UNITED STATES

National Residue Program for

Meat, Poultry, and Egg Products

2016 Residue Sampling Plans

United States Department of Agriculture

Food Safety and Inspection Service

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Preface

The United States National Residue Program (NRP) for Meat, Poultry and Egg Products: Residue Sampling Plans (traditionally known as the Blue Book) summarizes the process of sampling meat, poultry, and egg products for chemical contaminants of public health concern used by the Food Safety and Inspection Service (FSIS). This document details the principles and methods used to plan and design the following NRP sampling plans for: veterinary drugs, pesticides, and environmental contaminants. Explanations are provided with summary tables. The link on page 4 details the FSIS laboratory analytical methods, with species and tissue(s) validated for each method.

Contacts and Comments

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Acronyms

AMDUCA – Animal Medicinal Drug Use Clarification Act
AMS – Agricultural Marketing Service
APHIS – Animal and Plant Health Inspection Service
ARS – Agricultural Research Service
CDC – Centers for Disease Control and Prevention
CHCs – Chlorinated Hydrocarbons
COPs – Chlorinated Organophosphates
FDA – Food and Drug Administration
FSIS – Food Safety and Inspection Service
EPA – Environmental Protection Agency
HACCP – Hazard Analysis and Critical Control Points
IPP – Inspection Program Personnel
IRSP – Import Reinspection Sampling Program
KIS™ test – Kidney Inhibition Swab Test
NASS – National Agricultural Statistics Service
NRP – U. S. National Residue Program (Domestic & Import)
NSAID – Non-Steroidal Anti-inflammatory Drug
OFO – Office of Field Operations
OPHS – Office of Public Health Science
PHIS – Public Health Information System
PHV – Public Health Veterinarian
SAT – Surveillance Advisory Team
TOI – Types of Inspection

Introduction

The U.S. National Residue Program (NRP) for Meat, Poultry, and Egg Products, administered by the U.S. Department of Agriculture's (USDA), Food Safety and Inspection Service (FSIS), is an interagency program designed to identify, rank, and analyze for chemical contaminants in meat, poultry, and egg products. FSIS publishes the NRP Residue Sampling Plans (traditionally known as the Blue Book) each year to provide information on the process of sampling meat, poultry, and egg products for chemical contaminants of public health concern.

FSIS administers this regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 453 et seq.), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 et seq.). The NRP's purpose is to protect the health and welfare of the consumers by regulating the meat, poultry, and egg products produced in federally inspected establishments and to prevent the distribution in commerce of any such products that are adulterated or misbranded.

The NRP requires the cooperation and collaboration of several agencies for its successful design and implementation. FSIS, along with the Department of Health and Human Services' (HHS), Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) are the primary Federal agencies managing this program. The FDA, under the Federal Food, Drug, and Cosmetic Act, establishes tolerances for veterinary drugs and action levels for food additives and environmental contaminants. The EPA, under the Federal Insecticide, Fungicide, and Rodenticide Act (as modified by the Food Quality Protection Act), establishes tolerance levels for registered pesticides. Title 21 Code of Federal Regulations (CFR) includes tolerance levels established by FDA; and Title 40 CFR includes tolerance levels established by EPA. The Surveillance Advisor Team (SAT) consist of representatives from FSIS, FDA, EPA, USDA's Agricultural Research Service (ARS), and the USDA's Agricultural Marketing Service (AMS), as well as HHS' Centers for Disease Control and Prevention (CDC). The SAT consists of experts in veterinary medicine, toxicology, chemistry, and public health who provide professional advice, as well as information on veterinary drug and pesticide use in animal husbandry. Coordinated by FSIS, the SAT meets annually to evaluate chemical compounds for inclusion in the NRP scheduled sampling plans. FSIS is currently evaluating two science-based approaches to identify and prioritize chemicals based on their relative public health concern. This process would allow FSIS to strengthen decisions to allocate resources to chemical of high public health concerns. These evaluations include veterinary drugs, pesticides, and environmental contaminants that may appear in FSIS-regulated products, including xenobiotics and naturally occurring compounds that may pose a potential human health hazard. SAT discussions are used to decide which compounds represent a public health concern and warrant inclusion in the NRP scheduled sampling plans In addition, the SAT may propose, based on professional judgment and reliable field information, the initiation of exploratory assessments for directed sampling on a production class or region of the country. These agencies work together to create the annual sampling plan, based on the following: prior NRP findings of chemical residues in meat, poultry, and egg products, FDA veterinary drug inventories completed during on-farm visits and, investigation information, and pesticides and environmental contaminants of current importance to EPA. Ultimately, FSIS publishes the completed sampling plan in the yearly Blue Book.

Chemical compounds analyzed in the program include approved and unapproved veterinary drugs, pesticides, and environmental compounds. The NRP is designed to: (1) provide a structured process for identifying and evaluating chemical compounds used in food animals; (2) analyze chemical compounds of concern; (3) collect, analyze, and report results; and, (4) identify the need for regulatory follow-up subsequent to the identification of violative levels of chemical residues.

FSIS has administered the NRP by collecting and analyzing meat, poultry, and egg product samples for specific chemical compounds at FSIS laboratories since 1967 for meat and poultry, and beginning in 1995 for egg products. A violation occurs when an FSIS laboratory detects a chemical compound level in excess of an established tolerance or action level as well as if the residue detected has no approved tolerance. Once the laboratory analysis is complete, FSIS enters the detailed residue violation information into the FSIS Residue Violation Information System (RVIS), an FSIS/FDA interagency database. FSIS informs the establishment by providing them and the designated FSIS Inspection Program Personnel (IPP) with the analysis results and also notifies the producer via certified letter. Under best practices, the establishment also should notify the producer that an animal from that business has been identified as having a residue violation. In addition, FSIS shares the violation data with EPA and FDA, where the latter Agency has on-farm jurisdiction. FDA and cooperating State agencies investigate producers linked to residue violations and, if conditions leading to residue violations are not corrected, can enforce legal action.

