Food Safety and Inspection Service's Annual Sampling Program Plan

Microbiological and Residue Sampling Programs Fiscal Year 2013

> United States Department of Agriculture Food Safety and Inspection Service

> > November 2012

1.0 Introduction

Introduction

The Food Safety and Inspection Service (FSIS) within the United States Department of Agriculture (USDA) inspects meat, poultry and processed egg product establishments to ensure that the food produced in them is safe, wholesome and properly labeled. A key component of FSIS' inspection activities is regular sampling of product to test for microbiological contaminants and/or chemical residues. The overall purpose of FSIS inspection and sampling is to verify that establishments' adhere to Agency regulations, policies, and performance standards, which FSIS believes helps protect the public from foodborne illnesses.

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 Inspection¹ 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' 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 In February 2012, FSIS released the Agency's Annual Sampling Program Plan, Fiscal Year 2012.⁴ The Fiscal Year (FY) 2012 Plan described FSIS' major activities related to microbiological and chemical residue sampling in domestic establishments, imports, and in-commerce facilities in FY2011 and described the Agency's overall strategy for directing its sampling resources for FY2012. The release of the FY2012 Plan continued FSIS' efforts to comprehensively identify Agency microbiological and chemical residue sampling activities and consider them in light of data-driven strategic planning efforts.⁵ This new FY2013 Plan seeks to accomplish similar goals, by describing FSIS' major activities related to microbiological and chemical residue sampling programs in domestic establishments, imports, and in-commerce facilities in FY2012 and describing the Agency's overall strategy for directing its sampling resources in FY2013.

³ Please see the following website for more information:

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.

 $http://www.fsis.usda.gov/PDF/FSIS_Sampling_Programs_Report.pdf.$

⁴ Please see the following website for more information:

http://www.fsis.usda.gov/PDF/Sampling_Program_Plan_FY2012.pdf

⁵ Please see the following website for more information: http://www.fsis.usda.gov/PDF/Sampling_Program_Plan_FY2012.pdf.

Background

The process of scheduling, collecting and analyzing routine samples typically consists of a sample request assigned to FSIS Inspection Program Personnel (IPP) through the Agency's Public Health Information System (PHIS) or via paper forms mailed to the IIP.⁶ The IPP then collect and ship the samples to one of three FSIS testing laboratories, where the sample is tested for microbiological contaminants or chemical residues. Different tests are performed depending on the type of sample and the sampling program for which the sample was collected. For example, raw ground beef is usually tested for *E. coli* O157:H7, but can also be tested for *Salmonella*. In contrast, some sampling programs are triggered by positive test results from other programs and so they are not considered to be regularly scheduled. In general, sampling for a specific pathogen, such as *Salmonella*, is referred to in this plan as a "sampling program", whereas individual sampling for specific pathogens, such as HC01 for *Salmonella*, is considered a "sampling project".

In addition to microbiological and chemical residue sampling and testing, FSIS intends to conduct limited, non-routine nutritional analyses of products required to bear nutrition information on their labels. In FY2013, FSIS will also consider whether and how to collect verification samples from Cooperative Interstate Systems (i.e., "the same as") inspection systems, to be consistent with the verification testing conducted for product from foreign inspection systems.

All tables in this plan contain the following information; 1) the number of samples that were planned to be scheduled in FY2012⁷, 2) the number of samples actually scheduled in FY2012, 3) the number of samples actually analyzed in FY2012, and 4) the number of samples that are planned to be scheduled in FY2013. In FY2013, FSIS plans to schedule approximately 100,000 domestic microbiological samples, 7,000 domestic chemical residue samples, 2,200 import microbiological and chemical residue samples, and 460 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. 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 outbreak investigations. FSIS also has several other sampling programs either currently operating or scheduled to begin FY2013. These are described in this plan and include Advanced Meat Recovery (AMR), baseline studies, a Dioxin study, and a National Antimicrobial Resistance Monitoring System (NARMS) sampling program.

⁶ PHIS is used to send electronic sampling forms to IPP in establishments that use PHIS (federal meat and poultry establishments and import establishments). Paper forms are used for all other sampling forms (processed egg product establishments, state establishments, and in-commerce facilities). The transition from paper to electronic forms occurred through FY12. At the time this document was published, Egg, In Commerce, RLm, and IVT forms were still paper forms.

