UNITED STATES
National Residue Program for Meat, Poultry, and Egg Products

2012 Residue Sampling Plans

United States Department of Agriculture
Food Safety and Inspection Service
Office of Public Health Science

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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) to conduct the NRP. Detailed discussions describing the principles and methods used to plan and design the NRP sampling plans are provided. Development of the sampling plans is divided into individual sections for veterinary drugs, pesticides, and environmental contaminants. For convenience, tables that report summaries of FSIS sampling plans are provided before the detailed discussions. Two appendices detail the tissues required for laboratory analysis and FSIS laboratory analytical methods.

Contacts and Comments

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Introduction

The U.S. National Residue Program (NRP) for Meat, Poultry, and Egg Products, administered by the USDA FSIS, is an interagency program designed to identify, rank and test for chemical contaminants in meat, poultry, and egg products. FSIS publishes the NRP's *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. The Blue Book describes the sampling algorithms used to allocate 24,000 annually scheduled residue samples collected from meat, poultry and egg products and tested for the presence of more than 100 chemical compounds.

The NRP requires the cooperation and collaboration of several agencies for its successful design and implementation. The USDA FSIS, the EPA, and the Department of Health and Human Services (DHHS) FDA 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; Title 40 CFR includes tolerance levels established by EPA.

Representatives from FSIS, FDA, EPA, the USDA Agricultural Research Service (ARS), the USDA Agricultural Marketing Service (AMS), and the DHHS Centers for Disease Control and Prevention (CDC) collaborate to develop the scheduled sampling program. These agencies work together to create the annual sampling plans using prior NRP findings of chemical compounds in meat, poultry, and egg products, FDA veterinary drug inventories completed during on-farm visits, information from investigations, and pesticides and environmental contaminants of current importance to EPA. The agency representatives convene to identify the residues of public health concern in appropriate production classes, and evaluate FSIS laboratory capacity and analytical methods. FSIS publishes the finalized sampling plans in the Blue Book.

Chemical compounds tested 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 of concern 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 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 program is designed to protect the health and welfare of 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.

FSIS has administered the NRP by collecting meat, poultry, and egg product samples and analyzing the samples for specific chemical compounds at FSIS laboratories since 1967 for meat and poultry and 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. FSIS informs the establishment via certified letter, and, under best practices, the establishment should notify the producer that an animal from that business has a violative chemical level. FSIS also shares the violation data with FDA, which has on-farm jurisdiction, and EPA. 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.

Every week, FSIS posts a Residue Repeat Violator List on its Web site. The list identifies producers with more than 1 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. Because FSIS updates this list weekly, FDA may not have investigated each violation at the time of publication.

Transition to New NRP Operating Structure

The NRP, designed to identify, rank, and test for chemical contaminants in meat, poultry, and egg products, consists of three separate, but interrelated, chemical residue testing programs: scheduled sampling, inspector-generated sampling, and import sampling. This basic structure has been in existence since 1967, when FSIS began sampling and testing meat and poultry. Egg products were added in 1995. These testing programs provide data for FSIS to detect chemical residues of concern, and have been modified over the years to respond to emerging and re-emerging chemical residue concerns and improved testing methodologies.

In the late 1990s, FSIS implemented the Hazard Analysis and Critical Control Point (HACCP) inspection system in all federally inspected establishments. The HACCP regulation (9 CFR 417) requires FSIS-inspected slaughter and processing establishments to identify all food safety hazards (including drug residues, chemical contaminants, pesticides) that are reasonably likely to occur before, during, and after entry of the food animal or product into the 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 adequate 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.

In the past, the sampling program was designed to identify a select number of chemical hazards, primarily veterinary drugs and only a few pesticides and/or heavy metals, in meat, poultry and egg products to see if these chemicals were above established tolerances. For the past several years, FSIS has sampled 230 or 300 animals for each chemical compound and animal production class pair. Production classes refer to specific animal slaughter classes and broadly include bovine, porcine, caprine, ovine, avian, equine, and other species. Applying sampling rates of 230 or 300 ensures FSIS a 90 percent or 95 percent probability, respectively, of detecting chemical residue violations if the violation rate is equal to or greater than 1 percent in the population being sampled.

With greater public concern about the risks of chemical contaminants, there has been greater focus on strengthening the identification, ranking, and testing for chemical hazards in meat, poultry, and egg products in the U.S. The Calendar Year (CY) 2012 sampling plan for residues in FSIS-regulated products includes a shift towards a more public health-based sampling approach. This approach includes broader screens for veterinary drugs and pesticides, more analyses for each sample, and the use of performance-based methods.

During the first half of CY 2012, FSIS used a modified version of the 2011 NRP, sampling 9 production classes for more than 100 chemicals. Later in CY 2012, FSIS will transition to the updated NRP sampling scheme for the remainder of the year. The transition to using multi-analytic methods will eliminate pairing one compound class or individual compound with one production class and allow FSIS to analyze more compounds per sample while using fewer samples. To implement this new approach, FSIS will establish three tiers of sampling for the NRP. The three-tiered system refers to 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).

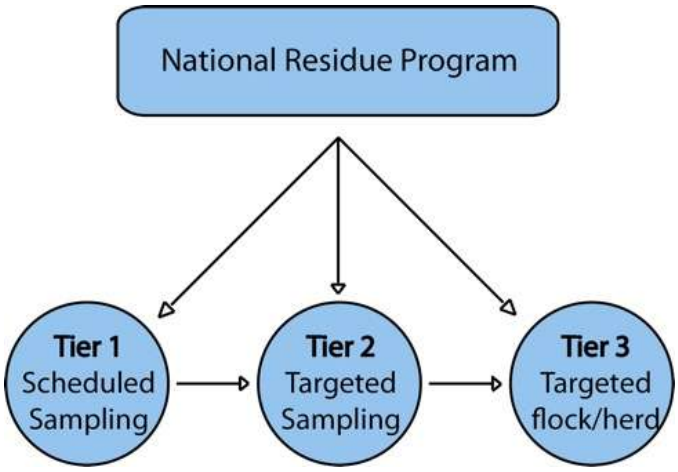
Tier 1 includes the current scheduled sampling program. Collection of these data will serve as a baseline level for chemical residue exposure. While the traditional program has required random sample collection from each production class regulated, the new FSIS program will rotate production classes through Tier 1 annually.

While FSIS allocated a maximum of 300 samples per chemical compound class in the traditional program, the new structure will allocate approximately 800 random samples per chemical compound class for each of the production classes tested in Tier 1. By increasing the number of samples taken, we increase our probability of finding a violation to 99 percent if the violation rate is equal to or greater than 1 percent in the population being sampled.

For Tier 1 within the 2012 domestic scheduled sampling program, FSIS will run 24,000 analyses across the nine production classes (beef cows, bob veal, dairy cows, steers, heifers, market hogs, sows, young chickens, and young turkeys) representing 95 percent of domestic meat and poultry consumption. This change will result in more analytical results for each production class. Beginning in mid-2012, the multi-residue screening methods (discussed below) will be conducted for Tier 1 in the Eastern and Western Laboratories.

Tier 2 will include the traditional inspector-generated sampling program at the establishment level. When FSIS Inspection Program Personnel (IPP) detects evidence of disease or use of a drug, they hold and test samples from those carcasses because they might contain violative levels of chemical residues. In 2010, IPP completed more than 200,000 in-plant residue screens using the Kidney Inhibition Swab test (KIS™ test) or the Fast Antimicrobial Screen Test (FAST). These screens resulted in approximately 7,000 positive samples submitted to the FSIS Midwestern Laboratory for confirmation, and 1,632 of these samples were confirmed to be violative. In mid-2012, FSIS will begin to test in-plant screen positives using a multi-residue screening method submitted to the Midwestern Laboratory.

In addition, the new Tier 2 will include directive-driven targeted testing at the production and compound class level as outlined in FSIS directives for show animals and bob veal calves. FSIS can adjust targeted sampling plans to respond to information about misuse of animal drugs and/or exposure to environmental chemicals gained from other agencies (such as FDA and EPA), as well as Tier 1 sampling data. FSIS is further planning a Tier 3 level, which FSIS anticipates will be similar in structure to the 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 region may be necessary on occasion to determine the level of exposure of a chemical or chemicals to which the livestock or flock may have been exposed. Tier 3 will provide a vehicle for developing information that will support future policy development within the NRP.



The import reinspection sampling program will be structured using the Tier 1 and 2 frameworks. In CY 2012, FSIS will collect 1,300 import samples. These import samples will comprise 500 samples under the Tier 1 scheduled sampling and, based on interagency discussions, 800 samples under Tier 2. In addition, FSIS will screen a subset of these samples for unknown compounds with the FSIS Food Emergency Response Network (FERN). FERN is a nation-wide integrated network of Federal, State, and local laboratories with the capability to detect and identify biological, chemical, and radiological agents in food.

New Methodologies

Based on interagency discussion and method improvements, FSIS is using a new screening method for antibiotics starting in the second half of 2012. The current screening methodology for antibiotics is a 7-plate bioassay. The new multi-residue method (MRM) provides the following significant improvements: 1) it screens for a variety of analytes, not just antibiotics; 2) it has been validated at levels appropriate to tolerances; 3) it clearly distinguishes individual analytes, even if multiple drugs are present in the same sample, using mass spectrometry; 4) it mitigates unknown microbial inhibition responses; and 5) it reduces the time and personnel needed to obtain results.

The FSIS pesticide method has been in place since 2011. This method diversifies testing capability, improving on the previous pesticide method. The previous method could only test for halogenated compounds; the new screen tests 57 pesticides across multiple classes and includes compounds such as carbaryl and piperonyl butoxide.

See Appendix II for a list of current methods used by FSIS laboratories.

Overview of the Sampling Plans

The NRP 2012 Residue Sampling Plans focus on chemical residues in domestic meat, poultry, and egg products and address import reinspection of meat and poultry 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. FSIS Directive 10,800.1, *Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program* provides further detail.

DOMESTIC SAMPLING PLAN

Scheduled Sampling

Scheduled sampling plans involve taking tissue samples from randomly selected food animals that have passed ante-mortem inspection. The development of scheduled sampling plans proceeds in the following manner: 1) determine which chemical compounds are of concern to food safety; 2) use algorithms to rank the selected chemical compounds; 3) pair these chemical compounds with appropriate food animals and egg products; and 4) establish the number of samples to be collected.

The Surveillance Advisory Team (SAT), an interagency committee comprising of representatives from FSIS, FDA, EPA, AMS, ARS and CDC, determines the chemical compounds and production classes (e.g., young chickens, bob veal, steers, etc.) of public health concern. FSIS calculates the number of samples needed for the scheduled sampling. The laboratories test the samples for the presence of chemical residues and report any positive findings above established tolerance levels. The resulting violation data are used to verify whether industry process controls and HACCP plans effectively control residues. FSIS, FDA, and EPA review and make final adjustments to the domestic scheduled sampling plan.

Inspector-Generated Sampling

Inspector-generated sampling is conducted by in-plant Public Health Veterinarians (PHVs) 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 10,220.3*. When an inspector-generated sample is collected and the carcass is not already condemned, only the carcass that is sampled is held. If the in-plant screen test result is negative, the carcass is released. 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.