To notify the public and the industry of repeated residue violations by the same producer, FSIS posts a weekly Residue Repeat Violators List on its Web site that identifies producers with more than one violation on a rolling 12-month period. In addition, the list provides helpful information to the AMS-School Lunch Program purchase clearance processors and producers who are working to avoid illegal levels of residues, serves as a deterrent for violators, and enables FSIS and FDA to make better use of resources (list for processors and producers). Because FSIS updates are posted weekly, FDA may not have investigated each violation at the time of publication.

FSIS Laboratory Analytical Methods

In January 1997, FSIS implemented the Hazard Analysis and Critical Control Point (HACCP) inspection system in all federally inspected establishments. The HACCP regulation (HACCP GPO CFR) requires FSIS-inspected slaughter and processing establishments to identify all food safety hazards (including drug residues, chemical contaminants, and pesticides) that are reasonably likely to occur before, during, and after the food animal or product enters the slaughter establishment. The regulation also requires establishments to identify preventive measures to control these hazards. FSIS takes regulatory action against establishments that do not have an effective chemical residue control program in place. Minimizing food safety hazards from farm-to-fork protects consumers from the public health risks associated with chemical contaminants in food.

With greater public concern about the risks of chemical contaminants, focus has increased on strengthening the identification, prioritization, and testing for chemical hazards in meat, poultry, and egg products in the United States. The sampling plan for residues in FSIS-regulated products includes strengthening the focus of public health-based sampling. This approach includes broader screens for veterinary drugs, pesticides, and heavy metals, as well as conducting more analyses per sample.

FSIS uses analytical methods to detect, identify, and quantify residues that may be present in meat, poultry, and processed egg products. The Agency utilizes these methods for monitoring and for surveillance activities to determine product adulteration and for evaluations of human risk assessments. The Agency uses available methodologies to take appropriate regulatory action against adulterated products in a manner consistent with the reliability of the analytical data. The link below lists the analytical methods with access to each method.

View the FSIS Analytical Chemistry Laboratory Guidebook here.

Based on interagency discussions and method improvements, FSIS began using a new screening method for animal drug residues in the second half of CY-2012. The multi-residue method (MRM) provides the following significant improvements: 1) screens and confirms for a variety of analytes, not just antibiotics; 2) target levels appropriate to each compound tolerance; 3) distinguishes individual analytes, even if multiple drugs are present in the same sample, by using mass spectrometry (MS); 4) mitigates unknown microbial inhibition responses; and 5) reduces the time and personnel needed to screen for multiple analytes.

The FSIS pesticide method has been in place since CY-2011. This method diversifies testing capability, improving on the previous pesticide method. The previous method (FY-2015) could only screen and confirm 87 pesticide compounds; the method now tests for 108 pesticides across multiple classes.

Actions taken on violations

A violation occurs when an FSIS laboratory confirms a residue that exceeds an established tolerance or action level, as well as if the residue detected has no tolerance. Once the laboratory analysis is complete, FSIS enters the detailed residue violation information into the FSIS Residue Violation Information System (RVIS), an FSIS/FDA interagency database. FDA has on-farm jurisdiction and evaluates the appropriate action to take as a follow-up to the violation. These actions range in severity from providing education to taking legal action.

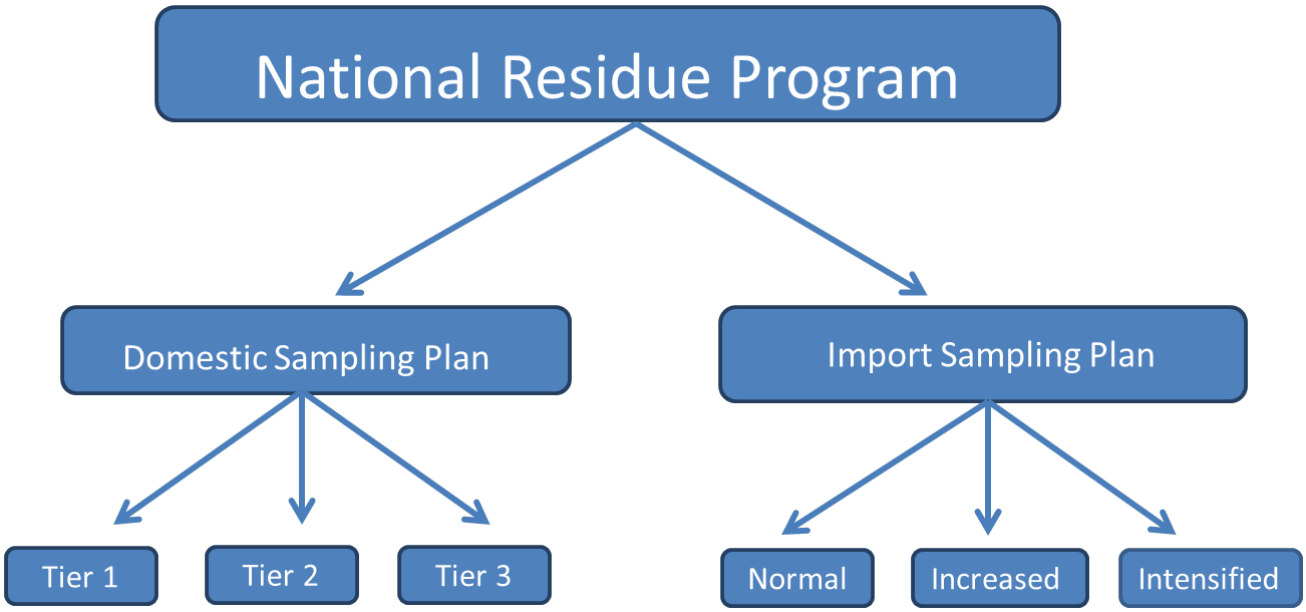
Every week, FSIS posts a Residue Repeat Violator List on the official Agency website. The list identifies producers with more than one violation on a rolling 12-month basis. In addition, the list provides helpful information to processors and producers who are working to avoid illegal levels of residues, serves as a deterrent for violators, and enables FSIS and FDA to make better use of resources (list for processors and producers). Because FSIS updates this list weekly, FDA may not have investigated each violation at the time of publication.

