Food Safety and Inspection Service's Annual Sampling Program Plan

Microbiological and Residue Sampling Programs

Fiscal Year 2012

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1.0 Introduction

Background

The overall purpose of FSIS inspection and sampling is to verify that establishments maintain control of their production processes and adhere to FSIS regulations, policies, and performance standards, which FSIS believes helps protect the public from foodborne illnesses.

FSIS inspects meat, poultry and processed egg product establishments to ensure that the food produced is safe, wholesome and properly labeled. A key component of FSIS' inspection activities is regular sampling of product to test for microbiological contaminants or violative levels of residues. This plan addresses microbiological and residue sampling programs in domestic establishments, imports, and in-commerce facilities and describes FSIS' overall strategy for directing its sampling resources for fiscal year (FY) 2012.

Several of FSIS' sampling programs consist of regularly scheduled samples that are submitted to FSIS testing laboratories for one or more laboratory tests. This process typically consists of a sample request sent to Inspection Program Personnel (IPP) who collect the samples and ship them to one of three FSIS testing laboratories where the sample is tested for microbiological contaminants and/or chemical residues. Different tests are performed depending on the type of sample and the sampling program. For example, raw ground beef is usually tested for *E. coli* O157:H7, but can also be tested for *Salmonella*. Further, starting in June 2012, FSIS will begin a testing program for six non-O157 Shiga Toxin-Producing *Escherichia coli* (STECs). Finally, some sampling programs are triggered by positive test results from other programs and so they are not considered to be regularly scheduled. In addition to microbiological and residue sampling and testing, FSIS intends to conduct limited, non-routine nutritional analyses of products required to bear nutrition information on their labels.

In FY2012, FSIS plans to schedule approximately 100,000 domestic microbiological samples, 216,000 domestic chemical residue samples, 6,600 import microbiological and residue samples, and 460 in-commerce microbiological samples. The FSIS pathogen and program-specific sample scheduling numbers planned for FY2012 are provided in this report. 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. Remarks are included where significant changes to sampling programs or projects have occurred or are planned for the fiscal year. Finally, this report does not include sample scheduling numbers for FSIS baseline studies or outbreak investigation sampling.

Finally, it is important to note that the number of samples scheduled to be collected in FY2012 may differ from the total number of samples collected and analyzed over the same period. This discrepancy occurs for a variety of reasons, including that not all sample requests are able to be collected by FSIS IPP. The Agency anticipates, with the full implementation of the Public Health Information System (PHIS) at the start of calendar year 2012, sample collection rates will markedly improve.

FSIS Sampling and 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*[1] and the *Data-Driven Inspection for Processing and Slaughter Establishments: Public Health Decision Criteria*.[2] 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's Microbiological and Residue Sampling Programs* in December 2011, which identifies all of FSIS' sampling programs and discusses the statistical and policy basis for the programs.[3] The release of this FY2012 Sampling Program Plan continues FSIS' efforts to comprehensively identify Agency microbiological and chemical residue sampling activities and consider them in light of data-driven strategic planning efforts.

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

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

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

Salmonella* and *Campylobacter

FSIS Domestic Sampling Projects

FSIS collects *Salmonella* samples in eight raw meat and poultry product classes (*Salmonella* Pathogen Reduction Performance Standards—project codes HC01 and HC11)[4], two RTE meat and poultry products (project codes ALLRTE and RTE001) and nine processed egg products categories (project codes EM). Broiler and turkey samples collected under HC11 are co-analyzed for *Campylobacter*. 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. Information on different domestic *Salmonella* sampling projects is summarized in Table 1.

Table 1: FSIS *Salmonella* and *Campylobacter* Domestic Sampling Projects

Product class	Sampling Projects	Pathogen	Number of Samples Analyzed FY2011	Number of Samples to be Scheduled FY2012
Steers/heifers	HC01	*Salmonella*	3,469	Program Suspended[5]
Cows/bulls	HC01	*Salmonella*	877	Program Suspended[6]
Raw ground beef	HC01	*Salmonella*	10,536	9,000[7]
Market hogs	HC01	*Salmonella*	2,410	Program Suspended[8]
Broilers	HC01 HC11	*Salmonella* and *Campylobacter*	4,512	10,000[9]

[4] As of July 1, 2011 all broiler and turkey sets are being co-analyzed for *Campylobacter* and scheduled as HC11, not HC01.