Sampling for individual suspect animals

The in-plant inspector selects a carcass for sampling based on professional judgment and public health criteria outlined in FSIS Directives 10,800.1 and 10,220.3 (i.e., animal with disease signs and symptoms, producer history, or results from random scheduled sampling). Some samples are screened in the plant by IPP and 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 test. If the result of a screening test is positive, the carcass is held (if it not already condemned

for other pathology or conditions that would make it unfit for human consumption), and the liver, kidney, and muscle sample from the carcass is sent to an FSIS laboratory for confirmation.

Sampling for suspect animal populations

Sampling for suspect animal populations is directed by an FSIS regulation (e.g., 9 CFR 310.21), directive (e.g., FSIS Directive 10,220.3) or FSIS notice.

Actions taken on violations

A violation occurs when an FSIS laboratory confirms a residue that exceeds an established tolerance or action level, or has no tolerance. Once the laboratory analysis is complete, FSIS enters the residue violation 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 on the violation. These actions range in severity, from providing education to taking legal action.

Every week, FSIS posts a Residue Repeat Violator List on its Web site. The list identifies producers with more than 1 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. Because FSIS updates this list weekly, FDA may not have investigated each violation at the time of publication.

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. 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 United States. Chemical residue sampling is included in the reinspection of imported products. The following are the three levels of chemical residue reinspection:

- 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 failed to meet U.S. requirements

For both normal and increased sampling, the lot is not required to be retained pending laboratory results; however, the importer may choose to retain the lot pending the laboratory results. The lot is subject to recall if it is not retained and is found to contain violative levels of residue. For intensified sampling, the lot must be retained pending laboratory results.

The data obtained from laboratory analyses are entered into the Automated Import Information System (AIIS), 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.

[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.

Summary of the Domestic and Import Reinspection Sampling Plans

Summary Tables I–V

Summary Tables I–IV provides an overview of both domestic and import sampling organized by chemical compound class. Each table covers one group of compounds: Animal Medicinal Drug Use Clarification Act (AMDUCA) prohibited drugs, veterinary drugs, pesticides, and environmental contaminants. Table V sorts the import samples by country and production class. The tables also identify the FSIS laboratory that conducts the analyses.

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 a meeting of the SAT 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 the import reinspection plan. These sampling plans guide the allocation of FSIS laboratory 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; and
- FSIS laboratory capacity to analyze chemical compounds or compound classes.

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. Importing countries use compounds that may not be approved in the U.S. and may allow different use practices for compounds that are approved in the U.S. For these reasons, the compounds analyzed in the import plan may not necessarily be the same as those in the U.S. domestic plan.

Summary Table I – Summary by Compound Class
Status of the AMDUCA-Prohibited Drugs
2012 NRP – Domestic and Import Scheduled Sampling

AMDUCA[2] Prohibited Drug	**Number of Scheduled Samples**		
	Domestic	**Import**	**Total**
Avoparcin (glycopeptide)	Not in the 2012 NRP	Not in the 2012 NRP	0
Chloramphenicol Analysis by EL	young chickens (267) young turkeys (267) **Total domestic: 534**	To start when method extended to muscle	534
Clenbuterol[3] Analysis by WL Part of beta-agonist method	steers (88) heifers (200) market hogs (133) **Total domestic: 421**	pork, fresh (154) beef, fresh (94) beef, processed (20) veal, fresh (132) **Total import: 400**	821
Diethylstilbestrol	Not in the 2012 NRP	Not in the 2012 NRP	0
Fluoroquinolones[4] Analysis by ML Part of antibiotics 7-plate bioassay analysis	beef cows (267) bob veal (400) dairy cows (176) heifers (200) sows (453) market hogs (133) steers (68) young chickens (267) young turkeys (267) **Total domestic: 2,231**	To start when method extended to muscle	2,231
Nitrofurans[5] Analysis by WL	dairy cows (135) market hogs (133) **Total domestic: 268**	No samples scheduled for imports in 2012	
Nitroimidazoles[6]	Not in the 2012 NRP	Not in the 2012 NRP	0
Phenylbutazone	Not in the 2012 NRP	Not in the 2012 NRP	0
Ronidazole	Not in the 2012 NRP	Not in the 2012 NRP	0
Vancomycin	Not in the 2012 NRP	Not in the 2012 NRP	0

[2] The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) refers to drugs banned by FDA from extra label use. These compounds are not evaluated using the ranking formula, but instead are automatically assigned a high sampling priority and will be included in the NRP if methodologies and resources are available.
[3] Clenbuterol, along with salbutamol, cimaterol, zilpaterol, and ractopamine are analyzed using the beta-Agonist method.
[4] Fluoroquinolones, along with enrofloxacin and danofloxacin are approved for use in steers and heifers.
[5] Nitrofurans are antimicrobials that include furazolidone and nitrofurazone.
[6] Nitroimidazoles are antiprotozoals that include dimetridazole and ipronidazole.

Summary Table II – Summary by Compound Class
Rank and Status of Veterinary Drugs
2012 NRP – Domestic and Import Scheduled Sampling

Rank	Score	Veterinary Drug	Number of Scheduled Samples				
			Domestic		Import		Total
1	16.0	Antibiotics[7] Analysis by ML	beef cows (267) bob veal (400) dairy cows (176) heifers (200) sows (453)	market hogs (133) steers (68) young chickens (267) young turkeys (267) **Total domestic: 2,231**	To start when method extended to muscle		2,231
2	15.0	Carbadox Analysis by WL	market hogs (133)	**Total domestic: 133**	No samples scheduled for imports in 2012		133
3	14.0	Avermectins[8] Analysis by EL	beef cows (267) dairy cows (176)	steers (68) **Total domestic: 511**	beef, fresh (206) beef, processed (118) goat, fresh (19) lamb/mutton, fr. (27)	pork, fresh (1) pork, processed (0) veal, fresh (29) **Total import: 400**	911
4	13.0	Sulfonamides[9]	Not in the 2012 NRP (only inspector generated)		beef, fresh (43) beef, processed (5) pork, fresh (30) pork, processed (5)	turkey, fresh (2) turkey, processed (2) veal, fresh (13) **Total import: 100**	100
5	12	Xenobiotic hormones	Not in the 2012 NRP		Not in the 2012 NRP		
6	11.3	Arsenicals Analysis by EL	market hogs (133)	young turkeys (267) **Total domestic: 400**	chicken, fresh (29) chicken, proc. (4) pork, fresh (57)	turkey, fresh (4) turkey, processed (6) **Total import: 100**	500
7	10	Flunixin Analysis by ML	dairy cows (176) beef cows (267) bob veal (400)	**Total domestic: 843**	To start when method extended to muscle		843
8	9.75	Florfenicol Analysis by EL	steers (88)	**Total domestic: 88**	To start when method extended to muscle		88
9	8	Hormones[10]	Not in the 2012 NRP		Not in the 2012 NRP		
10	7.5	Gamithromycin	Not in the 2012 NRP		Not in the 2012 NRP		
11	7.5	Tulathromycin Part of antibiotics 7-plate bioassay analysis	beef cows (267) bob veal (400) dairy cows (176)	market hogs (133) steers (68) young chickens (267)	To start when method extended to muscle		2,231

[7] The compounds in the 7-plate bioassay are listed on page 16 in the Domestic Scheduled Sampling Plan for Veterinary Drugs.
[8] Avermectins include doramectin, ivermectin, and moxidectin.
[9] The compounds in the sulfonamides method are listed on page 17 in the Domestic Scheduled Sampling Plan for Veterinary Drugs.
[10] The naturally-occurring hormones include 17-estradiol, testosterone, and progesterone.

Summary Table II – Summary by Compound Class
Rank and Status of Veterinary Drugs
2012 NRP – Domestic and Import Scheduled Sampling

			heifers (200) young turkeys (267) sows (453) **Total domestic: 2231**		
12	5.0	Dexamethasone	Not in the 2012 NRP	Not in the 2012 NRP	0
13	5.0	Methyl prednisone	Not in the 2012 NRP	Not in the 2012 NRP	0
14	4.125	Eprinomectin	Not in the 2012 NRP	Not in the 2012 NRP	0
15	3.5	Thyreostats[11]	Not in the 2012 NRP	Not in the 2012 NRP	0
16	3.375	Lasalocid	Not in the 2012 NRP	Not in the 2012 NRP	0
17	3.25	Dipyrone	Not in the 2012 NRP	Not in the 2012 NRP	0
18	3.0	Melengestrol acetate	Not in the 2012 NRP	Not in the 2012 NRP	0
19	2.75	Berenil	Not in the 2012 NRP	Not in the 2012 NRP	0
20	2.75	Beta-Agonists[12] Analysis by WL	heifers (200) **Total domestic: 421** market hogs (133) steers (88)	pork, fresh (154) veal, fresh (132) beef, fresh (94) **Total import: 400** beef, processed (20)	821
21	2.44	Thiamphenicol	Not in the 2012 NRP	Not in the 2012 NRP	0
22	2.25	Amprolium	Not in the 2012 NRP	Not in the 2012 NRP	0
23	2.0	Clorsulon	Not in the 2012 NRP	Not in the 2012 NRP	0
24	2.0	Veterinary tranquilizers[13]	Not in the 2012 NRP	Not in the 2012 NRP	0
25	1.88	Etodolac	Not in the 2012 NRP	Not in the 2012 NRP	0
26	1.88	Prednisone	Not in the 2012 NRP	Not in the 2012 NRP	0
27	1.5	Levamisole	Not in the 2012 NRP	Not in the 2012 NRP	0
28	1.0	Halofuginone	Not in the 2012 NRP	Not in the 2012 NRP	0
29	0.88	Benzimidazoles[14]	Not in the 2012 NRP	Not in the 2012 NRP	0
30	0.63	Morantel and pyrantel	Not in the 2012 NRP	Not in the 2012 NRP	0
31	0.63	Nicarbazan	Not in the 2012 NRP	Not in the 2012 NRP	0

EL= FSIS Eastern Laboratory (Athens, GA); ML = FSIS Midwestern Laboratory (St. Louis, MO); WL = FSIS Western Laboratory (Alameda, CA)

[11] Thyreostats include 2-thiouracil, 6-methyl-2-thiouracil, 6-propyl-2-thiouracil, 2-mercapto-1-methylimidazole, and 2- mercaptobenzimidazole.
[12] The beta-agonists include clenbuterol, ractopamine, zilpaterol, cimaterol, and salbutamol.
[13] Tranquilizers include azaperone; the metabolites of this compound include azaperol, xylazine, haloperidol, acetopromazine, propionylpromazine, and chlorpromazine.
[14] Benzimidazoles include thiabendazole and its 5-hydroxythiabendazole metabolite, albendazole 2-animosulfone metabolite, benomyl in the active hydrolyzed form carbendazim, oxfendazole, mebendazole, cambendazole, and fenbendazole.