Overview of the Sampling Plans

The United States Government fiscal year (FY) runs from October 1 through September 30. To match this, since 2012 FSIS switched from implementing the NRP on a Calendar Year (CY) to a Fiscal Year (FY) basis. This change allows the program to run concurrently with the Federal budget cycle.

The NRP consists of three separate, but interrelated, chemical residue testing programs: scheduled sampling (Tier 1), targeted sampling at the production or compound class level (Tier 2), and targeted sampling at the herd/flock or compound class level (Tier 3). This basic structure has been in existence since 1967. These testing programs provide data for FSIS to detect chemical residues of public health concern and have been modified over the years to respond to emerging chemical residue concerns and improved testing methodologies.

The FY 2016 NRP Residue Sampling Plans focus on chemical residues in domestic meat, poultry, and egg products and the import reinspection of meat, poultry and egg products. The domestic sampling plan includes scheduled sampling and inspector-generated sampling. The import reinspection sampling plan encompasses normal sampling, increased sampling, and intensified sampling. Directive 10,800.1, Rev 1 provides further detail on the sampling procedures.



DOMESTIC SAMPLING PLAN

1. Scheduled Sampling (Tier 1)

Tier 1 sampling plan is a statistical plan based on random selection of species from animals that have passed ante mortem inspection. Data collected from Tier 1 serves as a baseline level for chemical residue exposure. The sample request forms appear as a directed task on the Public Health Information System (PHIS). The sampling task provides information to the Inspection Program Personnel (IPP) on when to collect the sample (collection window) and which slaughter production class to sample. The establishment holds or controls livestock carcasses selected for testing pending the results of analysis. For directed residue testing of poultry, the IPP recommend to the establishment that the establishments hold the specific poultry carcasses selected for residue testing pending the analysis results.

Tier 1 results also can be used to identify producers or other entities marketing animals with violative concentrations of residues. Thus, the Tier 1 sampling plan not only gathers information, but also assists in deterring practices that lead to violative residues

In FY 2016, the Tier 1 sampling plan will consist of random samples collected from each of the following production classes: beef cows, bob veal, dairy cows, steers/ heifers, market hogs, sows, young chickens, and young turkeys. Please see the Appendix II. The FY 2016 NRP Tier 1 sampling program will include analyses across the 9 production classes representing 95 percent of domestic meat and poultry consumption.

2. Targeted Sampling (Tier 2)

a. Inspector-Generated Sampling

FSIS inspection program personnel (IPP) conduct inspector-generated sampling when they suspect that animals may have violative levels of chemical residues. Currently, inspector-generated sampling targets individual suspect animals and suspect populations of animals and animals condemned for specific pathologies listed in FSIS Directive 10,800.1, Rev 1. When Public Health Veterinarians (PHVs) detect evidence of a disease that may have been treated or suspect the administration of a drug, they retain the carcass and analyze samples from those carcasses to screen for the presence of chemical residues. If the in-plant test is negative for antimicrobial residues, the carcass is released to the establishment. If positive, the carcass is held pending the results of laboratory testing. The PHV condemns carcasses of animals found to contain violative levels of residues in the muscle or if an unapproved drug is detected in any tissue.

In FY 2016, IPP will continue to complete in-plant residue screens using the Kidney Inhibition Swab test (KIS™ test). The screen positive samples are submitted to the FSIS Midwestern Laboratory and analyzed by the laboratory to identify, quantify and confirm the contaminants. The laboratory uses a multi-residue screening method to test in-plant screen positives.

1. Sampling of Individual Suspect Animals

Under the direction of the PHV, IPP are to conduct a KIS™ test on any carcass that based on herd history or ante-mortem or post-mortem findings inspection findings may contain a violative drug residue. IPP are to follow the instructions provided in Directive 10,800.1, Rev 1, chapter three for circumstances warranting a KIS ™ test and Chapter Four for performing KIS™ tests and documenting the task in PHIS. The PHV selects a carcass for sampling based on the criteria outlined in FSIS Directive 10,800.1, Rev 1 (i.e., animal with disease signs and symptoms, producer history, or as a follow-up to results from random scheduled sampling).

Usually, the sample is screened in the plant by the IPP and the screen-result verified when necessary by a PHV. Other samples are sent directly to the laboratory for analysis. For example, if the IPP suspects the misuse of a veterinary drug in an animal, she/he can perform the relevant in-plant screening analysis. If the result of a screening analysis is positive, the carcass is held (if it is not already condemned for other pathology or conditions that would make it unfit for human consumption), and the liver, kidney, and muscle samples from the carcass are then sent to an FSIS laboratory for analysis and confirmation.

2. Sampling of Suspect Animal Populations

Sampling for suspect animal populations is directed by an FSIS regulation (9 CFR 310.21) and Directive 10,800.1, Rev 1. This is outlined for healthy appearing bob veal calves and show animals.

b. Targeted Sampling

FSIS implements targeted sampling plans (exploratory assessments) in response to information (obtained by FDA and EPA and provided to FSIS) about misuse of animal drugs and/or exposure to environmental chemicals, as well as in response to Tier 1 analytical results. These plans may not be conducted over a twelve month period. FSIS may conduct studies to develop information on the frequency and concentration at which some residues like trace metals and industrial components may be inadvertently present in animals. These sampling plans could be designed to distinguish components of livestock, poultry and egg products in which residue problems exist, to measure the extent of problems, and to evaluate the impact of actions taken to reduce the occurrence of residues in the food animal population.

The sample request forms appear as a directed task on the PHIS. The sampling task provides information to the IPP on when to collect the sample (collection window) and which slaughter production class to collect from. The establishment holds or controls livestock carcasses selected for testing pending the test results. For directed residue testing of poultry, the IPP recommend to the establishment that the establishments hold the specific poultry carcasses selected for residue testing pending the test results.

In FY 2016, targeted sampling includes old breeder turkey, sheep, goats and roaster pigs.