[5] Sample sets for Market Hogs, Cows/Bulls, or Steers/Heifers were not scheduled in the latter half of FY2011 as the positive pathogen rate was so low in these products that 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. FSIS *Salmonella* sample collection in these classes will continue to be suspended in FY2012, allowing for the redirection of samples to other projects. However, if a need arises, based on positive sample results or other events, FSIS can and will conduct "for-cause" *Salmonella* sampling in carcasses.

[6] Supra footnote 5

[7] FSIS is evaluating the feasibility of reallocating *Salmonella* samples collected as a part of a set for raw ground beef products. Specifically, rather than performing a *Salmonella* test on raw ground beef in a sample set, FSIS would perform an additional pathogen analysis for *Salmonella* on raw ground beef samples already collected as a part of the regular MT43 raw ground beef *E. coli* O157:H7 sampling project. Additional samples could therefore be collected in other products, such as beef trim or broiler chickens.

[8] Supra footnote 5.

[9] Number is an estimate based on the total number of establishments scheduled per month for FY2012 (broiler=16, turkey=4), multiplied by the total number of samples collected in a given set (broiler=53, turkey=56) and then multiplied by 12 to achieve a yearly total. More samples are being scheduled for collection given the implementation of the new performance standards and the need to complete two sets in every establishment in the next two years.

Product class	Sampling Projects	Pathogen	Number of Samples Analyzed FY2011	Number of Samples to be Scheduled FY2012
Ground chicken	HC01	*Salmonella*	474	4,000[10]
Turkeys	HC01 HC11	*Salmonella* and *Campylobacter*	1,141	1,300[11]
Ground turkey	HC01	*Salmonella*	745	4,000[12]
Raw ground beef	MT43S[13]	*Salmonella*	4,144	2,500[14]
RTE meat and poultry products	ALLRTE	*Salmonella*	3,270	4,400
RTE meat and poultry products	RTE001	*Salmonella*	8,740	10,400
Processed Egg Products	EM	*Salmonella*	1,425	1,400
Poultry Parts	TBD	*Salmonella* and *Campylobacter*	TBD	TBD[15]

Changes to Salmonella and Campylobacter Sampling Programs Planned for FY2012:

1. FSIS has suspended the Agency's *Salmonella* PR/HACCP sampling in beef carcasses and market hog carcasses.[16] There is no immediate plan to resume sampling in 2012 other than "for cause."

***E. coli* O157:H7**

FSIS Domestic 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.

[10] In early CY2012, FSIS anticipates issuing a Federal Register Notice informing stakeholders that the Agency will be sampling both comminuted and ground poultry products during *Salmonella* and *Campylobacter* set sampling.
[11] Supra footnote 9.
[12] Supra footnote 10.
[13] The MT43S sampling project is actually an additional pathogen test run on an MT43 *E. coli* O157:H7 sample. For this reason, the number of tests depends upon the distribution of MT43 sampling resources over the volume groups.
[14] FSIS is evaluating the feasibility of reallocating *Salmonella* samples collected as a part of a set for raw ground beef products. Specifically, rather than performing a *Salmonella* test on raw ground beef in a sample set, FSIS would perform an additional pathogen analysis for *Salmonella* on raw ground beef samples already collected as a part of the regular MT43 *E. coli* O157:H7 sampling project. Additional samples could therefore be collected in other products, such as beef trim or broilers.
[15] Based on the result of the FSIS baseline survey currently underway for chicken parts, FSIS will initiate a new *Salmonella* and *Campylobacter* sampling program in chicken and other poultry parts. This program is anticipated to start in FY2013.
[16] Supra footnote 5.

