Exhibit 40

UNITED STATES
National Residue Program

2011 Scheduled 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 (U.S. NRP) Blue Book is a summary of the scheduled domestic and imported meat, poultry, and egg product sampling plans and includes a summary of adjustments to the 2010 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 domestic and imported products and for veterinary drugs, pesticides, and unavoidable contaminants. For convenience, tables that report summaries of FSIS sampling plans are provided before the detailed discussions. Three appendices (I-III) examine tissues required for laboratory analysis; FSIS laboratory analytical methods; and a statistical table that describes the probability of detecting a violation given a specified sample size.

Contacts and Comments

Questions about the U.S. NRP should be directed to the USDA-FSIS-OPHS-Risk Assessment Division (RAD), Chemical Residue Risk Branch (CRRB), 333 Aerospace Center, 1400 Independence Avenue, SW, Washington, DC 20250-3700, telephone (202) 690-6409, fax (202) 690-6565.

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INTRODUCTION

The United States National Residue Program (U.S. NRP) 2011 Scheduled Sampling Plan (Blue Book) provides the scheduled sampling plan for testing chemical compounds in products from food animals and egg products produced domestically or imported into the United States for CY2011. In addition, this book provides detailed information on how the chemical compounds are selected for inclusion in the scheduled sampling plan.

The U.S. NRP is a collaborative interagency program established to protect the public from exposure to harmful levels of chemical residues in meat, poultry, and egg products produced or imported into the United States. The NRP is designed: (1) to provide a structured process for identifying and evaluating chemical compounds of concern in food animals; (2) to analyze chemical compounds of concern; (3) to collect, analyze and report results; and (4) to identify the need for regulatory follow-up when violative levels of chemical residues are found.

The U.S. Department of Agriculture Food Safety and Inspection Service (FSIS), the Environmental Protection Agency (EPA), and the Department of Health and Human Services Food and Drug Administration (FDA) are the federal agencies primarily involved in managing this program. The EPA and FDA have statutory authority for establishing residue tolerances through regulations that limit the quantity of a chemical for the protection of public health.[1] The FDA, under the Federal Food, Drug, and Cosmetic Act, establishes tolerances or action levels for veterinary drugs, 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. Through the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, FSIS regulates the safety of meat, poultry, and egg products produced in federally inspected establishments.

The U.S. NRP tests for chemical compounds, including approved (legal) and unapproved (illegal) veterinary drugs, pesticides, hormones, as well as environmental compounds that may appear in meat, poultry, and egg products. FSIS, FDA, EPA, and other federal agencies, including the USDA Agricultural Research Service (ARS) and Agricultural Marketing Service (AMS), as well as the Centers for Disease Control and Prevention (CDC), create an annual sampling plan (per calendar year) using sample results from the U.S. NRP, information that the Agencies have accumulated during investigations, and from FDA veterinary drug inventories completed during on-farm visits. The Agencies create a list of chemical compounds for testing and rank them using mathematical equations that include variables for public health risk and regulatory concern. The Agencies decide which chemical compounds are tested in which food animals and evaluate FSIS laboratory capacity and analytical methods to devise a final sampling plan. FSIS publishes the finalized sampling plan in the Blue Book.

Since 1967, FSIS has administered the U.S. NRP by collecting samples from meat, poultry, and egg products and analyzing the samples at one of three FSIS laboratories. A violation occurs when an FSIS laboratory detects a chemical compound level in excess of an established tolerance or action level in a sample. FSIS shares laboratory findings that exceed established tolerances and action levels with FDA and EPA. FDA has jurisdiction on-farm, and FSIS assists FDA in obtaining the names of producers and other parties involved in offering the animals for sale. FSIS informs producers through certified letters that an animal from their business has tested positive for violative residues.

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[1] Title 40 CFR includes tolerance levels established by EPA; Title 21 CFR includes tolerance levels established by FDA.

The FDA and cooperating state agencies investigate producers linked to residue violations. If a problem is not corrected, subsequent FDA visits could result in enforcement action, including prosecution. At the request of industry, FSIS posts the Residue Repeat Violator List weekly. The list includes establishments and producers associated with more than one violation on a rolling 12-month basis. Because FSIS updates this list weekly, FDA may not have investigated each violation. These lists provide helpful information to processors and producers working to avoid illegal levels of residues, serve as deterrents for violators, and enable FSIS and FDA to make better use of resources.

A scientifically sound chemical residue prevention program is essential to encourage the prudent use of veterinary drugs and pesticides in food animals. In the late 1990s, FSIS implemented the Hazard Analysis and Critical Control Points (HACCP) inspection system in all federally inspected establishments to verify chemical residue control under HACCP. The HACCP regulation, (9 CFR 417), requires slaughter and production establishments to identify all food safety hazards, including drug residues, pesticides, and chemical contaminants that are reasonably likely to occur before, during, and after entry into the establishment and determine preventive measures the establishment can apply to control these hazards. FSIS takes regulatory action against establishments that do not have an adequate chemical residue control program in place.

The U.S. NRP requires the cooperation and collaboration of several Agencies for successful design and implementation. The U.S. NRP exists to ensure that chemical compounds are used as intended and that the food supply is safe for consumption.

SAMPLING PLANS OF THE U.S. NATIONAL RESIDUE PROGRAM

The U.S. NRP sampling plans focus on domestic meat, poultry, and egg products and import reinspection of meat and poultry products. These plans are divided further to facilitate the management of chemical residues, such as veterinary drugs, pesticides, and environmental contaminants in meat, poultry, and egg products. The domestic sampling plan includes scheduled sampling and inspector-generated sampling. The import reinspection sampling plan is separated into normal sampling, increased sampling, and intensified sampling.

DOMESTIC SAMPLING PLAN

Scheduled Sampling

Scheduled sampling plans consist of the random sampling of tissue from 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 animal and egg products; and 4) establish the number of samples to be collected. At its annual meeting, the Surveillance Advisory Team (SAT), an interagency committee comprised of representatives from FSIS, FDA, EPA, AMS, ARS, and CDC, determines the compound/production class pairs of public health concern.[1] FSIS calculates the number of samples needed for the scheduled sampling. Since the 2006 NRP, FSIS has sampled 230 or 300 animals for each compound/production class pair. Applying sampling rates of 230 or 300 in food animals and egg products assures a 90 percent and 95 percent probability, respectively, for detecting residue violations if the violation rate is equal to or greater than one percent. The resulting violation data are used to verify whether industry process controls and HACCP plans effectively control residues. The FSIS, FDA, and EPA review and make final adjustments to the sampling plan.

The following types of sampling programs are being scheduled:

Exposure Assessments

Exposure Assessments are designed to determine the prevalence of chemical residues in the nation's food supply, and are used to guide:

- FSIS decisions to condemn carcasses with violative levels of residues;
- FDA regulatory decisions when a sample contains violative levels of residues to determine action against producers;
- industry decisions to retain product until the sample has been tested; and
- industry decisions to recall a product that was not retained while the sample was tested and found to contain violative levels of residue.

[1] Compound = chemical compounds; production class =food animals and egg products

Exploratory Assessments

Exploratory Assessments are designed to:

- reinvestigate animal populations from ongoing or previous exposure assessments if the violation rate is confirmed at one percent or greater;
- investigate animal populations when the compounds in question have no established tolerances;
- respond to intelligence regarding use of veterinary drugs, pesticides, and environmental contaminants reported from the field; .
- indicate the prevalence and concentration of residues; and
- evaluate residue trends.