3. Targeted Flock/Herd Sampling (Tier 3)

The Tier 3 sampling plan is similar in structure to the targeted sampling (exploratory assessment) program in Tier 2, with the exception that Tier 3 will encompass targeted testing at a herd or flock level. A targeted testing program designed for livestock or flocks originating from the same farm or geographic region may be necessary on occasion to determine the level of exposure to a chemical or chemicals. For instance, producers may administer some veterinary drugs to a herd or a flock (for example, growth promotants or antibiotics given in the feed) in a way that involves misuse. In addition, livestock and birds may be exposed unintentionally to an environmental contaminant. Therefore, a targeted testing program designed for livestock or flocks originating from the same farm or region may be necessary on occasion to determine the level of a chemical or chemicals to which the livestock or the birds in the flock have been exposed. Tier 3 will provide a vehicle for developing information that will support future policy development within the NRP.

In FY 2016 NRP sampling may be done as situations arise during the year.

IMPORT REINSPECTION SAMPLING PLAN

Imported meat, poultry, and egg products are sampled through the port-of-entry Import Reinspection Sampling Plan, a chemical residue monitoring program conducted to verify the equivalence of inspection

systems in exporting countries to the United States standards. All imported products are subject to reinspection, and one or more types of inspection (TOI) are conducted on every lot[1] of product before it enters the U. S. Chemical residue sampling is included in the reinspection of imported products. The following three levels of chemical residue reinspection include:

- normal sampling: random sampling from a lot;
- increased sampling: above-normal sampling resulting from an Agency management decision; and
- intensified sampling: additional samples taken when a previous sample for a TOI that failed to meet U. S. requirements.

The data obtained from laboratory analyses are entered into PHIS, an FSIS database designed to generate reinspection assignments, receive and store results, and compile histories for the performance of foreign establishments certified by the inspection system in the exporting country.

In FY 2016 NRP, the import reinspection sampling program will be structured using the Tier 1 and Tier 2 frameworks. FSIS intends to collect approximately 1,100 import samples, similar to FY 2015.

[1] An import lot is a group of products defined statistically and/or scientifically by production segments and certified from one country, one establishment. A lot consists entirely of the same species, process category, and product standard of identity (sub-category). A single lot can contain shipping cartons with varying sizes of immediate containers.

POLICY AND PROCEDURES FOR HOLDING OR CONTROLLING PRODUCT UNDER NRP

As of February 2013, the Agency requires official establishments and importers of record to hold or maintain control of lots of product tested for adulterants until acceptable results become available. FSIS stated that the policy would apply to livestock carcasses subject to FSIS testing for residue on domestic products. FSIS explained that it will not hold poultry carcasses pending test results for residues due to historically low residue problems and large lot size. This was outlined in a published Federal Register Notice 76 FRN 19955.

The Hold and Test policy also applies to normal and increased import reinspection sampling. Additionally, for intensified import sampling, the lot must be retained pending laboratory results.

ANIMAL PRODUCTION CLASSES

Production class nomenclature includes:

Bovine

- Beef cows are mature, female cattle bred for muscle development, ordinarily having given birth to one or more calves.
- Bulls are mature, uncastrated male cattle.
- Calves/veal: The agency is currently engaging in rulemaking to define "veal." For sampling purposes under the NRP, veal calves are defined as immature cattle (including dairy breeds) lacking a functional rumen and intended for meat production. They are recognized as a separate class from suckling calves because of their handling, housing, and proximity to slaughter.
- Dairy cows are mature, female cattle bred for milk production, ordinarily having given birth to one or more calves.
- Heifers are young, female cattle more than 1 year old that have not yet given birth to a calf.
- Steers are male cattle castrated before sexual maturity.

Porcine

- Boars are mature swine showing male sexual characteristics.
- Market hogs are swine, usually marketed near 6 months of age and 200 to 300 pounds live weight.
- Roaster Swine (Pigs) are animals of both sexes and any age that are marketed with the carcass unsplit and with the head on.
- Sows are mature, female swine, ordinarily having given birth to one or more litters.
- Stags are male swine castrated after they have reached sexual maturity.

Poultry

- Ducks are birds of both sexes and any age.
- Egg products include yolks, whites, or whole eggs after breaking; eggs are processed as dried, frozen, or liquid.
- Geese are birds of both sexes and any age.
- Mature chickens are adult female birds, usually more than 10 months of age.
- Old Breeder turkeys are birds of both sexes and usually more than 15 months of age.
- Young chickens include broilers/fryers birds of both sexes that are usually less than 10 weeks of age.
- Roasters are chickens of both sexes, usually less than 12 weeks of age.
- Capons are surgically castrated male chickens usually less than 8 months of age.
- Young turkeys include fryer/roaster birds that are of both sexes and usually less than 12 weeks of age.
- Other poultry include ratites (e.g., ostriches, emus, rheas), guineas, squabs (young, unfledged pigeons), adult pigeons, pheasants, grouse, partridge, quail, etc.

Other Livestock

- Goats are animals of both sexes and any age.
- Lambs are sheep younger than 14 months and having a break joint in at least one leg.
- Rabbits are any of several lagomorph mammals of both sexes and any age.
- Sheep are mature animals of both sexes.
- Other livestock include bison, deer, elk, etc.

Summary of the Domestic and Import Reinspection Sampling Plans

Summary Tables I and II (Tier 1)

Summary Tables I and II provide an overview of both domestic and import sampling organized by chemical compound class. Each table covers: Animal Medicinal Drug Use Clarification Act (AMDUCA)-prohibited drugs, veterinary drugs, pesticides, and environmental contaminants. The tables also identify the FSIS laboratory that would be conducting the analyses. Due to laboratory capacity, not every sample is analyzed for every compound class. Laboratory personnel make decision on which samples to analyze. Some of the factors that are included in the decision are (1) the number of samples that can be analyzed per run, (2) the number of samples received that week, and (3) the total number of samples for that compound class/slaughter class pair. The factors behind these decisions can be found in the individual laboratory procedures.