Summary Table III – Summary by Compound Class
Rank and Status of Pesticides
2012 NRP – Domestic and Import Scheduled Sampling

Rank	Score	Pesticide[15]	Number of Scheduled Samples		
			Domestic	Import	Total
1	16.0	Screening of Pesticides by LC/MS/MS and GC/MS/MS Analysis by WL[16]	young chickens (267) sows (347) steers (68) dairy cows (135) **Total domestic: 817**	beef, fresh (100) **Total import: 100**	917
2	16.0	Chlorinated organophosphates (COPs) and organophosphates (OPs) –	26 in new pesticide screen	26 in new pesticide screen	0
3	16.0	Beta-Cyfluthrin	Not in the 2012 NRP	Not in the 2012 NRP	0
4	16.0	Cyfluthrin	Not in the 2012 NRP	Not in the 2012 NRP	0
5	16.0	Imazalil	In new pesticide screen	In new pesticide screen	0
6	15.0	Triazines	1 in new pesticide screen	1 in new pesticide screen	0
7	14.0	Carbamates	4 in new pesticide screen	4 in new pesticide screen	0
8	14.0	Synthetic pyrethroids	6 in new pesticide screen	6 in new pesticide screen	0
9	14.0	1-(2,4-Dichlorophenyl)-2-(1H-imidazole-1-yl)-1-ethanol	Not in the 2012 NRP	Not in the 2012 NRP	0
10	14.0	1,1-(2,2-Dichloroethylidene)bis(4-methoxybenzene)	Not in the 2012 NRP	Not in the 2012 NRP	0
11	14.0	1-Methoxy-4-(1,2,2,2-tetrachloroethyl)benzene)	Not in the 2012 NRP	Not in the 2012 NRP	0
12	14.0	3-(1-(2,4-Dichlorophenyl)-2-(1H-imidazole-1-yl) ethoxy)-1,2-propane diol	Not in the 2012 NRP	Not in the 2012 NRP	0
13	14.0	Cyhalothrin, lambda	In new pesticide screen	In new pesticide screen	0
14	14.0	Fipronil	In new pesticide screen	In new pesticide screen	0
15	14.0	MB 45950	Not in the 2012 NRP	Not in the 2012 NRP	0
16	14.0	MB 46513	Not in the 2012 NRP	Not in the 2012 NRP	0
17	14.0	Methoxychlor olefin	Not in the 2012 NRP	Not in the 2012 NRP	0
18	13.0	Triazines	1 in new pesticides screen	1 in new pesticides screen	0
19	13.0	Arsanilic acid	Not in the 2012 NRP	Not in the 2012 NRP	0

[15] Only those pesticides that have been designated as representing a broad potential public health risk are included in this table.

[16] FSIS CHC/COP method includes alachlor, aldrin, azinphos methyl, bifenthrin, boscalid, carfentrazone ethyl, chlordane cis, chlordane trans, chlorpyrifos, chlorpyrifos methyl, L-cyhalortin, cypermethrin, deltamethrin, dichlorvos (DDVP), dieldrin, difenconazole, endosulfan I, endosulfan II, endosulfan sulfate, fipronil, heptachlor, heptachlor epoxide cis, heptachlor epoxide trans, mirex, nonachlor trans, oxychlordane, permethrin (cis & trans), piperonyl butoxide, pronamide, propachlor, propanil, propiconazole, tefluthrin, tetrachlorvinphos, and tetraconazole (as analyzed with GC/MS/MS), as well as 3-hydroxycarbofuran, acephate, carbaryl, carbofuran, clofentizine, diflubenzuron, diuron, ethofumesate, imazalil, imidacloprid, indoxacarb, linuron, metalaxyl, methomyl, methoxyfenozide, myclobutanil, norflurazon, pyridaben, simazine, tebufenozide, thiabendazole, thiamethoxam (as analyzed with as LC/MS/MS**)**.

Summary Table III – Summary by Compound Class
Rank and Status of Pesticides
2012 NRP – Domestic and Import Scheduled Sampling

Rank	Score	Pesticide[15]	Number of Scheduled Samples		
			Domestic	Import	Total
20	13.0	Etoxazole	Not in the 2012 NRP	Not in the 2012 NRP	0
21	13.0	Indoxacarb	In new pesticide screen	In new pesticide screen	0
22	13.0	Metconazole	Not in the 2012 NRP	Not in the 2012 NRP	0
23	13.0	Prothioconazole	Not in the 2012 NRP	Not in the 2012 NRP	0

WL = FSIS Western Laboratory (Alameda, CA)

Summary Table IV – Summary by Compound Class
Rank and Status of Environmental Contaminants
2012 NRP – Domestic and Import Scheduled Sampling

Environmental Contaminant	Number of Scheduled Samples		
	Domestic	Import	Total
Lead and cadmium Analysis by EL	market hogs (300) **Total domestic: 300**	No samples scheduled for imports in 2012	300

EL = FSIS Eastern Laboratory (Athens, GA)

Summary Table V
Summary by Production Class
2012 NRP – Import Scheduled Sampling

Exporting Country ▼	Beef, fresh	Beef, processed	Veal, fresh	Horse, fresh	Pork, fresh	Pork, processed	Lamb/Mutton, fresh	Goat, fresh	Chicken, fresh	Chicken, processed	Turkey, fresh	Turkey, processed	Other fowl, fresh	Varied comb., fresh	Varied comb., proc.	TOTALS
Argentina	-	46	-	-	-	-	-	-	-	-	-	-	-	-	-	46
Australia	51	-	18	-		-	12	4	-	-	-	-	-	-		85
Brazil	-	97	-	-	-	-	-	-	-	-	-	-	-	-	-	97
Canada	71	-	100		52	-	3	-	23	-	3	-	-	-	-	252
Chile	11	-	-	-	24	-	-	-	3	-	3	-	-	-	-	41
Costa Rica	66	-	-	-	-	-	-	-	-	-	-	-	-	-	-	66
Croatia	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	1
Denmark	-	-	-	-	17	-	-	-	-	-	-	-	-	-	-	17
Finland	-	-	-	-	11	-	-	-	-	-	-	-	-	-	-	11
Germany	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	1
Honduras	71	-	-	-	-	-	-	-	-	-	-	-	-	-	-	71
Hungary	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	1
Iceland	-	-	-	-	-	-	3	-	-	-	-	-	-	-	-	3
Ireland	-	-	-	-	14	-	-	-	-	-	-	-	-	-	-	14
Israel	-	-	-	-	-	-	-	-	-	4	-	5	-	-	-	9
Italy	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	1
Mexico	35	-	-	-	51	-	2	13	3	-	-	3	-	-		107
Netherlands	-	-	-	-	17	-	-	-	-	-	-	-	-	-	-	17
New Zealand	38	-	56	-	-	-	7	2	-	-	-	-	-	-	-	103
Nicaragua	48	-	-	-	-	-	-	-	-	-	-	-	-	-	-	48
N. Ireland	-	-	-	-	15	-	-	-	-	-	-	-	-	-	-	15
Poland	-	-	-	-	9	-	-	-	-	-	-	-	-	-	-	9
San Marino	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	1
Spain	-	-	-	-	8	-	-	-	-	-	-	-	-	-	-	8
Sweden	-	-	-	-	9	-	-	-	-	-	-	-	-	-	-	9
UK	-	-	-	-	15	-	-	-	-	-	-	-	-	-	-	15
Uruguay	52	-	-	-	-	-	-	-	-	-	-	-	-	-	-	52
TOTALS	443	143	174	-	242	5	27	19	29	4	6	8	-	-	-	1,100

Design of the Domestic Scheduled and Import Reinspection Sampling Plans for Veterinary Drugs

I. Selecting and Ranking Candidate Veterinary Drugs

Table 1 contains the candidate veterinary drugs of domestic concern selected by members of the SAT. These veterinary drugs are listed below. Veterinary drugs that may be detected using similar analytical methods are grouped together. Some veterinary drugs listed below are prohibited from extra label use in food animals under AMDUCA are high regulatory priorities.

FSIS does not have sufficient historical data on veterinary drugs in imported products to predict their violation rates. The import reinspection sampling plan (IRSP) will focus on the same candidate veterinary drugs as specified in the domestic sampling plan; the drugs will be ranked according to ranking scores generated for the domestic scheduled sampling plan. If FSIS believes that a compound is being misused in a foreign country, then the compound and country will be added to the IRSP.

For additional information on veterinary drugs, see the *Electronic Code of Federal Regulations, Title 21: Food and Drugs, Part 556: Tolerances for Residues of New Animal Drugs in Food* (21 CFR 556).

FSIS selects compound classes for sampling from the list of ranked veterinary drugs based on the relative public health concern. After identifying high-priority compounds and compound classes, FSIS applied other practical considerations to determine the compounds for sampling. The principal considerations include the availability of laboratory resources, especially the availability of appropriate analytical methods within the FSIS laboratories. When laboratory resources are limited, FSIS focuses resource allocation to domestic products because imported products have been inspected previously in the country of origin. Based on these considerations, the following compounds were evaluated for inclusion in 2012 scheduled sampling for domestic and imported products:

Antibiotics: At present, the following compounds are quantitated using the 7-plate bioassay[17]:

Tetracyclines: tetracycline, oxytetracycline, chlortetracycline [High Performance Liquid Chromatography or mass spectrometry (HPLC) for identification, quantitation by bioassay].

Aminoglycosides: spectinomycin, hygromycin, streptomycin, dihydrostreptomycin, amikacin, kanamycin, apramycin, gentamycin, neomycin, tobramycin [Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) for confirmation, quantitation of streptomycin, dihydrostreptomycin, gentamycin, and neomycin by bioassay].

Macrolides: Lincomycin, pirlymycin, clindamycin, tilmicosin, erythromycin, tulathromycin, and tylosin are confirmed by LC/MS/MS. Tilmicosin is quantitated also by HPLC. Erythromycin and tylosin are quantitated by the bioassay.

[17] FSIS quantitates most antibiotics using a 7-plate bioassay measuring microbial inhibition. The pattern of inhibition (i.e., the combination of plates showing inhibition) is used to identify the antibiotic. There are some antibiotics, however, that share the same pattern of inhibition. For these antibiotics, it is necessary to undertake follow-up testing (HPLC or mass spectrometry) to establish their identities, where such follow-up methodologies are available.

Beta-Lactams: amoxicillin, ampicillin, cloxacillin, naficillin, cefazolin, DCCD, dicloxacillin, penicillin G, oxacillin, and desacetyl cephaprin (LC/MS/MS for confirmation, quantitation by bioassay for penicillin G and ampicillin).

- Fluoroquinolones: ciprofloxacin, norfloxacin, danofloxacin, enrofloxacin, sarafloxacin, difloxacin, desethylene diprofloxacin, desmethyl danofloxacin (LC/MS/MS for confirmation).