Inspector-Generated Sampling

Public Health Veterinarians (PHVs) conduct inspector-generated sampling in-plant on animals suspected of having violative levels of chemical residues. Currently, inspector-generated sampling targets *individual suspect animals* and *suspect populations of animals* (i.e., show animals). When an inspector-generated sample is collected, the carcass is held pending the results of laboratory testing. If a carcass is found to contain violative levels of residues, the carcass is condemned.

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 disease signs and symptoms, producer history, or results from random scheduled sampling). Some samples are screened in the plant by the Inspector-in-Charge (IIC) and verified when necessary by a PHV. Other samples are sent directly to the laboratory for analysis. For example, if the IIC suspects the misuse of an antibiotic or sulfonamide drug in an animal, then he or she can perform an approved in-plant residue screening test, such as Fast Antimicrobial Screening Test (FAST) or Kidney Inhibition Swab (KIS™) test. If the result of a screening test is positive, then the sample is sent to a FSIS laboratory for confirmation. If the IIC/PHV does not have FAST or KIS™ Test capability, the sample can be sent directly to the FSIS laboratory for testing.

Sampling for suspect animal populations

Sampling for suspect animal populations is generally directed by a FSIS regulation, directive (e.g., FSIS Directive 10,800.1), or notice (e.g., show animals and bob veal).

IMPORT REINSPECTION SAMPLING PLAN

Imported meat, poultry, and egg products are sampled through the Port-of-Entry Reinspection Program, 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[2] of product before it enters the United States. Chemical residue sampling is included in the reinspection of imported products. The three levels of chemical residue reinspection include:

- normal sampling, defined as random sampling from a lot;
- increased sampling, defined as above-normal sampling resulting from an Agency management decision; and
- intensified sampling, defined as occurring 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.

The following summary tables outline the specifics of the sampling programs.

[2] A lot is a group of product defined statistically and/or scientifically by production segments and certified from one country, one establishment, and consisting 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

U.S. NRP Summary Organized by Compound Class

Summary Tables I–IV provide an overview of both domestic and import sampling organized by chemical compound class. Each of the four tables covers one group of compounds: Animal Medicinal Drug Use Clarification Act (AMDUCA) prohibited drugs, veterinary drugs, pesticides, and environmental contaminants, respectively. The tables also specify which FSIS laboratory conducts the analyses for each compound class.

U.S. NRP Summary Organized by Production Class

Summary Tables V–VII contain the data for the same sampling plans, but reorganized by production class, rather than chemical compound class. Domestic sampling is summarized in Table V and import sampling is summarized in Table VI. In addition, Table VII sorts the import samples by country and production class.

Summary Table I – Summary by Compound Class
Status of the AMDUCA[1]-Prohibited Drugs
2011 U.S. NRP Domestic and Import Scheduled Sampling

AMDUCA[1] Prohibited Drug	Number of Scheduled Samples				
	Domestic		Import		Total
Avoparcin (glycopeptide)	Not in the 2011 NRP		Not in the 2011 NRP		0
Chloramphenicol Analysis by EL	mature chickens (300) young chickens (300)	mature turkeys (300) young turkeys (300) **Total domestic: 1,200**	beef, fresh (91) chicken, fresh (90)	turkey, fresh (16) veal, fresh (89) **Total import: 286**	1,486
Clenbuterol[2] Analysis by WL	steers (300) formula fed veal (230) non-formula fed veal (90)	heifers (300) goats (90) market hogs (300) **Total domestic: 1,310**	pork, fresh (104)	veal, fresh (90) **Total import: 194**	1,504
Diethylstilbestrol	Not in the 2011 NRP		Not in the 2011 NRP		0
Fluoroquinolones[3] Analysis by ML Part of antibiotics 7-plate bioassay analysis	beef cows (300) boars/stags (300) bob veal (300) bulls (300) dairy cows (300) ducks (45) formula fed veal (300) geese (30) goats (90) heavy calves (90) heifers (300) lambs (300)	market hogs (300) mature chickens (300) mature turkeys (300) non-formula fed veal (90) rabbits (30) roaster pigs (300) sheep (300) sows (300) steers (230) young chickens (300) young turkeys (300) **Total domestic: 5,405**	beef, fresh (300) chicken, fresh (90) horse, fresh (8) other fowl, fresh (16)	pork, fresh (230) turkey, fresh (16) varied comb., fresh (8) veal, fresh (90) **Total import: 758**	6,163
Nitrofurans[4] Analysis by WL	dairy cows (230) market hogs (300)	roaster pigs (300) **Total domestic: 830**	No samples scheduled for imports in 2011		830
Nitroimidazoles[5] Analysis by EL	young turkeys (300)	**Total domestic: 300**	chicken, fresh (90)	**Total import: 90**	390
Phenylbutazone	Not in the 2011 NRP		Not in the 2011 NRP		0
Ronidazole	Not in the 2011 NRP		Not in the 2011 NRP		0
Vancomycin	Not in the 2011 NRP		Not in the 2011 NRP		0

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

[1] Refers to drugs banned by FDA from extralabel use under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). These drugs are not evaluated using the ranking formula. Instead, these drugs are automatically assigned a high sampling priority and will be included in the NRP if methodologies and resources are available.
[2] β-Agonist method is applicable to clenbuterol, salbutamol, cimaterol, zilpaterol, and ractopamine.
[3] The fluoroquinolones, enrofloxacin and danofloxacin, are approved for use in steers and heifers.
[4] Furazolidone and nitrofurazone are antimicrobials.
[5] Nitroimidazoles in the FSIS multi-residue method (MRM) include dimetridazole and ipronidazole; antiprotozoal.

Summary Table II – Summary by Compound Class
Rank and Status of Veterinary Drugs
2011 U.S. NRP Domestic and Import Scheduled Sampling

Rank	Score	Veterinary Drug[1]	Number of Scheduled Samples				
			Domestic		Import		Total
1	16.0	Antibiotics[2] Analysis by ML	beef cows (300) boars/stags (300) bob veal (300) bulls (300) dairy cows (300) ducks (45) formula fed veal (300) geese (30) goats (90) heavy calves (90) heifers (300) lambs (300)	market hogs (300) mature chickens (300) mature turkeys (300) non-form. fed veal (90) rabbits (30) roaster pigs (300) sheep (300) sows (300) steers (230) young chickens (300) young turkeys (300) **Total domestic: 5,405**	beef, fresh (300) chicken, fresh (90) horse, fresh (8) other fowl, fresh (16)	pork, fresh (230) turkey, fresh (16) var. comb., fresh (8) veal, fresh (90) **Total import: 758**	6,163
2	15.0	Carbadox Analysis by WL	market hogs (300)	roaster pigs (230) **Total domestic: 530**	No samples scheduled for imports in 2011		530
3	14.0	Avermectins[3] Analysis by EL	beef cows (300) boars/stags (300) bulls (230) dairy cows (300) formula fed veal (300)	goats (230) heavy calves (90) mature sheep (300) non-form. fed veal (90) steers (300) **Total domestic: 2,440**	beef, fresh (300) beef, processed (63) goat, fresh (24)	lamb/mutton, fr. (90) veal, fresh (90) **Total import: 567**	3,007
4	13.0	Sulfonamides[4] Analysis by EL	beef cows (300) boars/stags (300) bob veal (300) bulls (230) dairy cows (300) egg products (300) formula fed veal (300) heavy calves (90)	heifers (300) market hogs (300) mature chickens (300) non-form. fed veal (90) roaster pigs (230) sows (300) steers (300) **Total domestic: 3,940**	beef, fresh (300) beef, processed (63) horse, fresh (8) pork, fresh (230) pork, processed (48)	turkey, fresh (16) turkey, processed (16) var. comb., fresh (8) var. comb., proc. (24) veal, fresh (90) **Total import: 803**	4,743
5	12	Xenobiotic hormones	Not in the 2011 NRP		Not in the 2011 NRP		0
6	10	Flunixin Analysis by ML	dairy cows (300) beef cows (300) bob veal (300)	formula fed veal (300) heavy calves (90) **Total domestic: 1,290**	beef, fresh (90)	**Total import: 90**	1,380
7	9.75	Florfenicol Analysis by EL	formula fed veal (300) non-form. fed veal (90)	steers (300) **Total domestic: 690**	beef, fresh (90)	**Total import: 90**	780
8	8	Hormones[5]	Not in the 2011 NRP		Not in the 2011 NRP		0