Summary Tables III – IV (Tier 2)

Summary Tables III and IV provide an overview of both domestic and import sampling organized by animal production class. Each table includes the following: Animal Medicinal Drug Use Clarification Act (AMDUCA)-prohibited drugs, veterinary drugs, pesticides, and environmental contaminants. Table III shows domestic Tier 2 sampling (sheep, goats, and mature turkeys) and Table IV lists the sulfonamide sampling for imports.

Overview of the Program Design

The sampling plan design begins with a list of residues that may occur in meat, poultry, and egg products and are of concern to human health. FSIS coordinates an annual meeting of the SAT members to identify and prioritize chemical compounds of public health concern and assemble detailed information on each compound. FSIS combines this information with historical data on violation rates for each chemical compound to develop the domestic sampling and import reinspection plans. These sampling plans guide the allocation of FSIS laboratory, supply, and inspection resources.

Factors considered when developing the domestic and import scheduled sampling plans include:

- Qualitative public health risk associated with each chemical compound or compound class in meat, poultry, and egg products;
- The food animals affected by each chemical compound or compound class;
- The analytical methods that are available to identify the chemical compound or compound classes;
- FSIS laboratory capacity to analyze chemical compounds or compound classes; and
- The existence of a regulatory tolerance.

The import reinspection plan design is similar to the domestic plan, with two important exceptions. Raw product testing from samples collected at the U.S. port-of-entry is rare, because concerns about foreign animal diseases limit many countries to ship processed products only. When import of raw products is allowed, most shipped raw product consists of muscle tissue only. Exporting countries are required to identify the animal species in each product, but they are not required to identify the production class. Imported meat and poultry testing is categorized by species (e.g., poultry or porcine); egg products are distinguished as a separate category. There are different compound applications by importing countries: allowance in food animals that are not approved for such use in the United States and different use practices for compounds that are approved in the United States. For these reasons, the compounds selected for analysis in the import plan may not necessarily be the same as those in the U.S. domestic plan.

Summary Table I: No. of Analyses per Production Class by Compound Class
FY 2016 Domestic Scheduled Sampling: Tier 1

Methods	No. of Chemical Analyses per Production Class *								
	Beef cows (n=800)	Dairy cows (n=800)	Steers (n=400)	Heifers (n=400)	Bob veal (n=400)	Market hogs (n=800)	Sows (n=800)	Young chicken (n=800)	Young turkeys (n=800)
Multi-residue	800	800	400	400	400	800	800	800	800
Aminoglycoside	800	800	400	400	400	800	800	800	800
Pesticides	300	300	110	110	300	300	300	300	300
Metals**	100	100	100	100	100	100	100	150	150
β-Agonists	400	400	200	200	400	400			
Hormones	300	300	200	200	300				
Avermectins	400	400	200	200	400	400	400		
Arsenic	400	400	200	200	400	400	400	400	400
Nitrofurans								300	300

*Note: n= denotes the number of samples collected/submitted for each production class. E.g. 800 total samples collected/submitted for beef cows and 400 total samples collected/submitted for heifers.

**Metals are considered Tier 2 sampling, due to the fact there are no established tolerances.

Summary Table II: No. of Analyses per Production Class by Compound Class
FY 2016 Import Scheduled Sampling: Tier 1

Methods	No. of Chemical Analyses per Production Class*											
	Fresh beef (n=150)	Processed beef (n=150)	Fresh pork (n=150)	Processed Pork (n=150)	Fresh veal (n=75)	Processed Veal (n=25)	Fresh lamb/mutton (n=25)	Fresh goat (n=25)	Fresh chicken (n=150)	Processed chicken (n=50)	Fresh turkey (n=40)	Processed turkey (n=50)
Multi-residue	150	0	150	0	75	0	0	0	150	0	40	0
Aminoglycoside	150	0	150	0	75	0	0	0	150	0	40	0
Pesticides	100	0	100	0	50	0	25	25	75	0	25	0
Hormones	100	0	0	0	0	0	0	0	0	0	0	0
β-Agonists	75	0	75		50	0	0	0	0	0	0	0
Avermectins	75	150	75	25	25	25	20	15	0	0	0	0
Arsenic	75	150	75	25	25	25	20	15	75	50	15	50
Metals	35	12	35	12	25	12	0		35	12	12	12

*Note: n= denotes the number of samples collected/submitted for each production class. E.g. 150 total samples collected/submitted for fresh beef.

Summary Table III: No. of Analyses per Production Class by Compound

Class FY 2016 Domestic Scheduled Sampling: Tier 2

Methods	No. of Chemical Analyses per Production Class*			
	Sheep (n=300)	Goats (n=300)	Roaster Swine (Pigs) (n=300)	Old Breeder Turkey (n=100)
MRM	300	300	300	100
Aminoglycosides	150	150	300	
Pesticides	150	150		
Avermectins	150	150		
Arsenic	150	150		
Carbadox			300	
β-Agonists			300	
Metals				100

*Note: n= denotes the number of samples collected/submitted for each production class. Ex) 300 total samples collected/submitted for sheep.

Summary Table IV: No. of Analyses of Imported Processed Products Tested for Sulfonamides FY 2016 Import Scheduled Sampling: Tier 2

Compounds for Analysis	Import Production Class	Import Sample Size
Sulfonamides	Processed beef	25
	Processed pork	15
	Processed turkey	10