⁷ The total number of samples planned to be scheduled in FY2012 was included in the *FSIS Annual Sampling Program Plan, Fiscal Year 2012.* Please see the following website for more information: http://www.fsis.usda.gov/PDF/Sampling_Program_Plan_FY2012.pdf.

Finally, it is important to note that the number of samples that were anticipated to be scheduled in FY2012⁸ may differ from the total number of samples analyzed over the same period. This discrepancy occurs for a variety of reasons, including that FSIS IPP are generally not able to collect all sample requests received, and changes in the sampling frames due to more complete PHIS establishment profile data precluded full collection of all scheduled samples. This same discrepancy may exist moving forward for samples scheduled in FY2013.

⁸ Please see the following website for more information: http://www.fsis.usda.gov/PDF/Sampling_Program_Plan_FY2012.pdf.

Salmonella and Campylobacter

FSIS Domestic Sampling Projects

FSIS conducts *Salmonella* sampling through a variety of projects. Sampling is conducted for the *Salmonella* Pathogen Reduction Performance Standards in two projects (codes HC01 and HC11) and broiler chicken and turkey carcasses collected under HC11 are co-analyzed for *Campylobacter*. Project codes ALLRTE and RTE001 are used to collect samples of ready-to-eat (RTE) meat and poultry products (see table 3). Project code EM is used to collected samples of processed egg products in nine product categories. 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 the different domestic *Salmonella* sampling projects is summarized in Table 1.

Product class	Sampling Projects	Pathogen	<i>Planned</i> Number of Samples Scheduled in FY2012	Number of Samples Scheduled in FY2012	Number of Samples Analyzed FY2012	<i>Planned</i> Number of Samples Scheduled in FY 2013
Raw ground beef	HC01	Salmonella	9,000	22,040 ¹⁰	$15,409^{10}$	15,000 ¹¹
Broilers ¹²	HC01/HC11	Salmonella and Campylobacter	10,000	13,016	9,244	15,000 ¹³

Table 1: FSIS Salmonella and Campylobacter Domestic Sampling Projects⁹

⁹ Salmonella sample sets for Market Hogs, Cows/Bulls, and Steers/Heifers were suspended in the latter half of FY2011 to allow for the redirection of samples to other projects. However, if a need arises, FSIS can and will conduct "for-cause" Salmonella sampling in carcasses.

¹⁰ The implementation of PHIS resulted in more complete establishment product information, which caused the raw ground beef sampling frame to change.

¹¹ 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. Therefore, samples to be scheduled in FY2013 may change based on implementation of this new, merged *Salmonella* sampling project.

¹² As of July 1, 2011, all broiler chicken and turkey sets were co-analyzed for *Campylobacter* and scheduled as HC11, not HC01.

¹³ Number provided is an estimate based on the total number of establishments scheduled per month for FY2012 (broiler=25, turkey=5), multiplied by the total number of samples collected in a given set (broiler=51, 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	<i>Planned</i> Number of Samples Scheduled in FY2012	Number of Samples Scheduled in FY2012	Number of Samples Analyzed FY2012	<i>Planned</i> Number of Samples Scheduled in FY 2013
Ground chicken ¹⁴	HC01	Salmonella	4,000	5,759	1,221	12,000
Turkeys ¹⁵	HC01/HC11	Salmonella and Campylobacter	1,300	2,581	2,241	2,500
Ground turkey ¹⁶	HC01	Salmonella	4,000	2,307	969	5,500
Raw ground beef ¹⁷	MT43S	Salmonella	2,500	5,695	2,241	4,000
Processed Egg Products	EM	Salmonella	1,400	2,411	1,531	1,400
Poultry Parts ¹⁸	TBD	Salmonella and Campylobacter	TBD	TBD	TBD	TBD

Table 1 (cont.): FSIS Salmonella and Campylobacter Domestic Sampling Projects

Major Activities in Salmonella and Campylobacter Sampling Projects in FY2012:

^{1.} Using new data from PHIS, FSIS refined the Agency's scheduling algorithm for *Salmonella* to better define establishments that are eligible for sampling.