Summary Table II – Summary by Compound Class
Rank and Status of Veterinary Drugs
2011 U.S. NRP Domestic and Import Scheduled Sampling

Rank	Score	Veterinary Drug[1]	Number of Scheduled Samples				
			Domestic		Import		Total
9	6.75	Arsenicals[6] Analysis by EL	egg products (300) market hogs (300) mature turkeys (300)	young chickens (300) young turkeys (300) **Total domestic: 1,500**	chicken, fresh (90) chicken, proc. (8) pork, fresh (104)	turkey, fresh (16) turkey, processed (16) **Total import: 234**	1,734
10	5.0	Dexamethasone	Not in the 2011 NRP		Not in the 2011 NRP		0
11	5.0	Methyl prednisone	Not in the 2011 NRP		Not in the 2011 NRP		0
12	4.125	Eprinomectin	Not in the 2011 NRP		Not in the 2011 NRP		0
13	3.5	Thyreostats[7]	Not in the 2011 NRP		Not in the 2011 NRP		0
14	3.375	Lasalocid	Not in the 2011 NRP		Not in the 2011 NRP		0
15	3.25	Dipyrone	Not in the 2011 NRP		Not in the 2011 NRP		0
16	3.0	Melengestrol acetate	Not in the 2011 NRP		Not in the 2011 NRP		0
17	2.75	Bereníl	Not in the 2011 NRP		Not in the 2011 NRP		0
18	2.75	ß-agonists[8] Analysis by WL	formula fed veal (230) goats (90) heifers (300)	market hogs (300) non-form. fed veal (90) steers (300) **Total domestic: 1,310**	pork, fresh (104)	veal, fresh (90) **Total import: 194**	1,504
19	2.44	Thiamphenicol	Not in the 2011 NRP		Not in the 2011 NRP		0
20	2.25	Amprolium	Not in the 2011 NRP		Not in the 2011 NRP		0
21	2.0	Clorsulon	Not in the 2011 NRP		Not in the 2011 NRP		0
22	2.0	Veterinary tranquilizers[9]	Not in the 2011 NRP		Not in the 2011 NRP		0
23	1.88	Elodolac	Not in the 2011 NRP		Not in the 2011 NRP		0
24	1.88	Prednisone	Not in the 2011 NRP		Not in the 2011 NRP		0
25	1.5	Levamisole	Not in the 2011 NRP		Not in the 2011 NRP		0
26	1.0	Halofuginone	Not in the 2011 NRP		Not in the 2011 NRP		0
27	0.88	Benzimidazoles[10]	Not in the 2011 NRP		Not in the 2011 NRP		0
28	0.63	Morantel and pyrantel	Not in the 2011 NRP		Not in the 2011 NRP		0
29	0.63	Nicarbazin	Not in the 2011 NRP		Not in the 2011 NRP		0

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

[1] For classifications of these drugs, please see the chapter "Design of the Domestic Scheduled Sampling Plan for Veterinary Drugs."
[2] 7-plate bioassay. Tetracyclines: tetracycline, oxytetracycline, chlortetracycline. Aminoglycosides: spectinomycin, hygromycin, streptomycin, dithydrostreptomycin, amikacin, kanamycin, apramycin, gentamicin, neomycin, tobramycin, paromomycin. Macrolides: lincomycin, pirlymycin, clindamycin, tilmicosin, erythromycin, tulathromycin and tylosin.

Beta Lactams: amoxicillin, ampicillin, cloxacillin, naficillin, cefazolin, DCCD, dicloxacillin, penicillin G, oxacillin, and desacetyl cephaprin. Fluroquinolones: ciprofloxacin, norfloxacin, danofloxacin, enrofloxacin, sarafloxacin, difloxacin, desethylene diprofloxacin, desmethyl danofloxacin.

[3] Doramectin, ivermectin, and moxidectin.

[4] Sulfonamides in the FSIS multi-residue method (MRM): Sulfapyridine, sulfadiazine, sulfathiazole, sulfamerazine, sulfamethazine, sulfachloropyridazine, sulfadoxine, sulfamethoxypyridazine, sulfaquinoxaline, sulfadimethoxine, sulfisoxazole, sulfacetamide, sulfamethoxazole, sulfamethizole, sulfanilamide, sulfaguanidine, sulfabromomethazine, sulfasalazine, sulfaethoxypyridazine, sulfaphenazole, and sulfatroxazole.

[5] Naturally-occurring hormones, including 17-estradiol, testosterone, and progesterone.

[6] Detected as elemental arsenic.

[7] 2-thiouracil, 6-methyl-2-thiouracil, 6-propyl-2-thiouracil, 2-mercapto-1-methylimidazole, 2- mercaptobenzimidazole.

[8] Ractopamine, zilpaterol, cimaterol, and salbutamol.

[9] Azaperone and its metabolite azaperol, xylazine, haloperidol, acetopromazine, propionylpromazine, and chlorpromazine.

[10] Benzimidazoles in the FSIS multi-residue method (MRM): 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
2011 U.S. NRP Domestic and Import Scheduled Sampling