Other Antibiotics:

- Avoparcin (classification: glycopeptide; AMDUCA prohibited)
- Chloramphenicol (classification: antibiotic; AMDUCA prohibited)
- Florfenicol (classification: antibiotic; chloramphenicol derivative)
- Fluoroquinolones (classification: antibiotic; AMDUCA prohibited; compounds: ciprofloxacin, desethyleneciprofloxacin, danofloxacin, difloxacin, enrofloxacin, marbofloxacin, orbifloxacin, and sarafloxacin)
- Thiamphenicol (classification: antibiotic; chloramphenicol derivative)
- Vancomycin (classification: glycopeptide; AMDUCA prohibited)

Other Veterinary Drugs:

- Amprolium (classification: coccidiostat)
- Arsenicals (detected as elemental arsenic)
- Avermectins (classification: anthelmintics; compounds: doramectin, ivermectin, and moxidectin)
- Benzimidazoles (classification: anthelmintics; compounds: thiabendazole and its 5-hydroxythiabendazole metabolite, albendazole 2-animosulfone metabolite, benomyl in the active hydrolyzed form carbendazim, oxfendazole, mebendazole, cambendazole, and fenbendazole)
- Carbadox (classification: antimicrobial)
- Beta-Agonists (ractopamine, clenbuterol, cimaterol, zilpaterol, and salbutamol; growth promotants)
- Clorsulon (classification: anthelmintic)
- Dexamethasone (classification: glucocorticoid)
- Diethylstilbestrol (DES) (AMDUCA prohibited synthetic hormone)
- Dipyrone (classification: NSAID[18])
- Eprinomectin (classification: antiparasitic; avermectin)
- Etodolac (classification: NSAID)
- Flunixin (classification: NSAID)
- Halofuginone (classification: antiprotozoal, coccidiostat)
- Hormones, endogenous production (17-β estradiol, progesterone, testosterone)
- Hormones, xenobiotics (Melengestrol acetate, trenbolone, zeranol)
- Lasalocid (classification: coccidiostat)
- Levamisole (classification: anthelmintic)
- Methyl prednisone (classification: glucocorticoid)
- Morantel and pyrantel (classification: anthelmintic)
- Nicarbazin (classification: coccidiostat)
- Nitrofurans (compounds: furazolidone, nitrofurazone; AMDUCA prohibited antimicrobials)

[18] NSAID = non-steroidal anti-inflammatory drug

- Nitromidazoles (classification: antiprotozoals; compounds: dimetridazole, ipronidazole)
- Phenylbutazone (classification: NSAID)
- Prednisone (classification: glucocorticoid)
- Ronidazole (classification: antimicrobial; compound: nitroimidazole)
- Sulfonamides (classification: antimicrobials, and some are coccidiostats; compounds: sulfapyridine, sulfadiazine, sulfathiazole, sulfamerazine, sulfamethazine, sulfachlorpyridazine, sulfadoxine, sulfamethoxypyridazine, sulfaquinoxaline, sulfadimethoxine, sulfisoxazole, sulfacetamide, sulfamethoxazole, sulfamethizole, sulfanilamide, sulfaguanidine, sulfabromomethazine, sulfasalazine, sulfaethoxypyridazine, sulfaphenazole, and sulfatroxazole)
- Sulfanitran (classification: antibacterial, coccidiostat)[19]
- Thyreostats (compounds: 2-thiouracil, 6-methyl-2-thiouracil, 6-propyl-2-thiouracil, 2-mercapto-1-methylimidazole (tapazole), 6-phenyl-2-thiouracil, and 2-mercaptobenzimidazole)
- Veterinary tranquilizers (compounds: azaperone and its metabolite azaperol, xylazine, haloperidol, acetopromazine, propionylpromazine, and chlorpromazine)

Veterinary Drugs Banned from Extra Label Use under AMDUCA

Veterinary drugs banned from extra label use under AMDUCA are of high public health concern. Therefore, these AMDUCA-prohibited veterinary drugs are not evaluated for inclusion using the ranking formula presented below. Instead, all AMDUCA-prohibited veterinary drugs are assigned a high sampling priority and are included in the NRP if methodologies and resources are available. AMDUCA-prohibited veterinary drugs are listed in Summary Table I (page 8).

Compound Scoring

Using a simple 4-point scale (4 = high; 3 = moderate; 2 = low; 1 = none), the SAT scored each of the above veterinary drugs or veterinary drug classes in each of the following categories:

- NRP Historical Testing Information on Violations;
- Lack of NRP Testing Information on Violations;
- Regulatory Concern;
- Withdrawal Time;
- Impact on New and Existing Human Disease;
- Relative Number of Animals Treated; and
- Acute or Chronic Toxicity Concerns.

Compound Ranking

1. Background

Initially, FSIS employs qualitative risk assessment techniques to rank the relative public health concern represented by each candidate chemical compound or compound class. FSIS shares this ranking with other members of the SAT for further discussion.

FSIS combines detailed historical data on the levels for each of the candidate compounds or compound classes in meat, poultry, and egg products with consumption data to estimate exposure. The relative toxicity is measured as the tolerance (set by FDA) or action level of a compound or compound class.

[19] FSIS, in consultation with FDA, rotated sulfanitran out of the NRP beginning in the 2005.

Specifically, the frequency of violation of a tolerance or action level is used as an indicator of the risk-per-unit of consumption of a product. FSIS estimates risk by combining exposure estimates with toxicity information for each compound or compound class.

FSIS defines category designation based on the percent of tested carcasses found to have residues in excess of the tolerance or action level (see Table 1). This percentage is determined from data obtained from the domestic scheduled sampling plan. Veterinary drug compounds are scored by two methods: (a) the maximum violation rate seen in any production class, and (b) the maximum, for any production class, of the violation rate, weighted by the size of the production class. Each veterinary drug is assigned the higher of these two scores.[20]

The equation below provides the violation rate scores assigned in Table 1 and represents a rough overall estimate of *relative* risk per unit of consumption.[21] Data on violation rates are not available for all candidate compounds or compound classes of concern; therefore, we generated an estimate of the overall violation rate for each of these untested compounds and compound classes.

$$\begin{aligned} \text{Risk} &= \text{Exposure} \times \text{Toxicity} \\ &= \text{Consumption} \times \text{Residue Levels} \times \text{Toxicity} \\ &= \text{Consumption} \times \text{Risk per Unit of Consumption} \end{aligned}$$

2. Estimating the Violation Rate

FSIS expects the variables "Regulatory Concern," "Withdrawal Time," and "Relative Number of Animals Treated" to be correlated positively with the violation rate. They were chosen to serve as predictors of violations in those compounds or compound classes when reliable historical testing information is absent. "Regulatory Concern" predicts the likelihood of occurrence of violations, based on regulatory intelligence information about possible misuse. "Withdrawal Time" correlates with "NRP Historical Testing Information on Violations" because a longer withdrawal time is less likely to be observed properly. An abbreviated withdrawal time may lead to violative levels of residues in carcasses because the time necessary for sufficient metabolism and elimination of the veterinary drug would not have passed. "Relative Number of Animals Treated" correlates with "NRP Historical Testing Information on Violations" because heavy compound use increases the likelihood of violations.

The SAT uses violation rate data to score selected compounds and compound classes; these compounds are listed in Table 1 under the category "NRP Historical Testing Information on Violations." These scores provide an opportunity to evaluate how well the above criteria correlate. A least squares linear regression model was applied to impute values for the missing data. The category "NRP Historical Testing Information on Violations" provides the dependent variable in this model, while the only significant independent variable is the product of the scores for "Relative Number of Animals Treated" and "Withdrawal Time."

[20] For a more detailed explanation, refer to the *Scoring Key for Veterinary Drugs.*

[21] While some consideration was given to the size of the production class in scoring "NRP Historical Testing Information on Violations," no systematic weighting was applied to the scores in this category based upon consumption. Hence, the scores assigned to this category represent relative *risk per unit of consumption*, rather than relative risk.

A regression analysis examines the relation of a dependent variable (response variable) to specified independent variables. The model has a regression value (R^2) of 0.44, which explains 44 % of the data variability. Where current, reliable historical testing data are available for a compound or compound class, FSIS used the score assigned in Table 1. Where not available, FSIS used a predicted score.

3. Rating the Veterinary Drugs According to Relative Public Health Concern

As indicated above, the score for the category "NRP Historical Testing Information on Violations" combines information on residue levels and toxicity, and, thus, represents an overall estimate of the relative risk per unit of consumption for each veterinary drug or veterinary drug class. This score, once multiplied by relative consumption data for each production class, yields a risk-based ranking. In addition to historical violation data, FSIS includes scores for acute and chronic toxicity concerns, impact on new and existing human disease, and lack of testing information on violations as parameters for the relative public health concern calculation.

A veterinary drug violation means that a compound was found at a level that exceeds FDA standards; the concentration poses a toxic effect. To address the *severity* of the toxic effect, FSIS used the variable "Acute or Chronic Toxicity Concerns." Compounds designated to this category have the highest degree of human toxicity and receive the highest score.

The category "Impact on New and Existing Human Disease" represents a potential public health concern not captured by the violation rate. It represents the extent that the use or misuse of a compound contributes to new and existing human disease. For example, the creation of antibiotic-resistant human pathogens could result from the use of antibiotics in animals.

The relative public health concern is presented in the column "Relative Public Health Concern Score" in Table 1. The score for "NRP Historical Testing Information on Violations" has been multiplied by a weighted average of the categories for negative potential public health effects: "Acute or Chronic Toxicity Concerns" and, with three times less weight in the calculation, "Impact on New and Existing Human Disease."

Summary Table II (page 10) ranks the veterinary drugs by their rating scores. The scores enable FSIS to bring consistency, grounded in formal risk-based considerations, to differentiate among a very diverse range of veterinary drugs and veterinary drug classes in a situation that is marked by minimal data on relative exposures**.** These rankings do not account for exposure variability due to differences in overall consumption. Relative consumption data is based on estimates of relative exposure values for each compound and production class.

II. Prioritizing Candidate Veterinary Drugs

After ranking veterinary drugs, the SAT used the scores for relative public health concern as criteria for selecting compounds and compound classes to include in the 2012 NRP. FSIS and FDA prioritize compounds and compound classes that rank 1 to 10 and represent a potential public health concern.

After identification of AMDUCA drugs for high-priority compounds and compound classes, FSIS applied practical considerations to determine the compounds for sampling. In addition, FSIS considered the availability of laboratory resources and appropriate analytical methods within the FSIS laboratories. FSIS has scheduled the following veterinary drugs for 2012 domestic sampling:

- Antibiotics (7-plate bioassay)
- Arsenicals

- Avermectins
- Beta-Agonists
- Carbadox
- Chloramphenicol
- Florfenicol
- Flunixin
- Nitrofurans

In the 2012 NRP, FSIS will employ a number of analytical methodologies to identify and quantitate veterinary drug residues. These methodologies analyze individual compounds and compound classes. Summary Table II lists the original candidate veterinary drugs in rank order and specifies individual compounds and compound classes scheduled for domestic sampling.

III. Allocation of Sampling Resources

Domestic:
Table 2 lists the estimated consumption of each production class as a percentage of the total consumption of all the production classes in the table. These estimates were developed based on production data for animals and egg products that were presented for slaughter (or processing) in federally inspected establishments during calendar year 2010 as a surrogate for consumption. The production data for calves were collected, collated, and reported by FSIS using the Automated Disposition Reporting System. The production data for all other production classes were collected by FSIS and were collated and reported by the USDA National Agricultural Statistical Service. The estimated relative percent of consumption represented by each production class was calculated by dividing the estimated total annual U.S. domestic production (pounds dressed weight) for that class by the total poundage for all production classes.

Import:
Egg products
Residue analysis samples for imported egg products are selected in a different manner than the other product classes. In order to establish a history of compliance with the U.S. requirements for each category of egg product, the first 10 shipments from individual foreign establishments are subjected to 100 percent reinspection. If the egg product is in compliance, the rate of inspection is reduced to a random selection of one reinspection out of eight product lots from each foreign establishment. This reinspection rate continues as long as the product is in compliance. FSIS is not testing imported egg products in 2012.