Appendix I
List of Chemical Residues by Class/Method

1. Veterinary Drugs

For FY 2016 domestic sampling, FSIS has scheduled the following classes of veterinary drug analytes:

a. Multi-residue method

2-Aminosulfone Albendazole	DCCD	Flunixin	Oxacillin	Sulfamethazine
2-amino-Flubendazole	Desethylene Ciprofloxacin	Gamithromycin	Oxyphenylbutazone	Sulfamethizole
2-Quinoxaline Carboxylic Acid (QCA)	Diclofenac	Haloperidol	Oxytetracycline	Sulfamethoxazole
Abamectin	Dicloxacillin	Ipronidazole	Penicillin G	Sulfamethoxypyridazine
Albendazole	Difloxacin	Ipronidazole - OH	Phenylbutazone	Sulfanitran
Amoxicillin	Dimetridazole	Ketamine	Pirlimycin	Sulfapyridine
Ampicillin	Dimetridazole - OH	Ketoprofen	Prednisone	Sulfaquinoxaline
Azaperone	Dipyrone	Levamisole	Ractopamine	Sulfathiazole
Butorphanol	Doramectin	Lincomycin	Ronidazole	Tetracycline
Carazolol	Doxycycline	Melengestrol	Salbutamol	Thiabendazole
Cefazolin	Emamectin Benzoate	Meloxicam	Sarafloxacin	Tildipirosin
Chloramphenicol	Enrofloxacin	Metronidazole	Selamectin	Tilmicosin
Chlortetracycline	Eprinomectin	Metronidazole - OH	Sulfachloropyridazine	Tolfenamic Acid
Cimaterol	Erythromycin A	Morantel	Sulfadiazine	Tulathromycin A
Ciprofloxacin	Fenbendazole	Moxidectin	Sulfadimethoxine	Tylosin
Clindamycin	Fenbendazole	Nafcillin	Sulfadoxine	Tyvalosin
Cloxacillin	Florfenicol	Norfloxacin	Sulfaethoxypyridazine	Virginiamycin
Danofloxacin	Flubendazole	Orbifloxacin	Sulfamerazine	Xylazine

b. Aminoglycoside Method

Amikacin	Gentamicin	Neomycin
Apramycin	Hygromycin B	Spectinomycin
Dihydrostreptomycin	Kanamycin	Streptomycin

c. Hormones Method

Megestrol	Melengestrol Acetate	Hexestrol	Zeranol

d. Beta-Agonist Method

Cimaterol	Ractopamine	Zilpaterol
Clenbuterol	Salbutamol	

e. Avermectin Method

Doramectin	Ivermectin	Moxidectin

f. Nitrofuran Method

mino-2-oxazolidinone (AOZ)	1-aminohydatoin (AHD)	semicarbazide (SEM)
3-amino-5-morpholinomethyl-2-oxazolidinone (AMOZ)		

g. Carbadox Method

Quinoxaline-2-carboxylic acid

2. Pesticides and environmental contaminants

a. Pesticide Method

1-Naphthol	Coumaphos O	Fluroxypyr-1-Methylhepyl-Ester	Pentachlorobenzene (PCB)
3-Hydroxycarbofuran	Coumaphos S	Fluvalinate	Permethrin (cis&trans)
Acephate	DDD o,p’	Heptachlor	Piperonyl butoxide
Acetamiprid	DDD p,p’ + DDT, o,p'	Heptachlor epoxide (cis+ trans) or (B+A)	Pirimiphos methyl
Alachlor	DDE o,p’	Hexachlorobenzene (HCB)	Prallethrin
Aldicarb	DDE p,p’	Hexazinone	Profenofos
Aldicarb sulfone	DDT p,p’	Hexythiazox	Pronamide
Aldicarb sulfoxide	Deethylatrazine	Imazalil	Propachlor
Aldrin	Diazinon	Imidacloprid	Propanil
Atrazine	Dichlorvos (DDVP)	Indoxacarb	Propetamphos
Azinphos methyl	Dieldrin	Lindane (BHC gamma)	Propiconazole
Azoxystrobin	Difenoconazole	Linuron	Pyraclostrobin
Benoxacor	Diflubenzuron	Malathion	Pyrethrin I
Bifenthrin	Dimethoate	Metalaxyl	Pyrethrin II
Boscalid	Diuron	Methamidophos	Pyridaben
Buprofezin	Endosulfan I	Methomyl	Pyriproxyfen
Carbaryl	Endosulfan II	Methoxyfenozide	Resmethrin (cis&trans)
Carbofuran	Endosulfan sulfate	Metolachlor	Simazine
Carfentrazone ethyl	Ethion	Metribuzin	Sulprofos
Chlordane cis	Ethion monoxon	MGK-264 (isomers 1 & 2)	Tebufenozide
Chlordane trans	Ethofumesate	Myclobutanil	Tefluthrin
Chloroneb	Fenoxaprop ethyl	Nonachlor cis	Tetrachlorvinphos
Chlorothalonil	Fenpropathrin	Nonachlor trans	Tetraconazole
Chlorpropham	Fipronil	Norflurazon	Thiabendazole
Chlorpyrifos	Fipronil desulfinyl	Omethoate	Thiamethoxam
Chlorpyrifos methyl	Fipronil sulfide	Oxychlordane	Thiobencarb
Clothianidin	Fluridone	Pentachloroaniline (PCA)	Trifloxystrobin

b. Metals Method

Aluminum (Al)	Copper (Cu)	Selenium (Se)
Barium (Ba)	Iron (Fe)	Strontium (Sr)
Boron (B)	Lead (Pb)	Thallium (Tl)
Cadmium (Cd)	Manganese (Mn)	Vanadium (V)
Chromium (Cr)	Molybdenum (Mo)	Zinc (Zn)
Cobalt (Co)	Nickel (Ni)	

Appendix II
Statistical Table

Scheduled Sampling is done to provide some assurance of detection of a violation that affects a given percentage of the samples population.

Prior to FY 2012, FSIS tested 230 to 300 samples from each production class/residue compound class pairing to obtain results that were statistically meaningful. The testing sample sizes of 230 or 300 ensured FSIS a 90 percent or 95 percent probability, respectively, of detecting at least one chemical residue violation if the violation rate is equal to or greater than 1 percent in the population being sampled.

Starting FY 2012, FSIS stated in its residue sampling plan that sample size selected/tested would increase its goal to about 800 samples for each of the nine major production class tested under Tier-I. By increasing the number of samples taken, it would increase its statistical probability of finding at least one violation to at even lower true violation rates.

The statistical table provides the calculated number of samples required to ensure detection of at least one violation that affects a given percentage of the sampled population. Statistically, for a binomial distribution with sample size "n" and violation rate "v" (in decimal number), if v is the true violation rate in the population and n is the number of samples, the probability, p, of finding at least one violation among the n samples (assuming random sampling) is $p = 1-(1-v)^n$.