Rank	Score	Pesticide[1]	Number of Scheduled Samples		
			Domestic	Import	Total
1	16.0	Chlorinated hydrocarbons and chlorinated organophosphates (CHC/COP) – MRM[2] Analysis by WL	boars/stags (300) young chickens (300) sows (230) roaster pigs (300) steers (230) dairy cows (230) mature chickens (230) **Total domestic: 1,820**	beef, fresh (300) beef, processed (90) horse, fresh (8) lamb/mutton, fresh (90) goat, fresh (24) turkey, fresh (16) turkey, processed (16) other fowl, fresh (16) varied comb., fresh (8) varied comb, proc. (24) **Total import: 592**	2,412
2	16.0	Chlorinated organophosphates (COPs) and organophosphates (OPs) – non-MRM[3]	Not in the 2011 NRP	Not in the 2011 NRP	0
3	16.0	Beta-Cyfluthrin	Not in the 2011 NRP	Not in the 2011 NRP	0
4	16.0	Cyfluthrin	Not in the 2011 NRP	Not in the 2011 NRP	0
5	16.0	Imazalil	Not in the 2011 NRP	Not in the 2011 NRP	0
6	15.0	Triazines – non-MRM[4]	Not in the 2011 NRP	Not in the 2011 NRP	0
7	14.0	Carbamates – MRM[5]	Not in the 2011 NRP	Not in the 2011 NRP	0
8	14.0	Synthetic pyrethroids – MRM[6]	Not in the 2011 NRP	Not in the 2011 NRP	0
9	14.0	1-(2,4-Dichlorophenyl)-2-(1H-imidazole-1-yl)-1-ethanol	Not in the 2011 NRP	Not in the 2011 NRP	0
10	14.0	1,1-(2,2-Dichloroethylidene)bis(4-methoxybenzene)	Not in the 2011 NRP	Not in the 2011 NRP	0
11	14.0	1-Methoxy-4-(1,2,2,2-tetrachloroethyl)benzene)	Not in the 2011 NRP	Not in the 2011 NRP	0
12	14.0	3-(1-(2,4-Dichlorophenyl)-2-(1H-imidazole-1-yl) ethoxy)-1,2-propane diol	Not in the 2011 NRP	Not in the 2011 NRP	0
13	14.0	Cyhalothrin, lambda	Not in the 2011 NRP	Not in the 2011 NRP	0
14	14.0	Fipronil	Not in the 2011 NRP	Not in the 2011 NRP	0
15	14.0	MB 45950	Not in the 2011 NRP	Not in the 2011 NRP	0
16	14.0	MB 46513	Not in the 2011 NRP	Not in the 2011 NRP	0
17	14.0	Methoxychlor olefin	Not in the 2011 NRP	Not in the 2011 NRP	0
18	13.0	Triazines – MRM[7]	Not in the 2011 NRP	Not in the 2011 NRP	0
19	13.0	Arsanilic acid	Not in the 2011 NRP	Not in the 2011 NRP	0

Summary Table III – Summary by Compound Class
Rank and Status of Pesticides
2011 U.S. NRP Domestic and Import Scheduled Sampling

Rank	Score	Pesticide[1]	Number of Scheduled Samples		
			Domestic	Import	Total
20	13.0	Etoxazole	Not in the 2011 NRP	Not in the 2011 NRP	0
21	13.0	Indoxacarb	Not in the 2011 NRP	Not in the 2011 NRP	0
22	13.0	Meteonazole	Not in the 2011 NRP	Not in the 2011 NRP	0
23	13.0	Prothioconazole	Not in the 2011 NRP	Not in the 2011 NRP	0

WL = FSIS Western Laboratory (Alameda, CA)

[1] Only those pesticides that have been designated as representing a broad potential public health risk are included in this table.
[2] FSIS CHC/COP multi-residue method (MRM). Includes all of the following: *Chlorinated Hydrocarbons and Chlorinated Organophosphates (CHC/COP):* Aldrin, BHC alpha, BHC beta, BHC delta, carbophenothion, chlordane-cis (-alpha), chlordane-trans, chlordene, chlorfenvinphos, Chlorpyrifos, Chlorpyrifos methyl, coumaphos O, Coumaphos S, Dichlorfenthion, Fenchlorphos (Ronnel), Heptachlor, Hexachlorobenzene (HCB), Lindane, Mirex, trans-nonachlor, o,p'-DDE (2,4), o,p'-DDT, p,p'-DDE (4,4), p,p'-DDT, o,p'-TDE (DDD), p,p'-TDE (DDD), Phosalone, tetrachlorvinphos (stirofos), and Toxaphene. *Organochlorides (OC):* Captan, Dieldrin, Endosulfan I, Endosulfan II, Endosulfan sulfate, Endrin, Endrin Ketone, Heptachlor epoxide A, Heptachlor epoxide B, Kepone, Linuron, Methoxychlor, and Oxychlordane. *Environmental Contaminants:* 2,2',4,4',5,5'-hexabromobiphenyl (HBB), halowaxes, polybrominated biphenyls, and polychlorinated biphenyls (aroclors 1254, 1260) (PCBs).
[3] Those compounds not included in FSIS CHC/COP multi-residue method (MRM).
[4] Compounds not in the FSIS triazine multi-residue method (MRM).
[5] Compounds in the FSIS carbamate triazine multi-residue method (MRM).
[6] Compounds in the FSIS synthetic pyrethrin multi-residue method (MRM).
[7] Compounds in the FSIS triazine multi-residue method (MRM)

Summary Table IV – Summary by Compound Class
Rank and Status of Environmental Contaminants
2011 U.S. NRP Domestic and Import Scheduled Sampling

Environmental Contaminant[1]	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 2011	300

EL = FSIS Eastern Laboratory (Athens, GA)

[1] Environmental contaminants are not assigned a ranking score in the NRP.

Summary Table V – Summary by Production Class
2011 U.S. NRP Domestic Scheduled Sampling

Production Class ▼	Antibiotics	Arsenic	Avermectins	β-Agonists	Carbadox	Pesticides	Chloram-phenicol	Florfenicol	Flunixin	Lead and Cadmium	Nitrofurans	Nitroimidazoles	Sulfonamides	TOTALS
Beef cows	300	-	300	-	-	-	-	-	300	-	-	-	300	1,200
Bob veal	300	-	-	-	-	-	-	-	300	-	-	-	300	900
Bulls	300	-	230	-	-	-	-	-	-	-	-	-	230	760
Dairy cows	300	-	300	-	-	230	-	-	300	-	230	-	300	1,660
Formula-fed veal	300	-	300	230	-	-	-	300	300	-	-	-	300	1,730
Heavy calves	90	-	90	-	-	-	-	-	90	-	-	-	90	360
Heifers	300	-	-	300	-	-	-	-	-	-	-	-	300	900
Non-formula-fed veal	90	-	90	90	-	-	-	90	-	-	-	-	90	450
Steers	230	-	300	300	-	230	-	300	-	-	-	-	300	1,660
Subtotal, Cattle	**2,210**	**-**	**1,610**	**920**	**-**	**460**	**-**	**690**	**1,290**	**-**	**230**	**-**	**2,210**	**9,620**
Boars/Stags	300	-	300	-	-	300	-	-	-	-	-	-	300	1,200
Market hogs	300	300	-	300	300	-	-	-	-	300	300	-	300	2,100
Roaster pigs	300	-	-	-	230	300	-	-	-	-	300	-	230	1,360
Sows	300	-	-	-	-	230	-	-	-	-	-	-	300	830
Subtotal, Swine	**1,200**	**300**	**300**	**300**	**530**	**830**	**-**	**-**	**-**	**300**	**600**	**-**	**1,130**	**5,490**
Goats	90	-	230	90	-	-	-	-	-	-	-	-	-	410
Lambs	300	-	-	-	-	-	-	-	-	-	-	-	-	300
Sheep	300	-	300	-	-	-	-	-	-	-	-	-	-	600
Subtotal, Ovine	**690**	**-**	**530**	**90**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**1,310**
Total, All Livestock	**4,100**	**300**	**2,440**	**1,310**	**530**	**1,290**	**-**	**690**	**1,290**	**300**	**830**	**-**	**3,340**	**16,420**
continued next page														

Summary Table V – Summary by Production Class
2011 U.S. NRP Domestic Scheduled Sampling