¹⁴ In FY2013, FSIS anticipates issuing a Federal Register Notice informing stakeholders that the Agency will be sampling all types of comminuted poultry products during *Salmonella* and *Campylobacter* set sampling (ground, mechanically separated, and other non-intact poultry).

¹⁵ As of July 1, 2011, all broiler chicken and turkey sets were co-analyzed for *Campylobacter* and scheduled as HC11, not HC01.

¹⁶ In FY2013, FSIS anticipates issuing a Federal Register Notice informing stakeholders that the Agency will be sampling all types of comminuted poultry products during *Salmonella* and *Campylobacter* set sampling (ground, mechanically separated, and other non-intact poultry).

¹⁷ The MT43S sampling project is an additional pathogen test run on an MT43 *E. coli* O157:H7 sample in low-volume raw ground beef establishments. For this reason, the number of samples depends upon the distribution of MT43 sampling resources over the volume groups.

¹⁸ Based on the result of a FSIS baseline survey for chicken parts, the Agency may initiate a new *Salmonella* and *Campylobacter* sampling project in chicken and other poultry parts.

Changes to Salmonella and Campylobacter Sampling Projects Planned for FY2013:

- 1. FSIS anticipates issuing a *Federal Register* Notice (FRN) informing stakeholders that the Agency will be sampling all comminuted poultry products during *Salmonella* and *Campylobacter* set sampling; this includes ground poultry, mechanically separated poultry, and other non-intact types of poultry. This FRN will also announce a sampling program in raw ground and comminuted poultry. Results from this program will be used to compute updated performance standards in these products.
- 2. Based on the results of the FSIS baseline survey for chicken parts, FSIS may initiate a new *Salmonella* and *Campylobacter* sampling program in chicken and other poultry parts.

Shiga toxin producing E. coli (STEC)

FSIS Domestic Sampling Projects

FSIS maintains many Shiga toxin producing *E. coli* (STEC) sampling projects for domestic establishments. The different STEC sampling projects are summarized in Table 2.

Table 2: FSIS STEC Domestic Sampling Projects

Product class	Sampling Projects	Pathogen	<i>Planned</i> Number of Samples Scheduled in FY2012	Number of Samples Scheduled in FY2012	Number of Samples Analyzed FY2012	<i>Planned</i> Number of Samples Scheduled in FY 2013
Raw ground beef	MT43	<i>E. coli</i> O157:H7	15,600	15,380	11,643	15,600
Follow up testing to a raw ground beef positive*	MT44	<i>E. coli</i> O157:H7	170^	200	85	N/A
Beef Manufacturing trim	MT50/ MT60 ^{19,20}	<i>E. coli</i> O157:H7/ Non-O157 (STEC)	2,600	3,070 ²¹	1,940 ²²	3,500 ²³
Raw ground beef components other than trim	MT54	<i>E. coli</i> O157:H7	780	772	278	780

 $^{^{19}}$ MT50 was replaced by MT60 on May 1st, 2012. The MT60 project is data-driven and allows large establishments to be scheduled multiple times during the same month. The MT60 sampling window is two months instead of the standard one month to facilitate collection in small and very small establishments.

²⁰ In 2012, FSIS began conducting additional STEC testing in manufacturing trimmings from product slaughtered after June 4, 2012.

²¹ On June 1st, 2012, FSIS began over-scheduling MT60 to adjust for non-response and seasonal scheduling. This resulted in an increased number of samples being scheduled during the high *E. coli* prevalence season.

²² The relative frequency of beef manufacturing trim sampled and analyzed by FSIS for *E. coli* O157:H7 and non-O157 STEC is available on the FSIS website at: http://www.fsis.usda.gov/Science/RGBC_STEC_Results/index.asp.

²³ The higher number of samples to be scheduled in FY2013 is representative of over-scheduling to increase the number of samples actually collected to 2,600.