Table 2: FSIS *E. coli* O157:H7 Domestic Sampling Projects

Product Type	*E. coli* Sampling Projects	Number of *E. coli* Samples Analyzed FY2011	Number of Samples to be Scheduled FY2012
Raw ground beef	MT43	12,030	15,600
Follow up testing to a raw ground beef positive*	MT44	169	170
Beef Manufacturing trim	MT50	1,224	2,600
Raw ground beef components other than trim	MT54	207	780
Bench trim	MT55	651	1,800
Follow up testing at supplier establishments following MT43, MT44, or MT55 positive*	MT52	496	500
Follow up testing to a MT50, MT54, MT55, or MT52 positive*	MT53	159	160

* Dependent on positive findings from other *E. coli* O157:H7 sampling projects.

Changes Planned to E. coli O157:H7 Sampling Programs for FY2012:

1. FSIS intends to begin testing for six non-O157 STECS in raw beef trim and other components in June 2012. This should not affect sample collection numbers, but will increase the lab testing numbers for these programs.
2. In response to the Office of the Inspector General (OIG) audit of the FSIS N60 Sampling Program, FSIS plans to announce in the *Federal Register* that it intends to develop a more targeted and risk-based approach to its sampling and testing programs for beef manufacturing trimmings and other raw ground beef components. FSIS intends to ask for comment on this approach.
3. FSIS is considering changes in follow-up sampling and testing related to traceback for *E. coli* O157:H7.

Ready-to-Eat (RTE) for *Salmonella* and *Listeria monocytogenes (Lm)*

FSIS Domestic Sampling Projects

FSIS conducts microbiological testing of RTE meat and poultry products for *Listeria monocytogenes (Lm)* and *Salmonella*.[17] *Lm* domestic sampling projects are summarized in Table 3.

[17] 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. 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.

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

Product class	RTE Sampling Projects	Pathogens Tested	Number of FY2011 Samples analyzed	Number of Samples to be Scheduled FY2012
Both post-lethality exposed and non-post-lethality exposed RTE products	ALLRTE	*Lm*, *Salmonella*	3,270	4,420
Post-lethality exposed RTE products	RTE001	*Lm*, *Salmonella*	8,740	10,400
RLm product samples	RLMPROD	*Lm*	1,970	3,700[18]
RLm food contact surface samples	RLMCONT	*Lm*	6,790	8,600
RLm non-food contact environ. samples (Comp. 5-sample Units; *Lm*)	RLMENVC	*Lm*	690	860
IVT product samples*	INTPROD	*Lm* or *Salmonella*	470	470
IVT food contact surface samples*	INTCONT	*Lm* or *Salmonella*	1,740	1,740
IVT non-food contact environmental samples*	INTENV	*Lm* or *Salmonella*	985	990

*Dependent on positive findings from ALLRTE, RTE001and RLm sampling projects.

Changes Planned to RTE Sampling Projects for Salmonella and Lm for FY2012:

1. No significant changes to *Lm* sampling in ready-to-eat products are approved at this time.[19]

Chemical Residues

FSIS Domestic Sampling Projects

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

[18] FSIS is considering a proposal to change from 3 to 5 RLMPROD samples per sampling unit, coupled with the compositing of 25 gram test portions from each of the 5 samples per sampling unit into a single 125 gram composite sample. A similar increase from 3 to 5 INTPROD samples per sampling unit, but with no compositing (e.g., samples to be tested as 5 individual 25 gram test portions), is also undergoing review. The changes to RLMPROD and INTPROD are being proposed in part to achieve consistency with *Codex Alimentarius* guidelines for testing of RTE meat and poultry products for *Lm*.

[19] Supra footnote 18.

Table 4: FSIS Domestic Sampling Projects for Chemical Residues

Residue Sampling Projects	Number of Residue Analyzed samples FY2011	Number of Samples to be Scheduled FY2012
Routine-NRP[20]	15,873	6,400*[21]
KIS™ Test-Field	181,126	181,000
KIS™ Test –Lab[22]	5,791	6,000
FAST-Field	21,479	21,480
FAST-Lab	564	1,000

*Tier 1 Residue Samples are those that are collected as a part of exposure assessment activities.