Animal product classes
Table 3 lists the estimated amount and percentage of all the product classes imported into the United States. Table 4 lists the estimated annual amount (in pounds and percentages) of product imported per country. The data for the product classes were obtained from the AIIS. The percent of each product class imported annually is calculated from the amount of product class imported per all meat, poultry, and egg imports. The relative sampling priority is calculated by multiplying the percent product class imported by the veterinary drug scores. Production class nomenclature includes**:**

<u>Bovine</u>
- 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 definitions are under FSIS review.
- 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 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.
- Mature turkeys are birds of both sexes and usually more than 15 months of age.
- Other poultry include ratites (e.g., ostriches, emus, and rheas), guineas, squabs (young, unfledged pigeons), adult pigeons, pheasants, grouse, partridge, quail, etc.
- Young chickens include broilers/fryers birds of both sexes that are usually less than 10 weeks of age. Roasters are birds of both sexes, usually less than 12 weeks of age; capons are surgically castrated male birds 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 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.

FSIS will not test (1) processed products from eligible foreign countries that also ship fresh products to the United States and (2) processed products from countries that source all their raw materials from other foreign countries that are eligible to ship fresh product and are actively exporting to the United States. Processed products that are not tested due to this policy include:

(a) processed beef from Australia, Canada, Costa Rica, Mexico, New Zealand, and Uruguay;
(b) processed veal from Australia, Canada, and New Zealand;
(c) processed pork from Canada, Denmark, Mexico, the Netherlands, Poland, and Spain;
(d) processed mutton and lamb from Australia, Canada, and New Zealand;
(e) processed chicken from Canada and Mexico;
(f) processed turkey from Canada;
(g) other processed fowl from Canada and France; or
(h) processed varied combination products from Canada

IV. Scoring Key for Domestic Products

Regulatory Concern

Based on regulatory intelligence information (e.g., FDA on farm investigations) about possible misuse of veterinary drugs, FSIS makes professional judgments about the likelihood violations may occur. By conferring with subject matter experts, FSIS synthesizes information and recommends the level of regulatory concern. Due to the public health significance of veterinary drug residue violations, information concerning a compound must meet only one of the requirements listed under each number below to receive that numerical ranking.

4 = Well-documented intelligence information gathered from a variety of reliable sources indicates possible widespread misuse of the compound and/or this compound is not approved for use in food animals in the United States.
3 = Intelligence information gathered through a variety of reliable sources indicates only occasional misuse of this compound. The dosage form/packaging of this compound has potential for misuse.
2 = Intelligence information rarely indicates misuse of this compound.
1 = Intelligence information has never indicated misuse of this compound.

Withdrawal Time
Producers using approved animal veterinary drugs are required to follow "conditions of use." Each veterinary drug in the approved production class specifies the dosing regimen and the withdrawal time. The withdrawal time, which is the number of days that must pass between completion of the dosing regimen and the time of slaughter, provides sufficient time for the concentration of the veterinary drug in the animal to decrease below the tolerance. For unapproved veterinary drugs, scores in this category were assigned based on estimates of the veterinary drug's half-life. Approved veterinary drugs were scored as follows:

4 = withdrawal time is greater than 14 days
3 = withdrawal time is between 8 and 14 days
2 = withdrawal time is between 1 and 7 days
1 = there is a zero-day withdrawal time

Impact on New and Existing Human Disease
The use or misuse of a veterinary drug may contribute to new and existing human disease by changing the patterns of antibiotic resistance in human pathogens. A score for impact on new and existing human disease is determined as follows:

4 = scientific information gathered from a variety of reliable sources indicates that possible widespread use of this compound might significantly modify drug resistance patterns of human pathogenic organisms.
3 = limited scientific information is available to suggest or document public health risk, but the compound has the potential to affect microflora.
2 = no scientific information is available to suggest or document public health risk.
1 = current scientific information available suggests no public health risk.

Relative Number of Animals Treated
Animal treatment scores are based on economic data of doses sold, as well as surveys of treatment practices in animal populations that are representative of national feedlot, dairy, poultry, and swine production. Note: Where data were unavailable, scores were estimated, based on comparison to related veterinary drugs with known usage levels. Numbers estimated in this way are in parentheses.

4 = Products containing this veterinary drug fall within the top one-third of those administered to animals treated within a particular category and dosage form of active ingredient.

3 = Products containing this veterinary drug fall within the middle one-third of those administered to animals treated within a particular category and dosage form of active ingredient.
2 = Products containing this veterinary drug fall within the bottom one-third of those administered to animals treated within a particular category and dosage form of active ingredient, but have more usage than products given a score of "1."
1 = Products containing this veterinary drug are estimated to have extremely limited usage.

Acute or Chronic Toxicity Concerns
Compound toxicity and the severity associated with the compound's toxic endpoint are scored as follows:

4 = The compound is a carcinogen, potentially life threatening, or has significant acute effects, including anaphylactic response to an allergen.
3 = Systemic No Observed Effect Levels (NOELs) seen at intermediate to low doses in laboratory test animals, but has antimicrobial effects that have the high potential to alter intestinal microflora.
2 = Systemic NOELs seen at high oral doses in laboratory test animals and have antimicrobial effects with a moderate potential to alter intestinal microflora.
1 = The compound generally shows no toxicity in laboratory test animals, even at doses much higher than present in edible tissues at zero-day withdrawal.

Table 1
Scoring Table for Veterinary Drugs
2012 NRP, Domestic Scheduled Sampling

Compound / Compound Class	Historical Testing Info. on Violations (FSIS) (V)[22]	Regulatory Concern (CVM) (R)[23]	Withdrawal Time (CVM) (W)[24]	Relative Number Animals Treated (CVM) (N)[25]	Predicted V V= 0.25(R*N)[26]	Impact New & Existing Human Disease (CDC) (D)[27]	Acute or Chronic Toxicity Concerns (CVM) (T)[28]	Relative Public Health Concern Score = V*[(D+3*T)/4]
Antibiotics quantitated by the FSIS Bioassay	4	4	4	4	4	4	4	**16.0**
Carbadox (antimicrobial)	4	4	4	3	4	3	4	**15.0**
Avermectins (incl. doramectin, ivermectin, moxidectin) (antiparasitics)	4	3	4	4	4	2	4	**14.0**
Sulfonamides (antimicrobials, some are coccidiostats)	4	4	3	4	4	4	3	**13.0**
Xenobiotic hormones (zeranol, trenbolone)	4	4	1	3	4	3	3	**12.0**
Arsenicals	3	4	2	4	3	3	4	**11.3**
Flunixin	4	4	2	3	4	1	3	**10.0**
Florfenicol (chloramphenicol derivative)	NT[29]	3	4	4	3	4	3	**9.75**
Hormones (naturally occurring)	NT	4	1	4	4	2	2	**8.0**
Gamithromycin	NT	3	4	4	3	4	2	**7.5**
Tulathromycin	NA[30]	3	4	4	3	4	2	**7.5**
Dexamethasone (glucocorticoid)	NA-O	4	2	2	2	1	3	**5.0**

[22] Scores for historical testing for residue violations (V) are provided by USDA FSIS
[23] Scores for regulatory concern (R) are provided by the FDA Center for Veterinary Medicine (CVM)
[24] Scores for withdrawal time(W) are provided by the FDA CVM
[25] Scores for relative number of animals treated (N) are provided by the FDA CVM
[26] The equation is derived from linear regression. For an explanation, see section on *Compound Rankings, Estimated Violation Rates*. Note the predicted value is used unless V is known.
[27] Scores on impact of new and existing human diseases(D) are provided by the CDC
[28] Scores for acute or chronic toxicity concerns (T) are provided by the CDC
[29] NT = Not tested by FSIS
[30] NA = Tested by FSIS, but violation information does not apply

Table 1 *(continued)*
Scoring Table for Veterinary Drugs
2012 NRP, Domestic Scheduled Sampling

Methyl prednisone (glucocorticoid)	NT	4	2	2	2	1	3	**5.0**
Eprinomectin (avermectin)	NT	2	2	3	1.5	2	3	**4.13**
Clorsulon (anthelmintic, trematodes)	NT	2	3	2	2.3	2	2	**4.7**
Thyreostats (incl. thiouracil)	1	4	3	1	1	2	4	**3.5**
Lasalocid (coccidiostat)	NT	2	1	3	1.5	3	2	**3.38**
Dipyrone (NSAID)	NT	4	3	1	1	1	4	**3.25**
Melengestrol Acetate (MGA; synthetic hormone)	1	2	1	4	1	3	3	**3.0**
Berenil (antiprotozoal, histomonas)	NT	4	4	1	1	2	3	**2.75**
Beta-Agonists (ractopamine, zilpaterol, cimaterol, salbutamol)	1	4	2	3	1	2	3	**2.75**
Thiamphenicol (chlor-amphenicol derivative)	NT	3	2	1	0.75	4	3	**2.44**
Amprolium (coccidiostat)	NT	2	2	2	1	3	2	**2.25**
Clorsulon (anthelmintic, trematodes)	NT	2	3	2	1	2	2	**2.0**
Veterinary tranquilizers	NT	4	2	2	2	1	1	**2.0**
Etodolac (NSAID)	NT	3	2	1	0.75	1	3	**1.88**
Prednisone (glucocorticoid)	NT	3	2	1	0.75	1	3	**1.88**
Levamisole (anthelmintic, Nematodes)	NA-1	3	3	2	1.5	1	1	**1.5**
Halofuginone (antiprotozoal, coccidiostat)	NA-1	1	2	2	0.5	2	2	**1.0**
Benzimidazoles (anthelmintic)	NT	1	3	2	0.5	1	2	**0.88**
Morantel and pyrantel (anthelmintic)	NT	1	1	2	0.5	2	1	**0.63**
Nicarbazin (coccidiostat)	NT	2	2	1	0.5	2	1	**0.63**

Table 2
Estimated Relative Consumption for Domestically Produced Meat, Poultry, and Egg Products Based on 2010 Animal and Egg Production Data
2012 NRP, Domestic Scheduled Sampling Plan

Production Class	Number of Head Slaughtered[31]	Pounds per Animal (dressed weight)[32]	Total Pounds (dressed weight)	Percent Estimated Relative Consumption
Bulls	636,271	875	556,737,125	0.502%
Beef cows	3,638,008	607	2,208,270,856	1.992%
Dairy cows	2,820,225	607	1,711,876,575	1.544%
Heifers	10,042,691	768	7,712,786,688	6.956%
Steers	16,577,057	835	13,841,842,595	12.484%
Bob veal	450,785	75	33,808,875	0.030%
Formula-fed veal	367,788	245	90,108,060	0.081%
Non-formula-fed veal	11,653	350	4,078,550	0.004%
Heavy calves	42,096	400	16,838,400	0.015%
SUBTOTAL, CATTLE	**34,586,574**		**26,176,347,724**	**23.609%**
Market hogs	105,237,779	204	21,468,506,916	19.363%
Roaster pigs	720,167	70	50,411,690	0.045%
Boars/Stags	411,058	201	82,622,658	0.075%
Sows	2,996,622	305	913,969,710	0.824%
SUBTOTAL, SWINE	**109,365,626**		**22,515,510,974**	**20.307%**
Sheep	2,096,583	65	136,277,895	0.123%
Lambs	154,532	69	10,662,708	0.010%
Goats	605,278	50	30,263,900	0.027%
SUBTOTAL, OVINE	**2,856,393**		**177,204,503**	**0.160%**
Bison	52,858	607	32,084,806	0.029%
TOTAL, ALL LIVESTOCK	**146,861,451**		**48,901,148,007**	**44.104%**
Young chickens	8,676,848,876	Not Reported	49,413,242,779	44.566%
Mature chickens	141,004,196	Not Reported	805,719,873	0.727%
Young turkeys	241,882,882	Not Reported	7,027,002,908	6.338%
Mature turkeys	1,434,115	Not Reported	38,297,443	0.035%
Ducks	23,637,893	Not Reported	162,695,418	0.147%
Geese	222,248	Not Reported	3,132,780	0.003%
Other fowl (includes squab)	2,300,299	Not Reported	2,540,489	0.002%
SUBTOTAL, POULTRY	**9,087,330,509**		**57,452,631,690**	**51.817%**
Rabbits	225,550	Not Reported	1,121,584	0.001%
Egg products	Not Applicable	Not Applicable	4,521,355,458	**4.078%**
GRAND TOTAL in POUNDS, ALL PRODUCTION CLASSES			**110,876,256,739**	**100%**