Product class	Sampling Projects	Pathogen	<i>Planned</i> Number of Samples Scheduled in FY2012	Number of Samples Scheduled in FY2012	Number of Samples Analyzed FY2012	<i>Planned</i> Number of Samples Scheduled in FY 2013
Bench trim	MT55	<i>E. coli</i> O157:H7	1,800	1,933	784	1,800
Follow up testing at supplier establishments following MT43, MT44, or MT55 positive*	MT52	<i>E. coli</i> O157:H7/ Non-O157 (STEC)	500^	324	225 ²⁴	N/A
Follow up testing to a MT50, MT54, MT55, or MT52 positive*	MT53	<i>E. coli</i> O157:H7/ Non-O157 (STEC)	160^	545	316 ²⁵	N/A

Table 2 (cont.): FSIS STEC Domestic Sampling Projects

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

^ Estimated based on historical sampling information.

Major Activities in STEC Sampling Projects in FY2012

- FSIS began testing for six non-O157 STECs in raw beef manufacturing trimmings from product slaughtered after June 4th, 2012. Non-intact products that have entered commerce and found to be contaminated with these pathogens, which can cause severe illness and even death, will be subject to recall.
- 2. On May 7th, 2012, FSIS announced in a FRN new procedures when FSIS or other Federal or State agencies find raw ground beef presumptive positive for *E. coli* O157:H7. This methodology will enable FSIS to better determine whether the establishments that produced the source materials for contaminated product have produced other product that may not be

²⁴ In 2012, FSIS began conducting additional STEC testing in manufacturing trimmings from product slaughtered after June 4, 2012. Not all product collected under MT52 is manufacturing trimmings.

²⁵ In 2012, FSIS began conducting additional STEC testing in manufacturing trimmings from product slaughtered after June 4, 2012. Not all product collected under MT52 is manufacturing trimmings.

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microbiologically independent from the contaminated product. At the same time, FSIS also announced its intention, as a matter of routine policy, to request a recall if an establishment was the sole supplier of beef trim source materials for ground product that FSIS or other Federal or State agencies find positive for *E. coli* O157:H7. Finally, this Notice announced the availability of compliance guidelines concerning establishment sampling and testing for shiga toxin-producing *E. coli* (STEC) organisms or virulence markers and compliance guidelines for *E. coli* O157:H7 sampled and tested labeling claims.²⁶

- 3. Based upon statistical research,²⁷ FSIS redesigned its beef manufacturing trimmings sampling project to improve detection of O157:H7 in regulated product using a data-driven approach. The new MT60 sampling project, which was implemented in May 2012, replaces the MT50 sampling project. A FRN²⁸ related to the Office of the Inspector General (OIG) audit of the FSIS N60 Sampling Program was also released. The Agency initially announced the implementation of the new design on April 12th, 2012 in FSIS Notice 27-12. This Notice also announced a change in the sampling window for the MT60 beef manufacturing trimmings project to a 60 day sampling window.
- 4. FSIS announced in FSIS Notice 35-12, dated May 25th, 2012, that the Agency changed its collection method in the *E. coli* sampling programs to using Whirl-Pak bags marked with a fill-line. This fill-line was added to the bag so that each bag will hold 325 grams of ground beef or trim. Under the N60 collection method, each bag is designed to hold 30 pieces if filled to the fill-line. FSIS clarified this Notice with FSIS Notice 56-12, dated September 14th, 2012, with additional instructions for ground beef.

Changes Planned to STEC Sampling Projects for FY2013:

1. In FY2013, FSIS will consider whether and how a targeted non-O157 STEC sampling program for veal could be conducted, as well as ensure that "hide on" and "swinging" carcasses are sampled, since trim may not be produced at the slaughter establishment; thereby preventing the collection of valuable information about the slaughter sanitary dressing process.

²⁶Please see the following website for more information:

http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2011-0009.htm.

²⁷ Berg-Devney, Sarah. Redesign of FSIS Sampling Methodologies to Improve Detection of *E. coli* O157:H7. (March 2012) See:

http://www.fsis.usda.gov/PDF/Redesign_Beef_Trim_Sampling_Methodology.pdf.

²⁸ Risk-Based Sampling of Beef Manufacturing Trimmings for *Escherichia coli* (*E. coli*) O157:H7 and Plans for Beef Baseline (Sep 19, 2012) Docket No. FSIS-2012-0020. See: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2012-0020.pdf.