For example,

Based on <u>1% true violation rate assumption</u>:

- The probability of detecting at least one violation with sampling levels of 230 is 0.90. This means:

  If no violations were found in 230 samples, then we are 90% confident that that the true population violation rate is less than 1%. On the other hand, if at least one violation were found in 230 samples, then we are 90% confident that the true population violation rate is at least 1%
- The probability of detecting at least one violation with sampling levels of 300 is 0.95. This means:

  If no violations were found in 300 samples, then we are 95% confident that that the true population violation rate is less than 1%. On the other hand, if at least one violation were found in 300 samples, then we are 95% confident that the true population violation rate is at least 1%
- The probability of detecting at least one violation with sampling levels of 460 is 0.99. This means:

  If no violations were found in 460 samples, then we are 99% confident that that the true population violation rate is less than 1%. On the other hand, if at least one violation were found in 460 samples, then we are 99% confident that the true population violation rate is at least 1%
- The probability of detecting at least one violation with sampling levels of 800 is 0.9997. This means:

  If no violations were found in 800 samples, then we are 99.97 % confident that that the true population violation rate is less than 1%. On the other hand, if at least one violation were found in 800 samples, then we are 99.97% confident that the true population violation rate is at least 1%

Using 800 samples

- The probability of detecting at least one violation with sampling levels of 800 is 0.90. This means:

  If no violations were found in 800 samples, then we are 90 % confident that that the true population violation rate is less than 0.29 %. On the other hand, if at least one violation were found in 800 samples, then we are 90% confident that the true population violation rate is at least 0.29 %
- The probability of detecting at least one violation with sampling levels of 800 is 0.95. This means:

  If no violations were found in 800 samples, then we are 95 % confident that that the true population violation rate is less than 0.37 %. On the other hand, if at least one violation were found in 800 samples, then we are 95 % confident that the true population violation rate is at least 0.37 %
- The probability of detecting at least one violation with sampling levels of 800 is 0.99. This means:

  If no violations were found in 800 samples, then we are 99 % confident that that the true population violation rate is less than 0.57 %. On the other hand, if at least one violation were found in 800 samples, then we are 99 % confident that the true population violation rate is at least 0.57 %

Statistical Table – FY 2016 U.S. National Residue Program

Percentage % Violative in the population (v)	Probability (p) of detecting at least one violation in (n) samples					
	0.90	0.95	0.99	0.999	0.9997	0.9999
	Sample Size required "n"					
10	22	29	44	66	77	87
5	45	59	90	135	158	180
1	230	300	459	688	807	916
0.57	403	525	806	1,208	1,419	1,611
0.50	460	598	919	1,378	1,618	1,837
0.37	620	808	1,242	1,864	2,188	2,485
0.29	793	1,032	1,586	2,379	2,793	3,171
0.10	2,302	2,995	4,,603	6,904	8,108	9,206
0.05	4,605	5,990	9,208	13,812	16,219	18,416

The procedure to calculate the required sample size needed:

$p = 1 - (1 - v)^n$ ← Probability of detecting at least one violation in n sample of binomial distribution with violation rate v

$1 - p = (1 - v)^n$ ← Subtract one from both side of the equation. This gives the probability of detecting No violations in n samples

$\log(1 - p) = \log(1 - v)^n$ ← Apply logarithmic function to both side of the equation

$\log(1 - p) = n * \log(1 - v)$ ← A logarithmic function property

$n = \dfrac{\log(1 - p)}{\log(1 - v)}$ ← Sample size based on violation rate (v) and probability of detecting (p)

Appendix III

FY 2016 NRP: Estimated Amount of Domestically Produced Meat, Poultry and Egg Products

Production Class	Number of Head Slaughtered /[3]	Pounds per Animal (dressed weight) /[4, 5, 6, 7]	Total Pounds (dressed weight)	Percent Estimated Relative Consumption
Bull/Stag	502,053	917.91	460,837,030	0.465%
Beef Cow	2,276,191	647.47	1,473,775,913	1.488%
Dairy Cow	2,904,681	647.91	1,881,967,596	1.900%
Heifer	7,545,358	809.16	6,105,367,037	6.163%
Steer	14,856,793	877.03	13,029,856,988	13.153%
Bob Veal	173,691	36.50	6,340,276	0.006%
Formula-fed Veal	255,448	269.20	68,765,817	0.069%
Non Formula-fed Veal	6,438	174.13	1,121,044	0.001%
Heavy Calf	19,056	288.90	5,505,213	0.006%
SUBTOTAL, CATTLE	**28,539,709**		**23,033,536,915**	**23.251%**
Market Swine	108,245,304	205.77	22,273,417,317	22.484%
Roaster Swine	781,817	67.98	53,149,474	0.054%
Boar/Stag Swine	385,197	180.29	69,445,672	0.070%
Sow	2,812,025	301.91	848,965,343	0.857%
SUBTOTAL, SWINE	**112,224,343**		**23,244,977,806**	**23.465%**
Mature Sheep	124,093	59.22	7,348,220	0.007%
Lamb	1,893,383	70.13	132,791,132	0.134%
Goat	456,624	31.75	14,496,800	0.015%
SUBTOTAL, OVINE	**2,474,100**		**154,636,151**	**0.156%**
Bison	51,487	587.61	30,254,318	0.031%
TOTAL, ALL LIVESTOCK	**143,289,639**		**46,463,405,189**	**46.903%**
Young Chicken	8,728,457,280	4.54	39,623,325,253	39.998%
Light Fowl	62,937,967	2.58	162,659,294	0.164%
Heavy Fowl	74,425,869	6.12	455,485,716	0.460%
Capon	98,972	7.16	708,269	0.001%
Young Turkey	235,699,017	22.54	5,312,417,858	5.363%
Young Breeder Turkey	1,185,118	87.07	103,190,937	0.104%
Old Breeder Turkey	1,546,453	21.21	32,794,825	0.033%
Fryer Roaster Turkey	55,305	12.42	686,966	0.001%
Duck	27,975,229	4.99	139,544,769	0.141%
Goose	68,746	10.51	722,334	0.001%
Squab	905,694	12.42	11,249,993	0.011%
Quail	820,962	0.33	273,338	0.000%
Pheasant	95,382	0.24	23,063	0.000%
Rhea	10	34.60	346	0.000%
Guinea	186,117	5.81	1,082,212	0.001%
SUBTOTAL,POULTRY	**9,133,355,650**		**45,842,786,215**	**46.276%**
Rabbit	338,285	5.11	1,728,728	0.002%
Egg Products			6,754,153,305	6.818%
GRAND TOTAL in POUNDS, ALL PRODUCTION CLASSES			**99,063,452,395**	**100.000%**