Production Class ▼	Antibiotics	Arsenic	Avermectins	β-Agonists	Carbadox	Pesticides	Chloram-phenicol	Florfenicol	Flunixin	Lead and Cadmium	Nitrofurans	Nitroimidazoles	Sulfonamides	TOTALS
Ducks	45	-	-	-	-	-	-	-	-	-	-	-	-	45
Geese	30	-	-	-	-	-	-	-	-	-	-	-	-	30
Mature chickens	300	-	-	-	-	-	300	-	-	-	-	-	300	900
Mature turkeys	300	300	-	-	-	230	300	-	-	-	-	-	-	1,130
Young chickens	300	300	-	-	-	300	300	-	-	-	-	-	-	1,200
Young turkeys	300	300	-	-	-	-	300	-	-	-	-	300	-	1,200
Subtotal, Poultry	**1,275**	**900**	**-**	**-**	**-**	**530**	**1,200**	**-**	**-**	**-**	**-**	**300**	**300**	**4,505**
Rabbits	30	-	-	-	-	-	-	-	-	-	-	-	-	30
Egg products	-	300	-	-	-	-	-	-	-	-	-	-	300	600
TOTALS	**5,405**	**1,500**	**2,440**	**1,310**	**530**	**1,820**	**1,200**	**690**	**1,290**	**300**	**830**	**300**	**3,940**	**21,555**

Summary Table VI – Summary by Production Class
2011 U.S. NRP Import Sampling

Production Class ▼	Antibiotics	Arsenic	Avermectins	β-Agonists	Pesticides	Chloram-phenicol	Florfenicol	Flunixin	Nitroimidazoles	Sulfonamides	TOTALS
Beef, fresh	300	-	300	-	300	91	90	90	-	300	**1,471**
Beef, processed	-	-	63	-	90	-	-	-	-	63	**216**
Veal, fresh	90	-	90	90	-	89	-	-	-	90	**449**
Horse, fresh	8	-	-	-	8	-	-	-	-	8	**24**
Pork, fresh	230	104	-	104	-	-	-	-	-	230	**668**
Pork, processed	-	-	-	-	-	-	-	-	-	48	**48**
Lamb/Mutton, fresh	-	-	90	-	90	-	-	-	-	-	**180**
Goat, fresh	-	-	24	-	24	-	-	-	-	-	**48**
Chicken, fresh	90	90	-	-	-	90	-	-	90	-	**360**
Chicken, processed	-	8	-	-	-	-	-	-	-	-	**8**
Turkey, fresh	16	16	-	-	16	16	-	-	-	16	**80**
Turkey, processed	-	16	-	-	16	-	-	-	-	16	**48**
Other fowl, fresh	16	-	-	-	16	-	-	-	-	-	**32**
Varied combination, fresh	8	-	-	-	8	-	-	-	-	8	**24**
Varied combination, proc.	-	-	-	-	24	-	-	-	-	24	**48**
TOTALS	**758**	**234**	**567**	**194**	**592**	**286**	**90**	**90**	**90**	**803**	**3,704**

Summary Table VII – Summary by Production Class and Country
2011 U.S. NRP Import 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	-	42	-	-	-	-	-	-	-	-	-	-	-	-	-	42
Australia	399	-	40	-	32	-	94	16	-	-	-	-	-	-	16	597
Austria	-	-	-	-	-	8	-	-	-	-	-	-	-	-	-	8
Brazil	-	174	-	-	-	-	-	-	-	-	-	-	-	-	-	174
Canada	426	-	229	24	268	-	16	-	280	-	40	-	16	24	-	1,323
Chile	56	-	-	-	32	-	-	-	48	-	40	-	-	-	-	176
Costa Rica	56	-	-	-	-	-	-	-	-	-	-	-	-	-	-	56
Croatia	-	-	-	-	-	8	-	-	-	-	-	-	-	-	-	8
Denmark	-	-	-	-	48	-	-	-	-	-	-	-	-	-	-	48
Finland	-	-	-	-	32	-	-	-	-	-	-	-	-	-	-	32
France	-	-	-	-	-	8	-	-	-	-	-	-	16	-	16	40
Germany	-	-	-	-	-	8	-	-	-	-	-	-	-	-	-	8
Honduras	56	-	-	-	-	-	-	-	-	-	-	-	-	-	-	56
Hungary	-	-	-	-	-	8	-	-	-	-	-	-	-	-	-	8
Iceland	-	-	-	-	-	-	16	-	-	-	-	-	-	-	-	16
Ireland	-	-	-	-	32	-	-	-	-	-	-	-	-	-	-	32
Israel	-	-	-	-	-	-	-	-	-	8	-	24	-	-	-	32
Italy	-	-		-	-	8	-	-	-	-	-	-	-	-	-	8
Japan	54	-	-	-	-	-	-	-	-	-	-	-	-	-	-	54
Mexico	56	-	-	-	32	-	16	16	32	-	-	24	-	-	16	192
Netherlands	-	-	-	-	32	-	-	-	-	-	-	-	-	-	-	32
New Zealand	-	-	-	-	32	-	-	-	-	-	-	-	-	-	-	32
Nicaragua	244	-	180	-	-	-	38	16	-	-	-	-	-	-	-	478
N. Ireland	64	-	-	-	-	-	-	-	-	-	-	-	-	-	-	64
Poland	-	-	-	-	32	-	-	-	-	-	-	-	-	-	-	32
Spain	-	-	-	-	32	-	-	-	-	-	-	-	-	-	-	32
Sweden	-	-	-	-	32	-	-	-	-	-	-	-	-	-	-	32
UK	-	-	-	-	32	-	-	-	-	-	-	-	-	-	-	32
Uruguay	60	-	-	-	-	-	-	-	-	-	-	-	-	-	-	60
TOTALS	1,471	216	449	24	668	48	180	48	360	8	80	48	32	24	48	3,704

Overview of the U.S. National Residue Program Design

The USDA FSIS obtains information on the occurrence and concentration of chemical compounds in meat, poultry, and egg products through the domestic and import scheduled sampling programs. 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 Surveillance Advisory Team (SAT), an interagency committee comprised of members from the EPA, FDA, CDC, AMS, ARS, and FSIS, to develop the list. The SAT identifies and prioritizes chemical compounds of public health concern and assembles detailed information on each compound. FSIS then combines this information with its 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:

- the qualitative public health risk associated with each chemical compound or compound class in meat, poultry, and egg products;
- the food animals in which each chemical compound or compound class is likely to be of concern;
- the availability of analytical methods to determine which chemical compound or compound classes can be analyzed; and
- FSIS laboratory capacity to analyze chemical compounds or compound classes.

Domestic residue testing often is targeted towards organ tissues (i.e., kidney and liver) where many residues concentrate, thus allowing for better detection. Because of this concentration effect, FDA often bases its tolerances for veterinary drugs upon the levels found in those organs. The import reinspection plan design is similar to domestic plan, with two important exceptions. Raw product testing at U.S. port-of-entry is rare, because many countries ship processed products only. 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), and egg products are distinguished as a separate category. Importing countries often have different approved compounds and different use practices than domestic plans, so the compounds analyzed in the import plan may not necessarily be the same as those in the domestic plan.

Design of the Domestic Scheduled Sampling Plan for Veterinary Drugs

I. Selecting, Scoring, and Ranking Candidate Veterinary Drugs

Table 1 includes the candidate veterinary drugs of concern selected by SAT members. These veterinary drugs also are presented 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 the Animal Medicinal Drug Use Clarification Act (AMDUCA) and are high regulatory priorities.