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*. RTE domestic sampling projects are summarized in Table 3.

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

Product class	Sampling Projects	Pathogen	<i>Planned</i> Number of Samples Scheduled in FY2012	Number of Samples Scheduled in FY2012	Number of Samples Analyzed FY2012	<i>Planned</i> Number of Samples Scheduled in FY 2013
Both post-lethality exposed and non-post- lethality exposed RTE products	ALLRTE	Lm	4,400	3,776	3,342	4,400**
Post-lethality exposed RTE products	RTE001	Lm	10,400	8,921	7,722	10,400**
RTE meat and poultry products	ALLRTE	Salmonella	4,400	3,776	3,339	4,400**
RTE meat and poultry products	RTE001	Salmonella	10,400	8,921	7,701	10,400**
RLm product samples ²⁹	RLMPROD	Lm	2,600	2,102	2,203	3,250
RLm food contact surface samples	RLMCONT	Lm	8,600	7,025	7,497	8,600

²⁹ Assumes the RLMPROD sampling project will be increased from three to five samples per unit during December 2012 (Q1, FY2013); compositing not factored into determination.

Product class	Sampling Projects	Pathogen	<i>Planned</i> Number of Samples Scheduled in FY2012	Number of Samples Scheduled in FY2012	Number of Samples Analyzed FY2012	<i>Planned</i> Number of Samples Scheduled in FY 2013
RLm non-food contact environmental. samples (Composited 5-sample Units; <i>Lm</i>)	RLMENVC	Lm	860	929	756	860
IVT product samples	INTPROD	Lm	N/A**	470	457	N/A*
IVT food contact surface samples	INTCONT	Lm	N/A**	1,740	1,738	N/A*
IVT non-food contact environmental samples	INTENV	Lm	N/A**	990	954	N/A*
IVT product samples	INTPROD	Salmonella	N/A*	120	114	N/A*
IVT food contact surface samples	INTCONT	Salmonella	N/A*	120	120	N/A*
IVT non-food contact environmental samples	INTENV	Salmonella	N/A*	192	192	N/A*

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

*Scheduling dependent on positive findings from ALLRTE, RTE001, RLMPROD and RLMCONT sampling projects. ** It is anticipated that ALLRTE and RTE001 will be combined into a single risk-based sampling project called RTEPROD in FY13.

Major Activities in RTE Sampling Projects for Salmonella and Lm in FY2012:

1. FSIS did not make any major changes to the RTE meat and poultry products sampling projects for *Lm* and *Salmonella* in FY2012.

Changes Planned to RTE Sampling Projects for Salmonella and Lm for FY2013:

- 1. FSIS is increasing the number of RLMPROD samples per sampling unit from three to five. These samples will be composited into a single 125 gram sample for analysis. A similar increase from three to five INTPROD samples per sampling unit, but with no compositing (e.g., samples to be tested as five individual 25 gram test portions) is also being implemented. A FRN announcing these changes was released on September 24, 2012.³⁰
- 2. FSIS is considering combining the ALLRTE and RTE001 sampling projects into a new sampling project.

³⁰ Please see the following website for more information:

http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2012-0032.htm.

Chemical Residues

FSIS Domestic Sampling Projects

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

Table 4: FSIS Domestic Sampling Projects for Chemical Residues

Sampling Projects	<i>Planned</i> Number of Samples Scheduled in FY2012	Number of Samples Scheduled in FY2012	Number of Samples Analyzed FY2012	<i>Planned</i> Number of Samples Scheduled in FY2013
Scheduled Program (NRP) ³¹	6,400*	11,345	8,580 ³²	6,400
European Union (EU)	N/A	345	N/A ³³	660
KIS™ Test-Field	181,000 ³⁴	N/A^	180,724	N/A^
KIS TM Test –Lab ³⁵	6,000	N/A^	4,405	N/A^

³¹ The U.S. National Residue Program (U.S. NRP) samples on a calendar year basis for meat, poultry and processed egg products. The numbers represented in this row represent the risk-based, FSIS headquarters-driven testing program.