/1 Mature Chickens = Heavy Fowl + Light Fowl
/2 Other fowl = Pheasant+Quail+Rhea+Squab
/3 Source - Slaughter Volume Data from September 1st 2014 to August 31st 2015 (Data Source: PHIS, September 29th, 2015)
/4 Cattle, Hogs, Sheep - USDA, NASS Livestock Slaughter 2014 Summary (April 2015), 2014 Dressed Weight
/5 Young Chicken, Mature chickens, Young Turkey, Old Breeder Turkey, Duck = 2014 Average Live Weight (USDA, NASS Poultry Slaughter 2014 Summary (February 2015)) * .75 (North Carolina Cooperative Extension (December 2007) Grower Guidelines for Poultry and Fowl Processing)
/6 Bob Veal, Formula-fed Veal, Non Formula-fed Veal, Heavy Calf, Roaster Swine, Goat, Bison = Calculated using PHIS
/7 Goose = PHIS Average Live Weight
/8 Other Fowl = PHIS Average Live Weight
/9 Rabbit = PHIS Average Live Weight

Appendix IV
FY 2016 NRP: Estimated Annual Amount of Product Imported in the United States

Product	Product Weight in Pounds	Product Imported Percent
Beef, Fresh	2,575,785,696	57.79
Beef, Processed	149,286,467	3.35
Chicken, Fresh	147,699,169	3.31
Chicken, Processed	88,004,394	1.97
Duck, Fresh	2,602,384	0.06
Duck, Processed	350,108	0.01
Egg Products, Fresh	14,592,610	0.33
Goat, Fresh	38,737,587	0.87
Lamb, Fresh	153,189,591	3.44
Lamb, Processed	110,531	0.00
Mutton, Fresh	37,713,832	0.85
Mutton, Processed	296,148	0.01
Ostrich, Fresh	12,350	0.00
Pork, Fresh	1,020,001,587	22.89
Pork, Processed	139,397,971	3.13
Turkey, Fresh	35,025,132	0.79
Turkey, Processed	4,319,766	0.10
Varied Combination, Fresh	1,619	0.00
Varied Combination, Processed	7,905,531	0.18
Veal, Fresh	42,032,085	0.94
Veal, Processed	3,717	0.0001
Total	**4,457,068,275**	**100.00**

Appendix V
NRP In-plant Screening Pilot Project

In 2014, FSIS launched a nation-wide questionnaire to better understand the thought process Public Health Veterinarians (PHVs) undergo when selecting animals or carcasses for in-plant screening. The questionnaire also queried PHVs as to their needs to improve their technical acumen. Questionnaire results indicated PHVs were interested in more Agency guidance and training (correlation) regarding NRP in-plant screening.

Based on the result of the questionnaire, FSIS believes that there may be conditions seen in a given slaughter class that are more likely to result in a laboratory confirmed positive result (either non-violative or violative). This led to the development of the pilot project. FSIS launched Phase 1 of a pilot project in order to increase efficiencies of in-plant testing and to provide inspection program personnel (IPP) with specific guidance. The intent of the pilot structure is to test two hypotheses:

1) Conditions selected for in-plant screening vary within a slaughter class and should be prioritized to maximize agency resources.

2) Conditions should be developed for individual slaughter classes because of varying husbandry practices including the purpose of animals and the age at which they are slaughtered.

Phase 1 of the pilot covers a 6-month period, from October 2015 through April 2016, with dairy cow and bob veal. Theses slaughter classes have previously been identified to have the highest frequency of veterinary drug residue violation, in the past several years. For Phase 1, the conditions selected for prioritization represent the top one-third of conditions found associated with positive (both non-violative and violative) laboratory results on a national basis.

On April 2016, FSIS launched Phase 2 of the pilot project, which includes three swine slaughter classes (market hogs, sows, and roaster pigs). Similar to Phase 1, Phase 2 will test the same hypothesis and the conditions selected for prioritization represent the top one third conditions found associated with positive (both non-violative and violative) laboratory results on a national basis.

PHVs in the pilot establishments will select from these conditions for residue screen testing on a primary emphasis basis. However, this project does not eliminate professional judgment. Other conditions, not included on the primary selection list, can still be screen tested on a secondary emphasis basis.

In order to reduce unnecessary burden to establishments, FSIS have chosen high slaughter volume establishments for participation into the pilot project. FSIS anticipates this pilot project (Phase 1 and Phase 2) will continue for a period of six months.

Appendix VI
2016 FSIS Residue Sampling for Siluriformes

On December 2, 2015, FSIS published the final rule, "Mandatory Inspection of Fish of the Order Siluriformes and Products Derived From Such Fish." The 2008 Farm Bill amended the Federal Meat Inspection Act (FMIA), to make Siluriformes a species amendable to the FMIA and therefore, subject to FSIS inspection. FSIS is providing an 18 month transitional period for the inspection of Siluriformes and the residue testing will be done based on parameters set forth in the final rule. During the first 18 months FSIS will schedule routine testing of Siluriformes for malachite green, nitrofurans, veterinary drugs, gentian violet, metals, and pesticides residues. FSIS plans to take at least one sample per month per domestic slaughter establishment. FSIS plans to sample every import shipment that is scheduled for re-inspection.

Note: The sampling scheme may change during the 18 month transitional period based on sampling results and findings by FSIS.