This table aims to estimate, for each individual production class for which FSIS has regulatory responsibility, the amount of domestically-produced product consumed relative to the total for all of these production classes. FSIS estimated this value by assuming that the relative amount of each production class consumed would be approximately proportional to the total poundage (based on dressed weight) of each production class presented for slaughter or processing in federally inspected establishments. Dressed weight, which represents the weight of the carcass after the hide, hoof, hair, and viscera have been removed, was used instead of live weight, because the former was thought to be more closely representative of total pounds consumed. *Note: This table estimates the amount of domestically produced product that is consumed, regardless of who consumes it (i.e., no distinction is made between domestic products consumed domestically and products that are exported).*

[31] Number of heads is obtained from the Animal Disposition Reporting System (ADRS).
[32] Average dressed weights are obtained from the publication: "Livestock Slaughter 2010 Summary," National Agricultural Statistics Service (NASS), April 2010. In instances when the average weight is not available, an average weight based on the previous calendar year's data was imputed.

Table 3
Estimated Annual Amount of Product Imported
2012 NRP, Import Reinspection Sampling Plan

Product	**Amount imported (in pounds)**	**Percent of all imported product**
Beef, fresh	1,671,937,227	53.426%
Beef, processed	106,812,640	3.413%
Horse, fresh	1,104,839	0.035%
Pork, fresh	763,811,979	24.407%
Pork, processed	143,056,606	4.571%
Veal, fresh	34,252,401	1.095%
Veal, processed	144,393	0.005%
Lamb/Mutton, fresh	149,125,441	4.765%
Lamb/Mutton, processed	322,636	0.010%
Goat, fresh	34,926,536	1.116%
Ratite, fresh	34,336	0.001%
Chicken, fresh	115,182,025	3.681%
Chicken, processed	66,711,303	2.132%
Turkey, fresh	24,310,807	0.777%
Turkey, processed	4,095,034	0.131%
Other Fowl, fresh	2,899,837	0.093%
Other Fowl, processed	396,295	0.013%
Varied combination, fresh	189,259	0.006%
Varied combination, processed	10,129,489	0.324%
Total	**3,129,443,083**	**100.000%**

Table 4
Estimated Annual Amount (in pounds and percentages) of Product Imported per Country
2012 NRP, Import Reinspection Sampling Plan

Production Class	Argentina		Australia		Austria		Brazil		Canada	
	lbs	%	lbs	%	lbs	%	lbs	%	lbs	%
Beef, fresh	-	-	429,174,541	25.67	-	-	-	-	689,152,877	41.22
Beef, processed	25,354,170	23.74	2,075,020	1.94	-	-	33,618,465	31.47	31,045,451	29.07
Equine, fresh	-	-	-	-	-	-	-	-	1,104,839	100.00
Pork, fresh	-	-	1,412	0.00	-	-	-	-	653,925,935	85.61
Pork, processed	-	-	-	-	41,413	0.03	-	-	100,885,974	70.52
Veal, fresh	-	-	1,901,362	5.55	-	-	-	-	19,142,745	55.89
Veal, processed	-	-	-	-	-	-	-	-	144,393	100.00
Lamb/Mutton, fresh	-	-	95,048,936	63.74	-	-	-	-	149,470	0.10
Lamb/Mutton, processed	-	-	200,706	62.21	-	-	-	-	33,453	10.37
Goat, fresh	-	-	34,418,912	98.55	-	-	-	-	-	-
Ratite, fresh	-	-	34,336	100.00	-	-	-	-	-	-
Chicken, fresh	-	-	-	-	-	-	-	-	88,345,674	76.70
Chicken, processed	-	-	-	-	-	-	-	-	52,109,064	78.11
Turkey , fresh	-	-	-	-	-	-	-	-	21,137,725	86.95
Turkey, processed	-	-	-	-	-	-	-	-	417,573	10.20
Other Fowl, fresh	-	-	-	-	-	-	-	-	2,899,837	100.00
Other Fowl, processed	-	-	-	-	-	-	-	-	388,417	98.01
Varied comb, fresh	-	-	-	-	-	-	-	-	189,259	100.00
Varied comb, processed	-	-	30,372	0.30	-	-	-	-	6,227,318	61.48
Total lbs/country	25,354,170		562,885,597		41,413		33,618,465		1,667,300,004	

Table 4
Estimated Annual Amount (in pounds and percentages) of Product Imported per Country
2012 NRP, Import Reinspection Sampling Plan

Production Class	Chile		Costa Rica		Croatia		Denmark		Finland	
	lbs	%	lbs	%	lbs	%	lbs	%	lbs	%
Beef, fresh	3,242,908	0.19	17,247,737	1.03	-	-	-	-	-	-
Beef, processed	-	-	-	-	-	-	-	-	-	-
Equine, fresh	-	-	-	-	-	-	-	-	-	-
Pork, fresh	3,199,624	0.42	-	-	-	-	76,739,885	10.05	1,635,936	0.21
Pork, processed	-	-	-	-	382,155	0.27	8,870,145	6.20	-	-
Veal, fresh	-	-	-	-	-	-	-	-	-	-
Veal, processed	-	-	-	-	-	-	-	-	-	-
Lamb/Mutton, fresh	-	-	-	-	-	-	-	-	-	-
Lamb/Mutton, processed	-	-	-	-	-	-	-	-	-	-
Goat, fresh	-	-	-	-	-	-	-	-	-	-
Ratite, fresh	-	-	-	-	-	-	-	-	-	-
Chicken, fresh	26,836,351	23.30	-	-	-	-	-	-	-	-
Chicken, processed	154,596	0.23	-	-	-	-	-	-	-	-
Turkey , fresh	3,173,082	13.05	-	-	-	-	-	-	-	-
Turkey, processed	-	-	-	-	-	-	-	-	-	-
Other Fowl, fresh	-	-	-	-	-	-	-	-	-	-
Other Fowl, processed	-	-	-	-	-	-	-	-	-	-
Varied comb, fresh	-	-	-	-	-	-	-	-	-	-
Varied comb, processed	-	-	-	-	-	-	-	-	-	-
Total lbs/country	36,606,561		17,247,737		382,155		85,610,030		1,635,936	

Table 4
Estimated Annual Amount (in pounds and percentages) of Product Imported per Country
2012 NRP, Import Reinspection Sampling Plan

Production Class	**France**		**Germany**		**Honduras**		**Hungary**		**Iceland**	
	lbs	**%**	**lbs**	**%**	**lbs**	**%**	**lbs**	**%**	lbs	%
Beef, fresh	-	-	-	-	3,192,288	0.19	-	-	-	-
Beef, processed	-	-	-	-	-	-	-	-	-	-
Equine, fresh	-	-	-	-	-	-	-	-	-	-
Pork, fresh	-	-	-	-	-	-	-	-	-	-
Pork, processed	47,032	0.03	1,086,683	0.76	-	-	418,632	0.29	-	-
Veal, fresh	-	-	-	-	-	-	-	-	-	-
Veal, processed	-	-	-	-	-	-	-	-	-	-
Lamb/Mutton, fresh	-	-	-	-	-	-	-	-	300,984	0.20
Lamb/Mutton, processed	-	-	-	-	-	-	-	-	-	-
Goat, fresh	-	-	-	-	-	-	-	-	-	-
Ratite, fresh	-	-	-	-	-	-	-	-	-	-
Chicken, fresh	-	-	-	-	-	-	-	-	-	-
Chicken, processed	-	-	-	-	-	-	-	-	-	-
Turkey , fresh	-	-	-	-	-	-	-	-	-	-
Turkey, processed	-	-	-	-	-	-	-	-	-	-
Other Fowl, fresh	-	-	-	-	-	-	-	-	-	-
Other Fowl, processed	7,878	1.99	-	-	-	-	-	-	-	-
Varied comb, fresh	-	-	-	-	-	-	-	-	-	-
Varied comb, processed	-	-	-	-	-	-	-	-	-	-
Total lbs/country	54,910	-	1,086,683		3,192,288		418,632		300,984	

Table 4
Estimated Annual Amount (in pounds and percentages) of Product Imported per Country
2012 NRP, Import Reinspection Sampling Plan

Production Class	Ireland		Israel		Italy		Japan		Mexico	
	lbs	%	lbs	%	lbs	%	lbs	%	lbs	%
Beef, fresh	-	-	-	-	-	-	56,381	0.00	86,622,472	5.18
Beef, processed	-	-	-	-	-	-	-	-	3,554,191	3.33
Equine, fresh	-	-	-	-	-	-	-	-	-	-
Pork, fresh	4,486,383	0.59	-	-	-	-	-	-	8,312,042	1.09
Pork, processed	-	-	-	-	10,113,609	7.07	-	-	1,863,366	1.30
Veal, fresh	-	-	-	-	-	-	-	-	-	-
Veal, processed	-	-	-	-	-	-	-	-	-	-
Lamb/Mutton, fresh	-	-	-	-	-	-	-	-	114,275	0.08
Lamb/Mutton, processed	-	-	-	-	-	-	-	-	-	-
Goat, fresh	-	-	-	-	-	-	-	-	135,079	0.39
Ratite, fresh	-	-	-	-	-	-	-	-	-	-
Chicken, fresh	-	-	-	-	-	-	-	-	-	-
Chicken, processed	-	-	911,728	1.37	-	-	-	-	13,535,915	20.29
Turkey , fresh	-	-	-	-	-	-	-	-	-	-
Turkey, processed	-	-	1,324,658	32.35	-	-	-	-	2,352,803	57.46
Other Fowl, fresh	-	-	-	-	-	-	-	-	-	-
Other Fowl, processed	-	-	-	-	-	-	-	-	-	-
Varied combination, fresh	-	-	-	-	-	-	-	-	-	-
Varied combination, processed	-	-	-	-	-	-	-	-	3,816,496	37.68
Total lbs/country	4,486,383		2,236,386		10,113,609		56,381		120,306,639	

Table 4
Estimated Annual Amount (in pounds and percentages) of Product Imported per Country
2012 NRP, Import Reinspection Sampling Plan