Changes Planned for Chemical Residue Sampling Programs FY2012:

1. The U.S. National Residue Program (NRP) Blue Book provides a summary of the scheduled domestic and imported meat, poultry, and egg product sampling plans. Detailed discussions describing the principles and methods used to plan and design the NRP sampling plans for 2012 will be provided when the report is released

Imports

The FSIS sampling project for imported processed egg products tests only for *Salmonella* (EGGIMP). There are two primary *E. coli* O157:H7 sampling projects for imported beef products: 1) Raw ground beef (MT08) and 2) Raw, non-intact beef (MT51). FSIS also maintains one sampling project (IMVRTE) for *Salmonella* and *Lm* in RTE products from importing countries. Finally, FSIS maintains a chemical residue sampling program for imported product.

Table 5: FSIS Import Sampling Projects

Product Type/Class	Pathogen/ Compound of Concern	Sampling Project	Total Samples Analyzed FY2011	Number of Samples to be Scheduled FY2012
Pasteurized imported liquid, frozen or dried egg products	*Salmonella*	EGGIMP	63	75
Imported raw ground beef	*E. coli O157:H7*	MT08	8	10
Trim and other raw ground beef components	*E. coli O157:H7*	MT51	848	850

[20] National Residue Program (NRP) samples for meat, poultry and processed egg products, as well as residue monitoring and inspector generated samples.

[21] Values for the number of samples analyzed in FY2011 differs from the total number of samples to be scheduled in FY2012 as FSIS schedules fewer samples for residue testing, but analyzes each sample for more analytes.

[22] Includes verification/confirmation sampling conducted by the FSIS laboratories and confirmatory KIS™ tests on field positives.

Product Type/Class	Pathogen/ Compound of Concern	Sampling Project	Total Samples Analyzed FY2011	Number of Samples to be Scheduled FY2012
Imported Intact RTE Product	*Salmonella*	IMVRTE	2,198	2,200
Imported Intact RTE Product	*Lm*	IMVRTE	2,213	2,200
Imported Intact RTE Product	*E. coli 0157:H7*	IMVRTE	66	Discontinued[23]
Imported Fresh and Processed Product	Residue	Residue	2,792	1,300[24]

Major Changes Planned for Import Sampling Programs for FY2012:

1. FSIS intends to begin testing for six non-O157 STECS in raw beef trim and other components in imported products. This should not affect sample collection numbers, but will increase the lab testing numbers for these programs.

In Commerce

Overview of Sampling Programs

FSIS has the following sampling projects 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

These projects are described in Table 6.

Table 6: FSIS *E. coli* O157:H7 Sampling Projects for In-Commerce Surveillance

Products	Sampling Projects	Total Samples analyzed in FY2011	Number of Samples to be Scheduled FY2012
Raw ground beef at retail stores	MT05	1280	460[25]
Follow-up testing to a MT05 sample*	MT06	0	0

* Dependent on positive findings from the MT05 sampling project.

[23] Supra footnote 1717.

[24] Values for the number of samples analyzed in FY2011 differs from the total number of samples to be scheduled in FY2012 as FSIS schedules fewer samples for residue testing, but analyzes each sample for more analytes.

[25] Please see description in text for explanation of samples to be scheduled in FY2012.

Changes Planned for In-Commerce Sampling Programs for FY2012:

In September 2011, as a result of a formal review of FSIS in-commerce activities by the National Academies of Science (NAS), the Agency switched retailers from Tier 2 to Tier 3, making them lower priority for Agency surveillance.[26, 27] As Tier 3 businesses, retailers will be surveilled only "for cause."[28] To address the change in how retail businesses are surveilled and the implications for retail sampling, the sampling program was modified in October 2011 to collect a 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%, and a 90% probability of detecting one or more positives if the true percent positive is 0.5%. If every FSIS Compliance Investigator (CI) collects approximately one sample quarterly, this will produce about 460 samples per year distributed evenly through the year and around the country. FSIS will monitor the number of retail samples that test positive for *E. coli* O157:H7 and respond appropriately to events that suggest a trend detrimental to public health.

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

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

[28] Tier 1 and Tier 2 businesses, generally, have significant inherent hazards, handle large volumes of meat, poultry, and processed 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.