of Samples to Analyze	Type of Sample	Pathogen/ Chemical Residue/ Chemistry
Siluriformes	TBD	200	Domestic	Salmonella, Speciation, Metals, Pesticides, Dyes, and possibly Chloramphenicol and Nitrofurans
Siluriformes	TBD	200	Import	Salmonella, Speciation, Metals, Dyes, Pesticides, and possibly Chloramphenicol and Nitrofurans

- 2. Advanced Meat Recovery (AMR01) and Follow-Up AMR (FAMR01)
  - a. 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 project.

#### 2. Baselines

a.

a. FSIS conducts baseline studies for which the Agency collects samples of meat and poultry products to estimate the national prevalence and levels of bacteria of public health concern. Each report produced after the completion of a baseline study is a compilation of data obtained for a particular species or type of animal or product.

<sup>&</sup>lt;sup>17</sup> The USDA Animal and Plant Health Inspection Service (APHIS) conducts an on-going surveillance program for bovine spongiform encephalopathy (BSE) where 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, <a href="http://www.fsis.usda.gov/wps/wcm/connect/09bf6ed8-1e4b-4ef5-a3e1-fa454b116b8e/10400.1.pdf?MOD=AJPERES.">http://www.fsis.usda.gov/wps/wcm/connect/09bf6ed8-1e4b-4ef5-a3e1-fa454b116b8e/10400.1.pdf?MOD=AJPERES.</a>

# 3. National Antimicrobial Resistance Monitoring System (NARMS)

a. NARMS is a national public health surveillance system that tracks antibiotic resistance in foodborne bacteria. NARMS monitors antimicrobial susceptibility among enteric bacteria from humans, retail meats, and food animals. The major bacteria currently under surveillance are *Salmonella*, *Campylobacter*, *E. coli*, and *Enterococcus*. In FY2013, FSIS began collecting intestinal cecal samples from cattle (steer, heifer, dairy cow, and beef cow), swine (market swine and sows), young chickens, and young turkeys presented for slaughter at FSIS-inspected establishments for the pathogens listed above. While FSIS schedules, collects, and analyzes livestock and poultry samples for the NARMS program, the remaining samples are analyzed by non-FSIS laboratories.

#### 4. Pathology Testing

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

## 5. Foodborne Illness Outbreak Sampling

a. 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. Food Chemistry

a. 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.

# 7. Compliance Testing

a. 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.

These projects are described in Table 9.

<sup>&</sup>lt;sup>18</sup> For more information about the NARMS program, please see the following website: http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm.

**Table 9: FSIS Other Sampling Programs** 

Type of Sampling Project	Project Codes	Planned Number of Samples to Analyze in FY2014	Actual Number of Samples Analyzed in FY2014	Planned Number of Samples to Analyze in FY2015
Advanced Meat Recovery	AMR01	180	129	150
Follow-up testing to a AMR01 Sample*	FAMR01	N/A	13	N/A
Baselines	Multiple	2660	1114	TBD
NARMS	NARMS [animal]	6000	5270	5400
$Pathology^{\scriptscriptstyle +}$	multiple	N/A	4089	N/A
Outbreaks <sup>+</sup>	multiple	N/A	3519	N/A
Compliance Testing <sup>+</sup>	COMPLIAN	N/A	136	N/A

<sup>\*</sup> Dependent on positive findings from the AMR01 sampling project.

## Major Activities in Other Sampling Programs in FY2014

- 1. The Nationwide Beef and Veal Carcass Microbiological Baseline Data Collection Program began on Aug 1<sup>st,</sup> 2014. FSIS will continue to collect samples for 12 months (through July 31, 2015).
- 2. FSIS conducted intensified testing of raw chicken products in response to the outbreak investigation and foodborne illnesses associated with *Salmonella* Heidelberg in 2013-2014, as well as additional intensified testing to respond to other persistent non-compliance situations, foodborne outbreaks, and related events in FY2014.

### Changes Planned for Other Sampling Programs for FY 2015:

1. In addition to potentially extending microbiological and chemical residue sampling to fish in the order of Siluriformes, FSIS anticipates revising the current version of the Chemistry Laboratory Guidebook (CLG) Multi Residue Method 1.04 (MRM1.04).

<sup>+</sup> Samples for these projects are not planned in advance, but rather are collector-generated in the field based on inspector findings or other circumstances.