- Antibiotics: (7-plate bioassay[1])
  Tetracyclines: tetracycline, oxytetracycline, chlortetracycline (High Performance Liquid Chromatography (HPLC) or mass spectrometry (MS)) for identification, quantitation by bioassay). Aminoglycosides: spectinomycin, hygromycin, streptomycin, dihydrostreptomycin, amikacin, kanamycin, apramycin, gentamicin, neomycin, tobramycin, paromomycin (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. 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). HPLC quantitative analysis for ceftiofur Fluoroquinolones: ciprofloxacin, norfloxacin, danofloxacin, enrofloxacin, sarafloxacin, difloxacin, desethylene diprofloxacin, desmethyl danofloxacin (LC/MS/MS for confirmation).
- 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 in FSIS Multi Residue Method (MRM): doramectin, ivermectin, and moxidectin)
- Benzimidazoles (classification: anthelmintics; compounds in FSIS MRM: 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)
- β-Agonists (ractopamine, clenbuterol, cimaterol, zilpaterol, and salbutamol; growth promotants)
- Clorsulon (classification: anthelmintic)
- Dexamethasone (classification: glucocorticoid)
- Diethylstilbestrol (DES; AMDUCA prohibited synthetic hormone)
- Dipyrone (classification: NSAID[2])

[1] FSIS quantifies most antibiotics using a 7-plate bioassay that measures microbial inhibition. Laboratory technicians use the pattern of inhibition (i.e., the combination of plates showing inhibition) to identify the antibiotic. Some antibiotics, however, share the same pattern of inhibition, which requires follow-up testing (HPLC or mass spectrometry, when available) to establish their identities.

- 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)
- Nitromidazoles (classification: antiprotozoals; compounds in FSIS MRM: dimetridazole, ipronidazole)
- Phenylbutazone (classification: NSAID)
- Prednisone (classification: glucocorticoid)
- Ronidazole (classification: antimicrobial; compound: nitroimidazole)
- Sulfonamides (classification: antimicrobials, and some are coccidiostats; compounds in FSIS MRM: 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)[3]
- 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 in FSIS MRM: azaperone and its metabolite azaperol, xylazine, haloperidol, acetopromazine, propionylpromazine, and chlorpromazine)

Veterinary Drugs Banned from Extra Label use Under AMDUCA

Veterinary drugs prohibited from extra label use under AMDUCA, referred to in this document as "AMDUCA-prohibited," 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 automatically 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.

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:

- U.S. NRP Historical Testing Information on Violations
- Regulatory Concern
- Lack of U.S. NRP Testing Information on Violations
- Withdrawal Time

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[2] NSAID = non-steroidal anti-inflammatory drug
[3] FSIS, in consultation with FDA, rotated sulfanitran out of the NRP beginning in the 2005 NRP.

- Impact on New and Existing Human Disease
- Relative Number of Animals Treated
- Acute or Chronic Toxicity Concerns

The Scoring Key for Veterinary Drugs, 2011 Domestic Residue Program in Section V, page 30, defines each of these categories and the criteria used for scoring.

The results of the compound scoring process are presented in Table 1.

Compound Ranking

1. Background

FSIS employs qualitative risk assessment techniques and principles to create an initial ranking of the relative public health concern represented by each candidate chemical compounds or compound classes. FSIS shares this ranking with other members of the SAT for further discussion.

If FSIS is in possession of detailed historical data on the distribution of levels for each of the candidate compounds or compound classes in meat, poultry, and egg products, then the information is combined with consumption data to estimate exposure. We estimate risk for each compound or compound class by combining these exposure estimates with toxicity information.

Category designation is 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 (averaged 2000 to 2009); and (b) the maximum violation rate (averaged 2000 to 2009) for ay production class, but weighted by the size of the production class. Each veterinary drug is scored according to the higher of these two scores.[4] Equation 1 provides the violation rate scores assigned in Table 1 and represents a rough overall estimate of *relative* risk per unit of consumption.[5] Data on violation rates are not available for the many candidate compounds or compound classes of concern. It was, therefore, necessary to generate an estimate of the overall violation rate for each of these untested compounds and compound classes.

Equation 1

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

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

[5] While some consideration was given to the size of the production class in scoring "U.S. 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. To obtain values for relative risk, the scores in this category must be multiplied by the consumption data for each individual production class. This calculation is implemented subsequently, using Equation 6; the results are presented in Table 3.

FSIS does not associate varying degree of risk when a tolerance level is exceeded by a certain amount or percentage. Instead, the relative toxicity is measured as the tolerance or action level of a compound or compound class. *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.*

2. Estimating the Violation Rate

The variables "Regulatory Concern," "Withdrawal Time," and "Relative Number of Animals Treated" are expected to correlate positively with the violation rate and were chosen as scoring categories to serve as predictors of violations in those compounds or compound classes for which no reliable historical testing information was available. "Regulatory Concern" predicts the likelihood of occurrence of violations, based on regulatory intelligence information about possible misuse. "Withdrawal Time" correlates with "U.S. NRP Historical Testing Information on Violations" because a longer withdrawal time is less likely to be observed properly. When a withdrawal time for a veterinary drug is not observed prior to slaughter, the carcass may contain violative levels of residues, because the time necessary for sufficient metabolism and elimination of the veterinary drug would not have passed. "Relative Number of Animals Treated" correlates with "U.S. NRP Historical Testing Information on Violations" because heavy compound use increases the likelihood of violations.

Violation rate data are available for selected compounds and compound classes to assign scores, which are listed in Table 1 under the category "U.S. NRP Historical Testing Information on Violations." Using the scores, it is possible to evaluate how well the above criteria correlate. A linear regression model was applied in order to impute values for the missing data. The dependent variable in this model is the category "U.S. NRP Historical Testing Information on Violations," while the only significant independent variable is the product of the scores for "Relative Number of Animals Tested" and "Withdrawal Time." Using the value of the 10 independent variables from the 10 scored compounds, a least squares linear regression model predicts scores for the 19 compounds lacking information. The following equation was derived:

Equation 2

$$Vp = 0.25\ (R \times N)$$

Vp = Predicted score for "FSIS Historical Testing Information on Violations"
R = Score for "Regulatory Concern"
N = Score for "Relative Number of Animals Treated"

This model is the result of using a stepwise regression with several possible independent variables. The independent variables available for the stepwise regression are:

- A score for Regulatory Concern (R)
- A score for Withdrawal Time (W)
- A score for Relative Number of Animals Treated (N)
- R^2
- W^2
- N^2
- The product of R and W
- The product of R and N
- The product of W and N

No terms involving "Regulatory Concern" were included in the final equation since none were found to be significant factors in the regression model.

In statistics, regression analysis examines the relation of a dependent variable (response variable) to specified independent variables. The model represented by Equation 2 has a regression value (R^2) of 0.44, which explains 44 % of the variability.

Where current, reliable historical testing data are available for a compound or compound class, FSIS used the score assigned in Table 1. Where current, reliable historical data were not available, FSIS used the predicted score generated by Equation 2.

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

As indicated above, the score for the category "U.S. NRP Historical Testing Information on Violations" combines information on residue levels and toxicity, and thus represents a rough 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. Equation 3 provides the calculation used to generate scores for relative public health concern, which are summarized in Table 1.