Production Class	Netherlands		New Zealand		Nicaragua		N. Ireland		Poland	
	lbs	%	lbs	%	lbs	%	lbs	%	lbs	%
Beef, fresh	-	-	329,534,245	19.71	75,296,461	4.50	-	-	-	-
Beef, processed	-	-	6,861,675	6.42	-	-	-	-	-	-
Equine, fresh	-	-	-	-	-	-	-	-	-	-
Pork, fresh	5,995,729	0.78	72,932	0.01	-	-	2,556,930	0.33	4,228,704	0.55
Pork, processed	247,755	0.17	-	-	-	-	-	-	17,723,338	12.39
Veal, fresh	-	-	13,208,294	38.56	-	-	-	-	-	-
Veal, processed	-	-	-	-	-	-	-	-	-	-
Lamb/Mutton, fresh	-	-	53,511,776	35.88	-	-	-	-	-	-
Lamb/Mutton, processed	-	-	88,477	27.42	-	-	-	-	-	-
Goat, fresh	-	-	372,545	1.07	-	-	-	-	-	-
Ratite, fresh	-	-	-	-	-	-	-	-	-	-
Chicken, fresh	-	-	-	-	-	-	-	-	-	-
Chicken, processed	-	-	-	-	-	-	-	-	-	-
Turkey , fresh	-	-	-	-	-	-	-	-	-	-
Turkey, processed	-	-	-	-	-	-	-	-	-	-
Other Fowl, fresh	-	-	-	-	-	-	-	-	-	-
Other Fowl, processed	-	-	-	-	-	-	-	-	-	-
Varied comb, fresh	-	-	-	-	-	-	-	-	-	-
Varied comb, processed	-	-	55,303	0.55	-	-	-	-	-	-
Total lbs/country	7,545,707		403,705,247		75,296,461		2,556,930		21,952,042	

Table 4
Estimated Annual Amount (in pounds and percentages) of Product Imported per Country
2012 NRP, Import Reinspection Sampling Plan

Production Class	San Marino		Spain		Sweden		UK		Uruguay	
	lbs	%	lbs	%	lbs	%	lbs	%	lbs	%
Beef, fresh	-	-	-	-	-	-	-	-	38,417,317	2.30
Beef, processed	-	-	-	-	-	-	-	-	4,303,668	4.03
Equine, fresh	-	-	-	-	-	-	-	-	-	-
Pork, fresh	-	-	101,083	0.01	580,970	0.08	1,974,414	0.26	-	-
Pork, processed	2,032	0.00	1,374,472	0.96	-	-	-	-	-	-
Veal, fresh	-	-	-	-	-	-	-	-	-	-
Veal, processed	-	-	-	-	-	-	-	-	-	-
Lamb/Mutton, fresh	-	-	-	-	-	-	-	-	-	-
Lamb/Mutton, processed	-	-	-	-	-	-	-	-	-	-
Goat, fresh	-	-	-	-	-	-	-	-	-	-
Ratite, fresh	-	-	-	-	-	-	-	-	-	-
Chicken, fresh	-	-	-	-	-	-	-	-	-	-
Chicken, processed	-	-	-	-	-	-	-	-	-	-
Turkey , fresh	-	-	-	-	-	-	-	-	-	-
Turkey, processed	-	-	-	-	-	-	-	-	-	-
Other Fowl, fresh	-	-	-	-	-	-	-	-	-	-
Other Fowl, processed	-	-	-	-	-	-	-	-	-	-
Varied comb, fresh	-	-	-	-	-	-	-	-	-	-
Varied comb, processed	-	-	-	-	-	-	-	-	-	-
Total lbs/country	2,032		1,475,555		580,970		1,974,414		42,720,985	

Design of the Domestic Scheduled and Import Reinspection Sampling Plans for Pesticides

I. Selecting and Ranking Candidate Pesticides

For the 2012 NRP, EPA SAT members selected the candidate pesticides of concern from a pool of 290 compounds/compound classes. Table 5 presents the domestic pesticides of concern. FSIS prioritizes *analyses*, grouping together compounds detected with the same analytical methods.

FSIS does not have sufficient historical data on pesticides in imported products to predict their violation rates. The import reinspection sampling plan (IRSP) will focus and rank the same pesticides as specified in the domestic sampling plan. If FSIS believes that a compound is being misused in a foreign country, then the compound and country will be added to the IRSP.

For additional information on pesticides, visit *Electronic Code of Federal Regulations, Title 40: Protection of Environment, Part 180: Tolerances and Exemptions for Pesticide Chemical Residues in Food* (40 CFR 180).

Compound Scoring

Using a 4-point scale (4 = high; 3 = moderate; 2 = low; 1 = none), SAT members scored each of the pesticides in the following categories (Note that some of these categories differ from those used for the veterinary drugs,):

- FSIS Historical Testing Information on Violations;
- Regulatory Concern;
- Pre-slaughter Interval;
- Bioconcentration Factor;
- Endocrine Disruption; and
- Toxicity.

Compound Ranking

1. Background: See explanation and equation in section I. Selecting and Ranking Candidate Veterinary Drugs on pages 14–18.

Unlike veterinary drugs, FSIS does not have historical data on a sufficient range of different pesticide compounds or compound classes to predict violation scores (and thus risk per unit of consumption) using a regression equation. Therefore, FSIS took a somewhat different approach to estimate the "Risk per Unit of Consumption" term.

2. Rating the Pesticides According to Relative Public Health Concern

The categories of "Regulatory Concern," "Pre-slaughter Interval," and "Bioconcentration Factor" predict risk per unit of consumption from pesticides in animal products. The "Regulatory Concern" category

reflects EPA's professional judgment of the likelihood that a compound or compound class will exceed EPA's level of concern in meat, poultry, or egg products. Thus, the category combines residue level and toxicity information.

FSIS expects that the "Withdrawal Time" category for veterinary drugs and the "Pre-slaughter Interval" category will correlate with residue level. The longer pre-slaughter intervals are less likely to be observed properly, and the carcass may contain violative levels of residues.

"Bioconcentration" measures the extent to which a pesticide concentrates within the fat deposits of animals. Pesticides that bioconcentrate are more likely to accumulate to higher levels within animal tissue, which is expected to increase the potential for human exposure. The "Toxicity" category reflects both the dose required to achieve a toxic effect and the severity of that effect.

EPA assigns a value to the regulatory concern, pre-slaughter interval, and bioconcentration factors for each pesticide compound or class of compounds. These values are multiplied by a weighted average and then by the toxicity value to give an estimate of the relative risk per unit of consumption.

The weighted average of "Regulatory Concern," "Pre-slaughter Interval," "Bioconcentration factor" has been used in place of "Predicted or Actual Score for FSIS Historical Testing Information on Violations" (as in the veterinary drugs ranking). FSIS did not include "Endocrine Disruption" in the equation because scores for this category were not available for most of the pesticides. The variable for regulatory concern (R) is weighted twice the pre-slaughter interval (P) and bioconcentration factor (B), because FSIS considers regulatory concern to be more of a direct measurement of exposure.

FSIS based the pesticide ratings on their relative public health concern. The Agency developed this formula based on the relative importance of each modifier and the degree each modifier alters the underlying risk-based score for Relative Public Health Concern. The formula enables others to observe and understand these adjustments, and it ensures consistency in how these adjustments were applied across a wide range of compounds.

The scores enable FSIS to bring consistency, grounded in formal risk-based considerations, to its efforts to differentiate among a very diverse range of pesticides and pesticide classes in a situation that is marked by minimal data on relative exposures**.** These rankings do not account for differences in exposure resulting from differences in overall consumption. Data on relative consumption are applied after estimation of relative exposure values for compound and production classes.

FSIS normalized the formulas for the veterinary drugs and pesticides to give the same maximum value. Because the formula for the pesticides uses different scoring categories than for the veterinary drugs, their scores are not comparable in a quantitative sense. However, the scores for the pesticides and veterinary drugs are comparable in magnitude, enabling a rough comparison to be made between the two different categories of compounds.

II. Prioritizing Candidate Pesticides

After ranking the pesticides according to their relative public health concern, SAT used the ranking scores to select compounds. Pesticide compounds and compound classes that received a ranking of 23 or greater represent a potential public health concern that is sufficient to justify their inclusion in the NRP.

Additionally, FSIS has implemented a new pesticide method that includes the following compounds:

3-Hydroxycarbofuran, Acephate, Alachlor, Aldrin, Azinphos methyl, Bifenthrin, Boscalid, Carbaryl, Carbofuran, Carfentrazone ethyl, cis-Chlordanes, trans-Chlordane, Chlorpyrifos, Chlorpyrifos methyl, Clofentezine, L-Cyhalothrin, Cypermethrin, Deltamethrin, Dichlorvos (DDVP), Dieldrin, Difenoconazole, Diflubenzuron, Diuron, Endosulfan I, Endosulfan II, Endosulfan sulfate, Ethofumesate, Fipronil, Heptachlor, cis-Heptachlor epoxide, trans-Heptachlor epoxide, Imazalil, Imidacloprid, Indoxacarb, Linuron, Metalaxyl, Methomyl, Methoxyfenozide, Mirex, Myclobutanil, trans-Nonachlor, Norflurazon, Oxychlordane, Permethrin (cis & trans), Piperonyl butoxide, Pronamide, Propachlor, Propanil, Propiconazole, Pyridaben, Simazine, Tebufenozide, Tefluthrin, Tetrachlorvinphos, Tetraconazole, Thiabendazole, Thiamethoxam.

Table 5 provides the sampling status of each compound or compound class in the 2012 scheduled domestic sampling plan. A brief explanation justifies the exclusion of each highly ranked compound or compound class not scheduled for 2012. A number of highly ranked pesticides could not be included due to methodological limitations. Summary Table III (page 10) may be used to identify future method development needs for pesticides. FSIS will implement this methodology when it is available.

The high priority compounds chosen for the IRSP are the same as the domestic plan. After identifying high-priority compounds and compound classes, FSIS applies other considerations to determine which compounds to sample, specifically the availability of analytical methods within the FSIS laboratories. The compounds identified by the new pesticides screen are listed in the section, *Design of the Domestic Scheduled Sampling Plan for Pesticides*.

III. Allocation of Sampling Resources

Domestic:
FSIS established a relative sampling priority for each compound and production class by multiplying the ranking score for the CHC/COPs by the estimated relative percent of domestic consumption for each production class. This calculation is identical to the calculation of the relative sampling priorities for the veterinary drugs. The results do not constitute an estimate of risk. Instead, it provides a numerical representation of the relative public health concern associated with each compound and production class; FSIS can use this information to prioritize analytical sampling resources. This risk ranking is based upon average consumption across the entire U.S. population, rather than upon maximally exposed individuals.

Import:
For information on egg products, animal product classes and animal production class nomenclature refer to Veterinary Drugs, Section III., Allocation of sampling resources, page 19-20.

IV. Scoring Key for Domestic Products

Regulatory Concern

These scores represent EPA's professional assessment of the extent to which the acute or chronic dietary exposure to this compound may exceed the level of concern established by the EPA. For compounds other than carcinogens, this score was determined by comparing either the compound's Acute or Chronic Population Adjusted Dose (PAD) (whichever was lower) to the estimated level of exposure. The Acute and Chronic PADs are calculated as described below, and both carry uncertainty spanning an order of magnitude or greater.

The Acute Reference Dose (Acute RfD) estimates a single oral exposure level for the human population (including sensitive subpopulations) that is likely to be without an appreciable risk of deleterious effects.