³² Values for the number of samples analyzed in FY2012 differ from the total number of samples to be scheduled in FY2013 as FSIS schedules fewer samples for chemical residue testing, but analyzes each sample for more analytes.

³³ EU Samples are collected for export purposes. These samples are not analyzed at FSIS laboratories.

³⁴ KISTM and FAST samples are not scheduled in advance by FSIS; rather they are collected at the discretion of field inspectors. The number provided here represents the total number of KISTM field samples historically collected and analyzed, rather than a formally scheduled number of samples.

³⁵ Includes verification/confirmation sampling conducted by the FSIS laboratories and confirmatory KISTM tests on field positives.

Sampling Projects	<i>Planned</i> Number of Samples Scheduled in FY2012	Number of Samples Scheduled in FY2012	Number of Samples Analyzed FY2012	<i>Planned</i> Number of Samples Scheduled in FY2013
FAST- Field ³⁶	21,480 ³⁷	N/A^	20,137	N/A^
FAST-Lab	1,000	N/A^	254	N/A^

Table 4 (cont.): FSIS Domestic Sampling Projects for Chemical Residues

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

^ KISTM and FAST samples are not scheduled in advance by FSIS; rather they are collected at the discretion of field inspectors.

Major Activities in Chemical Residue Sampling Programs in FY2012

- 1. On April 25th, 2012, FSIS announced in an FRN and posted on the Agency's website the availability of a compliance guide for the prevention of violative residues in livestock slaughter establishments.³⁸ This FRN also discussed changes to the FSIS *Residue Repeat Violator List* and announced the Agency's intention to subject to increased testing animals from producers who are under an injunction obtained by the Food and Drug Administration (FDA) because of drug use practices that have led to residue violations.³⁹
- 2. On July 6th, 2012, FSIS announced in an FRN that the Agency was restructuring the U.S. NRP with respect to how sampling of chemical compounds and animal production and egg product classes is scheduled and implementing several multi-residue methods for analyzing samples of meat, poultry, and processed egg products for animal drug residues, pesticides, and environmental contaminants in its inspector-generated testing program. These modern, high-efficiency methods will conserve Agency resources and provide useful and reliable results while enabling FSIS to analyze each sample for more chemical

³⁶ FSIS is in the process of phasing out FAST in-plant screening with KISTM testing as the current in-plant screen.

³⁷ KISTM and FAST samples are not scheduled in advance by FSIS; rather they are collected at the discretion of field inspectors. The number provided here represents the total number of FAST field samples historical collected and analyzed, rather than a formally scheduled number of samples.

³⁸ Compliance Guide is available on the FSIS website at: http://www.fsis.usda.gov/Regulations_&_Policies/Compliance_Guides_Index/index.asp.

³⁹ Federal Register Volume 77, Number 80 (Wednesday, April 25, 2012)]

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compounds than was previously possible.⁴⁰ In addition, FSIS implemented a new scheduling algorithm that will minimize over and under scheduling issues, as seen in previous years.

3. On August 6th, 2012, FSIS implemented a new sampling program using the multi-screen methods. Because the screens are capable of evaluating multi-classes of veterinary drugs, FSIS discontinued the practice of "paired sampling", that is, testing one sample for a single chemical or chemical compound class.

Changes Planned for Chemical Residue Sampling Programs for FY2013:

- 1. The U.S. NRP Residue Sampling Plan (otherwise known as the "Blue Book") provides a summary of the scheduled domestic and imported meat, poultry, and processed egg product sampling plans. Detailed discussions describing the principles and methods used to plan and design the NRP sampling plans for 2013 will be provided when the report is released.
- 2. FSIS intends to continue the sampling program implemented August 6th, 2012 testing in nine production classes: beef cow, bob veal, dairy cow, steer, heifer, market hog, sow, young chickens, and young turkeys. Please see Table 5 for more details.