Equation 3

Relative Public Health Concern = *Predicted* or *Actual* score for "U.S. NRP Historical Testing Information on Violations" (Estimate of Relative Hazard)

multiplied by:

-- a *modifier for* "Acute or Chronic Toxicity Concerns" and

-- a *modifier for* "Impact on New and Existing Human Disease"

A veterinary drug violation means that a compound was found at a level that exceeds FDA standards and may result in a toxic effect. However, this does not address the *severity* of the effect associated with the toxic endpoint. To capture this concern, FSIS examined "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 the extent to which the use or misuse of a compound will contribute to new and existing human disease. For example, there is a possibility that the creation of antibiotic-resistant human pathogens may result from the use of antibiotics in animals. This represents a potential public health concern that is not captured by the violation rate.

The categories for acute and chronic toxicity concerns and impact on new and existing human disease introduce an element of arbitrariness into the calculation for the relative public health concern because there are no fundamentally "correct" assumptions for the appropriate weight that should be given to each category. FSIS considered several possible sets of weighting factors for use in Equation 3. The various formulas differed principally in the relative weights given to the categories, "Acute or Chronic Toxicity Concerns" versus "Impact on New and Existing Human Disease."

Equation 4 developed by FSIS is presented in the column "Relative Public Health Concern Score" in Table 1. The equation is based on SAT consensus dealing with the relative importance of each category and how much each category should be allowed to alter the underlying risk-based score defined as "V" in Equation 4. In this formula, the score for "U.S. NRP Historical Testing Information on Violations" has been multiplied by a weighted average of the categories for "Acute or Chronic Toxicity Concerns" and "Impact on New and Existing Human Disease." These last two categories were combined because they both represent the negative potential public health effects associated with the use of a compound or compound class. "Acute or Chronic Toxicity Concerns" received three times the weight of "Impact on New and Existing Human Disease" because the former represents known direct health effects, while the latter represents possible indirect health effects. Equation 4 formalizes the basis of FSIS judgment for relative public health concern for each compound and enables others to observe and understand the adjustments made. This equation ensures consistency in how these adjustments were applied across a wide range of compounds.

Equation 4

Relative public health concern, R, rating for veterinary drugs:

$$R = V((D+3T)/4)$$

V = *Predicted* or *Actual* score for "U.S. NRP Historical Testing Information on Violations"
D = score for "Impact on New and Existing Human Disease"
T = score for "Acute or Chronic Toxicity Concerns"

The formulas developed for the veterinary drugs and pesticides have been normalized to give the same maximum value. Because the formula for the pesticides uses scoring categories that are different from the veterinary drugs, their scores are not comparable in a quantitative sense, but the scores for the pesticides and veterinary drugs are comparable in magnitude, which enables a rough comparison to be made between the two different categories of compounds.

Summary Table II ranks the veterinary drugs by their rating scores, using the above weighting formula. 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 application occurs during allocation of sampling resources based on estimates of relative exposure values for each compound/production class (C/PC) pair.

II. Prioritizing Candidate Veterinary Drugs

After ranking veterinary drugs, the ranking scores for relative public health concern were used as criteria for selecting compounds and compound classes to include in the 2011 U.S. NRP based on the availability of laboratory resources.

- FSIS and FDA prioritize compounds and compound classes that rank 1 to 10 (out of 29) and represent a potential public health concern sufficient to justify their inclusion in the 2011 U.S. NRP. In addition, FSIS is performing testing on β-Agonists (ranked 18th), based on guidance from FDA.

After identification of AMDUCA drugs, high-priority compounds and compound classes, FSIS applied practical considerations to determine the compounds for sampling. Availability of laboratory resources and appropriate analytical methods within the FSIS laboratories was a principle consideration. FSIS plans to schedule the following veterinary drugs in the 2011 U.S. NRP for domestic sampling:

- Antibiotics (7-plate bioassay)
- Arsenicals
- Avermectins
- β-Agonists
- Carbadox
- Chloramphenicol
- Florfenicol
- Flunixin
- Nitrofurans
- Nitroimidazoles
- Sulfonamides

In the 2011 U.S. NRP, FSIS will employ a number of analytical methodologies to characterize (i.e., identify and quantify) veterinary drug residues. The methodologies are effective for the analysis of individual compounds, and multi-residue methods (MRMs) are effective for antibiotics, avermectins, β-agonists, and sulfonamides that distinguish individual compounds in a compound class.

Summary Table II lists all of the original candidate veterinary drugs in rank order and specifies individual compounds and compound classes that will be scheduled for domestic sampling in the 2011 U.S. NRP. A brief explanation provides the reason for a highly ranked compound or compound class that is not included for domestic sampling in the 2011 U.S. NRP. This table also identifies future method development needs for veterinary drugs for the U.S. NRP.

III. Identifying Compound/Production Class (C/PC) Pairs for Veterinary Drugs

SAT participants identified production classes of concern for each of the veterinary drugs and veterinary drug classes to be included in the 2011 U.S. NRP. SAT participants used their professional judgment to determine the likelihood of finding violations within each production class combined with the proportion of total domestic meat consumption for each production class represented. The judgment is based on use approvals, extent of use, evidence of misuse, and past violation history.

Production class nomenclature:

Bovine

- Beef cows are mature, female cattle bred for muscle development, ordinarily having given birth to one or more calves.
- Bulls are mature, uncastrated male cattle.
- Calves/veal 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 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 six-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 are yolks, whites, or whole eggs after breaking that 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 (typically 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, birds of both sexes usually less than 12 weeks of age; and capons, surgically castrated male birds usually less than eight-months of age.
- Young turkeys include fryer/roaster birds that are of both sexes and usually less than 12 weeks of age, and turkeys that are birds of both sexes, usually less than six months of age.

Other Livestock

- Goats are animals of both sexes and any age.
- Lambs are generally defined as 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.

IV. Allocation of Sampling Resources

"Full-Resource" Sampling

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 2009 as a surrogate for consumption. The production data for calves were collected, collated, and reported by FSIS, using the Automated Data Reporting System (ADRS). The production data for all other production classes, including egg products, were collected by FSIS, and collated and reported by the National Agricultural Statistical Service. Equation 5 established the estimated relative percent of consumption represented by each production class, which 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:

Equation 5

Estimated Relative Percent of Domestic Consumption (ERC)

$$ERC = AP/TP \times 100$$

AP = Annual Production (dressed weight in pounds)
TP = Total Annual Production of all Production Classes

All calculations and results are presented in Table 2, *Estimated Relative Consumption, Domestically Produced Meat, Poultry, and Egg Products*.

To establish a relative sampling priority for each compound-production class pair, the ranking score (as calculated in Table 1) was multiplied by the estimated relative percent of domestic consumption for each production class (as calculated in Table 2 and presented in Table 3). The resulting priority score for compound-production class pairs is calculated in Equation 6.

Equation 6

Priority Score (PS)

$$PS = CP \times RPC$$

CP = Compound Priority Score Rating
RPC = Relative Percent Consumption

Equation 6 is analogous to the equation used to estimate risk in Equation 1, in which risk per unit of consumption is multiplied by consumption. While the results of Equation 6 do not constitute an estimate of risk, they provide a numerical representation of the relative public health concern represented by each compound-production class pair, and thus can be used to prioritize FSIS analytical sampling resources accordingly. Equation 6 risk-ranking is based on average consumption across the entire U.S. population, rather than upon maximally exposed individuals.