The Chronic Reference Dose (Chronic RfD) estimates a daily oral exposure level for the human population (including sensitive subpopulations) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

The Acute and Chronic RfDs are calculated by dividing the No Observed Adverse Effect Level[33] (NOAEL) or the Lowest Observed Adverse Effect Level[34] (LOAEL) by Uncertainty Factors. This calculation accounts for differences between different humans (intraspecies variability) and for differences between the test animals and humans (interspecies extrapolation). If the LOAEL is used, an additional Uncertainty Factor is required.

RfD = (NOAEL or LOAEL)/Total UF

The Acute and Chronic Population Adjusted Dose (PAD) are the Acute and Chronic RfD, respectively, modified by the Food Quality Protection Act (FQPA) Safety Factor:

Acute or Chronic PAD = (Acute or Chronic RfD)/FQPA Safety Factor

The acute and chronic dietary risks are expressed as a percentage of the Acute or Chronic PAD. A dietary risk of 100% of the Acute or Chronic PAD (whichever is lower) is the target level of exposure that should not be exceeded. In the following, PAD is defined by the lower value, either the Acute or Chronic PADs.

4 = PAD exceeded or carcinogenic.
3 = Close to PAD.
2 = Exposure estimated to be a low percentage of PAD.
1 = Exposure estimated to be a very low percentage of PAD.

Pre-Slaughter Interval

A numerical value of 1, 2, 3, or 4 is assigned by the EPA to pesticides for the category "Pre-Slaughter Interval" and listed in Summary Table III. For pesticides that have been approved for direct dermal application, the pre-slaughter interval is the required time between the last dermal application and the time of slaughter. FSIS determines a value for a pesticide in this category as follows:

4 = dermal application is permitted and the pre-slaughter interval is one day or greater.
3 = dermal application is permitted and the pre-slaughter interval is zero days.
2 = dermal application is not permitted, but the treatment of premises (e.g., holding cells, feedlots, barns, etc.) is permitted.
1 = neither dermal application nor premise treatment are permitted.

Bioconcentration Factor

A numerical value of 1, 2, 3, or 4 is assigned by EPA to pesticides for the category "Bioconcentration Factor" and presented in Table 5. Bioconcentration is a measure of a compound's relative affinity for fat, as measured by the $K_{o/w}$. The $K_{o/w}$ is defined as the logarithm of the partition coefficient between octanol and water (log $P_{o/w}$). Compounds that have a high affinity for octanol (and thus a high $K_{o/w}$) tend to bioaccumulate in body fat. A bioconcentration value is determined according to the following criteria:

4 = log $K_{o/w}$ is greater than 3.

[33] The highest dose that gave no observable adverse effect
[34] The lowest dose at which an adverse effect was seen

3 = log $K_{o/w}$ is between 2 and 3.
2 = log $K_{o/w}$ is between 1 and 2.
1 = log $K_{o/w}$ is less than 1.

Endocrine Disruption

The EPA assigned a numerical value to pesticides for the category "Endocrine Disruption," presented in Table 5. Endocrine disruption measures the extent that the compound changes endocrine function and causes adverse effects to individual organisms and/or their progeny, as well as to organism populations and subpopulations. A value for endocrine disruption is assigned as follows:

4 = endocrine disruption is likely.
3 = endocrine disruption is suspected.
NT = the compound has not been tested.

Toxicity

The EPA assigned a numerical value of 1, 2, 3, or 4 to pesticides for the category "Toxicity." The toxicity value represents EPA's professional judgment of the toxicity of the compound, including both the dose required to achieve a toxic effect and the severity of the toxic effect. In the following, "RfD" is the lower of the Acute and Chronic RfDs. A value for toxicity is determined as follows:

4 = the pesticide compound is a cholinesterase inhibitor, carcinogen, or has a low RfD.
3 = the pesticide compound has a low RfD.
2 = the pesticide compound has a medium RfD.
1 = the pesticide compound has a high RfD.

Table 5
Scoring Table for Pesticides
2012 NRP, Domestic Scheduled Sampling Plan

Compound /Compound Class	*Historical Testing for Violations (V)*	*Regulatory Concern (R)*[35]	*Pre-Slaughter Interval (P)*[36]	*Bioconcen-trations (B)*[37]	*Endocrine Disruption*[38]	*Toxicity[v] (T)*[39]	*Relative public health concern rating(((2*R)+P+B)/4)*T*
Screening of Pesticides by LC/MS/MS and GC/MS/MS	3	4	4	4	Not Available	4	16
Chlorinated organophosphates and organophosphates (COPs and OPs)	Not Tested	4	4	4	Not Available	4	16
Beta-Cyfluthrin	Not Tested	4	4	4	Not Available	4	16
Cyfluthrin	Not Tested	4	4	4	Not Available	4	16
Imazalil	Not Tested	4	4	4	Not Available	4	16
Triazines	Not Tested	4	4	3	4	4	15
Carbamates	Not Tested	4	4	2	3	4	14
Synthetic Pyrethroids	Not Tested	3	4	4	3	4	14
1-(2,4-dichlorophenyl)-2-(1H-imidazole-1-yl)-1-ethanol	Not Tested	3	4	4	Not Available	4	14
1,1-(2,2-dichloroethylidene) bis(4-methoxybenzene)	Not Tested	3	4	4	Not Available	4	14
1-methoxy-4-(1,2,2,2-tetrachloroethyl)benzene)	Not Tested	3	4	4	Not Available	4	14
3-(1-(2,4-dichlorophenyl)-2-(1H-imidazole-1-yl)ethoxy)-1,2-propane diol	Not Tested	3	4	4	Not Available	4	14
Cyhalothrin, lambda	Not Tested	4	4	2	Not Available	4	14
Fipronil	Not Tested	3	4	4	Not Available	4	14
MB 45950	Not Tested	3	4	4	Not Available	4	14
MB 46513	Not Tested	3	4	4	Not Available	4	14
Methoxychlorolefin	Not Tested	3	4	4	4	4	14
Triazines	Not Tested	4	2	3	4	4	13
Arsanilic acid	Not Tested	4	1	4	Not Available	4	13
Etoxazole	Not Tested	4	1	4	Not Available	4	13
Indoxacarb (DPX-MP062)	Not Tested	4	1	4	Not Available	4	13
Metconazole	Not Tested	4	1	4	Not Available	4	13
Prothioconazole	Not Tested	4	1	4	Not Available	4	13

[35] Scores for regulatory concern (*R*) are provided by EPA.
[36] Scores for withdrawal time (*P*) are provided by EPA.
[37] Scores for bioconcentration factor are provided by EPA. Scores for bioconcentration factor are provided by EPA.
[38] Scores for endocrine disruption are provided by EPA.
[39] Scores for toxicity are provided by EPA.

Scheduled Sampling Plans for Environmental and Processing Contaminants

SAT-selected environmental contaminants of concern are listed below. For additional information on environmental contaminants, see the *Electronic Code of Federal Regulations, Title 21: Food and Drugs, Part 109: Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material* (21 CFR 109).

Environmental Contaminants

- Heavy metals

FSIS will conduct a targeted sampling assessment of heavy metals, specifically lead and cadmium, in market hogs. This targeted sampling follows lead and cadmium sampling that began in 2003 for heifers and dairy cows. This study continued in 2004 for boars and stags, dairy cows, heifers, and mature chickens. In 2005, FSIS studied heavy metals in steers and mature chickens in 2006. FSIS continued this study for mature chickens in 2007 and beef cows in 2008. The study continued in 2009 with dairy cows. Since 2010, FSIS has studied heavy metals in market hogs.

Table 6
Number of Scheduled Samples per Product Class for Lead and Cadmium
2012 NRP Domestic Specifically Designed Survey

Production Class	Compound	Number of Samples
Market hogs	Lead	300
Market hogs	Cadmium	300
Total		**600**

Appendix I
Tissues Required for Laboratory Analysis

Table A-I lists the tissue, the quantity required for analysis, and the analytical laboratory (MWL = Midwestern Lab, WL = Western Lab, EL = Eastern Lab).

Table A-I

Residue	Tissue Analyzed	Quantity (lb)	Lab
Antibiotics	Kidney, liver, muscle	1	ML
Arsenicals	Liver, muscle	1	EL
Avermectins	Liver, muscle	1	EL
Beta-Agonists	Liver, muscle	1	WL
Carbadox	Liver	1	WL
Chloramphenicol	Muscle	1	EL
Pesticides	Muscle	1	WL
Florfenicol	Liver, muscle	1	EL
Flunixin	Liver, muscle	1	ML
Lead and Cadmium	Kidney, muscle	1	EL
Nitrofurans	Liver	1	WL
Sulfonamides	Liver, muscle	1	ML

Appendix II
FSIS Laboratory Analytical Methods

FSIS uses analytical methods to detect, identify, and quantify residues that may be present in meat, poultry, and processed egg products. The Agency uses these methods for monitoring and surveillance activities to determine product adulteration and for human risk assessment evaluations. 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 table below lists the analytical methods and provides links to each method. View the FSIS Analytical Chemistry Laboratory Guidebook here.

Compound	Method	Species	Tissue
Aminoglycosides	CLG-AMG2.03	bovine, porcine	kidney, liver, muscle
	CLG-AMG1.03	bovine, porcine, poultry	kidney, liver, muscle
Antibiotics	MLG-34.03	meat and poultry	kidney, liver, muscle
Avermectins	CLG-AVR.04	bovine, porcine, ovine, caprine, equine	liver, muscle
	CLG-AVR1.03	bovine, porcine, ovine, caprine, equine	liver, muscle
Beta-Agonists	CLG-AGON1.03	bovine, porcine, ovine, caprine	liver
		bovine, porcine	muscle
	CLG-RAC1.01	bovine, porcine	liver, muscle
Beta-lactams	CLG-BLAC.03	bovine, porcine	kidney, muscle
Carbadox	CLG-CBX1.02	pork	liver
	CLG-CBX2.00	pork	liver
Chloramphenicol	CLG-CAM1.01	beef, poultry, swine	muscle
	CLG-CAM.04	beef, poultry	muscle
Florfenicol	CLG-FLOR1.04	bovine, poultry	liver, muscle
	CLG-FLOR2.02	bovine, poultry	liver, muscle
Flunixin	CLG-FLX4.02	bovine, (porcine extension in progress)	liver, muscle
Fluoroquinolones	CLG-FLQ2.00	bovine	liver, muscle
Macrolides	CLG-MAL1.02	beef, pork, poultry	kidney, liver, muscle
Metals	CLG-TM3.02	beef, pork, poultry	kidney, liver, muscle
	CLG-TM4.01	meat and food products	kidney, liver, muscle
	CLG-ARS.04	all animal species, egg products	kidney, liver, muscle
MRM (multi-residue method)	CLG-MRM 1.00	beef, pork	kidney
Nitrofurans	CLG-NFUR2.01	bovine, porcine, poultry	liver
Pesticides*	CLG-PST5.01	chicken, pork, beef	muscle
Phenylbutazone	CLG-PBZ2.03	beef	kidney
Sulfonamides	CLG-SUL4.01	porcine, bovine, avian	liver, muscle
	CLG-SUL2.06	porcine, bovine, avian	liver, muscle
Tetracyclines	CLG-TET2.04	bovine, porcine, ovine	kidney, liver, muscle
		poultry	kidney, muscle
Tilmicosin	CLG-TIL1.02	bovine	kidney, liver, muscle
Zeranol	CLG-ANA.02	ovine, bovine	liver, muscle