Methods									
	Beef cow	Bob veal	Dairy	Steers	Heifers	Sows	Market	Young	Young
			cow				hogs	Chickens	Turkeys
Multi-class			\checkmark	\checkmark					
Aminoglycoside			\checkmark	\checkmark	\checkmark				
Pesticides			\checkmark	\checkmark					
Metals			\checkmark	\checkmark					
B -agonists			\checkmark	\checkmark	\checkmark				
Avermectins			\checkmark	\checkmark					
Carbadox									
Nitrofurans									
Arsenic				\checkmark	\checkmark				

Table 5: Relevant Animal Production Classes and Methods for FSIS' Residue Sampling Program

⁴⁰ Federal Register / Vol. 77, No. 130 / Friday, July 6, 2012 / Rules and Regulations

Imports

The FSIS sampling project (EGGIMP) for imported processed egg products tests only for *Salmonella*. There are two primary STEC sampling projects for imported beef products: 1) Raw ground beef (MT08) and 2) Raw, non-intact beef (MT51). FSIS also maintains follow-up sampling projects for imported beef products; 1) FMT08 and 2) FMT51. FSIS also maintains one sampling project (IMVRTE) for *Salmonella* and *Lm* in RTE products from importing countries. Finally, FSIS maintains a chemical residue sampling project for imported product. Please see Table 6 for more information on the sampling projects.

Table 6: FSIS Import Sampling Projects

Product Type/Class	Pathogen/ Compound of Concern	Sampling Project	<i>Planned</i> Number of Samples Scheduled in FY2012	Number of Samples Scheduled in FY2012	Number of Samples Analyzed FY2012	<i>Planned</i> Number of Samples Scheduled in FY 2013
Pasteurized imported liquid, frozen or dried egg products	Salmonella	EGGIMP	75	TBD	70	75
Imported raw comminuted beef	<i>E. coli</i> O157:H7	MT08	10	TBD	7	10
Follow up testing to an imported raw comminuted beef positive	<i>E. coli</i> O157:H7	FMT08	N/A	N/A	0	N/A
Trim and other raw ground beef components	<i>E. coli</i> O157:H7/non- O157 STEC	MT51 ⁴¹	850	TBD	790	850
Follow up testing to an imported trim or components positive	<i>E. coli</i> O157:H7/ non-O157 STEC	FMT51	N/A	N/A	4	N/A

⁴¹ In 2012, FSIS began conducting additional STEC testing in beef manufacturing trimmings from product slaughtered after June 4, 2012. Not all product collected under MT51 is manufacturing trimmings.

Table 6 (cont.): FSIS Import Sampling Projects

Product Type/Class	Pathogen/ Compound of Concern	Sampling Project	<i>Planned</i> Number of Samples Scheduled in FY2012	Number of Samples Scheduled in FY2012	Number of Samples Analyzed FY2012	<i>Planned</i> Number of Samples Scheduled in FY 2013
Imported Intact RTE Product	Salmonella	IMVRTE	2,200	N/D^	1,075	TBD
Imported Intact RTE Product	Lm	IMVRTE	2,200	N/D^	1,080	TBD
Imported Fresh and Processed Product	Residue	Residue	1,300	TBD	3,800*	1,300

^Not determined; PHIS for imports was initiated in the third quarter of FY2012, requiring changes in sample scheduling. *Original scheduling of 1,300 samples based on anticipated implementation of new National Residue Program during FY2012.

Major Activities in Import Sampling Projects in FY2012

- 1. In June 2012, FSIS began transitioning the import sampling projects into PHIS.
- 2. FSIS began conducting additional STEC testing in beef manufacturing trimmings from product slaughtered after June 4, 2012. Not all product collected under MT51 is manufacturing trimmings.

Major Changes Planned for Import Sampling Projects for FY2013:

1. No significant changes to import sampling programs are proposed at this time.

Data Current as of Q4, FY2012

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 for *E. coli* O157:H7.

These projects are described in Table 7.

Table 7: FSIS E.	coli O157:H7	Sampling	Projects for	In-Commerce	Surveillance
				0 0 0 - 0 0	

Products	Sampling Project	<i>Planned</i> Number of Samples Scheduled in FY2012	Number of Samples Scheduled in FY2012	Number of Samples Analyzed FY2012	<i>Planned</i> Number of Samples Scheduled in FY 2013
Raw ground beef at retail stores	MT05	460	TBD	338	460
Follow-up testing to a MT05 sample*	MT06	N/A	N/A	0	N/A

* Dependent on positive findings from the MT05 sampling project.

Major Activities in In-Commerce Sampling Projects in FY2012

1. In October 2011, FSIS modified the MT05 sampling project to collect approximately 460 samples per year, starting in FY2012, to provide a 99% probability of detecting at least one positive sample if the actual percent positive rate reaches as

high as 1%, and a 90% probability of detecting at least one positive sample if the true percent positive rate is 0.5%.⁴² Samples are collected throughout the year and across the country.

Changes Planned for In-Commerce Sampling Projects for FY 2013:

- 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.
- 2. In FY2013, FSIS will assess whether and how bench trim samples should be included as high risk products to be sampled at retail, rather than collecting samples solely from raw ground beef.

⁴² See the FSIS Annual Sampling Program Plan, Fiscal Year 2012 for additional information about the changes made in 2012.

Other Sampling Programs

Overview of Other Programs

FSIS also conducts sampling in four other areas:

- 1. 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. FSIS conducted sampling for two baseline studies in FY2012 (raw chicken parts and liquid egg products). In FY2013, FSIS intends to begin sampling for a beef carcass baseline survey.
- 3. Dioxin
 - a. FSIS conducts a periodic, statistically-based survey of dioxins and dioxin-like compounds in domestic meat and poultry to estimate the levels of dioxin and dioxin-like compounds in FSIS-regulated meat and poultry products, compare levels found in the various products to past years' results, and collaborate with other Agencies to investigate causes of any detected spikes in dioxin levels. In the last survey in 2007-2008, 17 toxic polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/Fs) and four nonortho-polychlorinated biphenyls (no-PCBs) were measured in 510 beef (steer/heifer), market hog, young turkey, and young chicken samples.⁴³ FSIS intends to begin a new survey in FY2013 and will collect the same number of samples in the same regulated products as were sampled in the 2007-2008 survey.
- 4. National Antimicrobial Resistance Monitoring System (NARMS)
 - a. NARMS is a national public health surveillance system that tracks antibiotic resistance in foodborne bacteria.⁴⁴ 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*. Starting in FY2013, FSIS will begin collecting intestinal cecal samples from cattle (dairy and beef), swine (market hogs and sows), broilers and turkey presented for slaughter at FSIS-inspected establishments for the pathogens listed above.

Sample scheduling and analysis for these programs are provided in Table 8.

⁴³ For more information about the 2007-2008 dioxin survey, please see the following website at: http://www.fsis.usda.gov/PDF/Dioxin_Report_1009.pdf. ⁴⁴ For more information about the NARMS program, please see the following website:

http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm.

Products	Sampling Projects	<i>Planned</i> Number of Samples Scheduled in FY2012	Number of Samples Scheduled in FY2012	Number of Samples Analyzed FY2012	Planned Number of Samples Scheduled in FY 2013
Advanced Meat Recovery	AMR01		192	103	228
Follow-up testing to a AMR01 Sample	FAMR01	N/A	144	49	N/A
Baselines	N/A	5,500^	5,405	3,764	1,330 ⁴⁵
Dioxin	N/A	N/A	N/A	N/A	510
NARMS	N/A	N/A	N/A	N/A	2,400 ⁴⁶

Table 8: FSIS Other Sampling Programs

* Dependent on positive findings from the AMR01 sampling project.

^ Estimated based on historical sampling information.

Major Activities in Other Sampling Programs in FY2012

- 1. FSIS completed the Chicken Parts Baseline Study in FY2012.
- 2. FSIS began a Liquid Egg Baseline Study in FY2012.

Changes Planned for Other Sampling Programs for FY 2013:

- 1. FSIS is planning on starting a Beef Carcass Baseline Survey in FY2013.
- 2. FSIS is planning to run a Dioxin survey in FY2013.
- 3. FSIS is planning to begin a NARMS sampling program in FY2013.

 ⁴⁵ Estimated number of samples based on the implementation of the beef carcass baseline survey, including a shakedown period and three months of full survey.
 ⁴⁶ Sampling is scheduled to begin in January 2013 and continue through calendar year 2013.