We used Equation 6 to calculate priority score measurements for antibiotics, arsenicals, avermectins, and sulfonamides, florfenicol, flunixin, xenobiotic hormones, carbadox, β-agonists, and thyreostats. Initially, the compound-production class pairs were sorted by their sampling priority scores, see Table 3. These priority scores were weighed against historical violation rate information, information on laboratory sampling capacity, and the number of slaughter facilities, to arrive at a final number of samples to be scheduled for each compound-production class pair. Statistically, if v is the true violation rate in the population and n is the number of samples, the probability, P, of finding at least one violation among the *n* samples (assuming random sampling) is: $P = 1-(1-v)^n$. Therefore, if the true violation rate is 1%, the probabilities of detecting at least one violation with sampling levels of 300 and 230 are 95% and 90%, respectively (see Appendix III: Statistical Table). The 300 per year sampling level is useful for scheduling production classes with somewhat lower violation rates, which is done typically for larger production classes that represent a larger potential consumer exposure.

Beginning in the 2006 NRP, low volume produced animals (i.e., ratites, squab, and bison) were not scheduled for the domestic sampling program, because the production of these animals is quite low. Not including these animals in the scheduling process allows FSIS to focus limited resources to develop of methodologies in areas that are of high public health concern.

Beginning in the 2008 NRP, rabbits and ducks were rotated back in the NRP and will continue in the 2010 domestic sampling program. Beginning in 2009, geese were rotated back in the NRP and will continue in the 2011 domestic sampling program. Based on field reports, FDA expressed an interest in continuing limited testing for these production classes.

Adjusting Relative Sampling Numbers

Adjusting for Historical Data on Violation Rates of Individual Compound-Production Class Pairs

FSIS uses "U.S. NRP Historical Testing Information on Violations" as a critical factor in ranking the various veterinary drugs and veterinary drug classes according to their relative public health concern. Because this information is available for each production class individually, it can be used also to refine the relative priority of sampling each compound-production class pair. Table 4 lists the number of analyses assigned to each compound-production class pair and reports the total number of samples analyzed in the scheduled sampling plan for the period 01/01/2000 to 12/31/2009. In addition, it reports the percent of samples found to be violative (i.e., in excess of the action level or regulatory tolerance or present at any detectable level for prohibited compounds) for each compound-production class pair. FSIS used these data to develop rules to adjust sampling numbers:

- If fewerthan 300 samples (i.e., 230 samples) were tested in the scheduled sampling plan for a compound-production class pair for the period of January 1, 2000 to December 31, 2009, then maintain the sampling level. If 300 samples were assigned initially, maintain 300 samples.
- Decrease the sampling level using Statistical Table in Appendix III if violations were found during the 2009 calendar year or the violation rate was greater than or equal to 0.70% ($\geq$ 0.70%) during this period.
- If 300 samples were tested in the scheduled sampling plan for a compound-production class pair for the period January 1, 2000 to December 31, 2009 and no violations were found during the 2009 calendar year, then maintain the sampling level.
- If at least 300 samples were tested in the scheduled sampling plan for a compound-production class pair for the period January 1, 2000 to December 31, 2009 and a violation rate of 0.00% was found, rotate the compound-production class pair out of the NRP.[6]
- The maximum number of samples to be scheduled for testing is 300.

Adjusting for Laboratory Capacity

After adjusting for historical data, it was necessary to make a final set of adjustments to match the total sampling numbers for each compound class with the analytical capabilities of the FSIS laboratories.

Adjustment for the Number of Slaughter Facilities

The total number of scheduled samples was adjusted to accommodate the number of production facilities. For this adjustment, FSIS considered the total number of production facilities (USDA Inspected

[6] Compound-production class pairs removed from scheduled sampling will be reintroduced at a later date.

Establishments for 2008) for each production class. If the total number of production facilities for a production class was found to be low relative to other production classes, the total number of scheduled samples was reduced for that production class. The number of samples selected for the reduction is based on FSIS professional judgment. If the number of facilities is less than 100, the number of scheduled samples was adjusted down by at least one level (i.e., if 300 were assigned initially, then decrease to at least 230 samples).

Adjustment for a Zero Percent (0%) Violation Rate for the three year Period, 2007 to 2009

FSIS examined historical violation data for the 2007 to 2009 production years. For compound slaughter class pairs that had a zero percent violation rate for the three-year period, the number of scheduled samples has been reduced to zero.

Final Adjustment

Table 4 lists the total number of scheduled samples for compound-production class pairs following adjustments for laboratory capacity, production, and violation rate data.

"Limited Resource" Sampling

The 2011 U.S. NRP includes a number of compounds for which FSIS does not have extensive sampling data. FSIS is interested in obtaining information on the occurrence in production classes when these compounds might be of concern. To enable FSIS to sample this entire range of compounds, it is necessary to limit the number of samples taken per compound. In apportioning this "limited resource" sampling among the production classes of concern, it was particularly important to ensure that a sufficient number of samples be taken from each production class analyzed. If too few samples are taken from a production class, and no violations are detected, it would be difficult to interpret such a result. Where possible, 300 analyses are scheduled in each production class to be sampled. This yields a 95% confidence of detecting a violation, if the true violation rate is 1%.

For the 2011 U.S. NRP, selection of production classes for the limited resource sampling for compounds (Table 4) was made as follows:

- Antibiotics are of concern in ducks, geese, goats, heavy calves, non-formula fed veal, bob veal, rabbits, and steers. FSIS has the analytical capacity to sample these animals at different levels for domestic production: ducks (45), geese (30), goats (90), heavy calves (90), non-formula fed veal (90), rabbits (30), and steers (230). FSIS will also allow sampling of the following animals for import: fresh beef (300), fresh chicken (90), fresh horse (8), fresh other fowl (16), fresh pork (230), fresh turkey (16), varied combination (8), and fresh veal (90).

- Avermectins are of concern in bulls, goats, heavy calves, and non formula-fed veal. FSIS has the analytical capacity to sample these animals at different levels for domestic production: bulls (230), goats (230), steers (230), heavy calves (90), and non formula-fed veal (90). FSIS will also allow sampling of the following animals for import: fresh beef (300), processed beef (63), fresh veal (90), fresh lamb/mutton (90), and fresh goat (24).

- β-Agonists are of concern for formula fed veal, goats, and non-formula fed veal. FSIS has the analytical capacity to sample these animals at different levels for domestic production: formula fed veal (230), goats (90) and non-formula fed veal (90). FSIS will also allow sampling of fresh pork (104) and fresh veal (90) for import.

- Carbadox is of concern in roaster pigs. FSIS has the capacity to test 230 samples for roaster pigs. No import samples are scheduled for carbadox.

- Florfenicol is of concern for non-formula fed veal. FSIS has the capacity to analyze 90 samples for non-formula fed veal. FSIS will also allow sampling of 90 fresh beef import samples.

- Flunixin is of concern for heavy calves. FSIS has the capacity to analyze 90 samples for heavy calves. FSIS will also allow sampling of 90 fresh beef import samples.

- Nitrofurans are of concerns in dairy cows. FSIS has the capacity to analyze 230 samples for dairy cows. No import samples are scheduled for nitrofurans.

- Sulfonamides are of concern for bulls, heavy calves, non-formula-fed veal, and roaster pigs. FSIS has the analytical capacity to sample these animals at different levels for domestic production: bulls (230), heavy calves (90), non-formula fed veal (90), and roaster pigs (230). FSIS will also allow sampling of the following animals for import: fresh beef (300), processed beef (63), fresh horse (8), fresh pork (230), processed pork (48), fresh turkey (16), processed turkey (16), fresh varied combination (8), processed varied combination (24), and fresh veal (90).

V. Scoring Key

U.S. NRP Historical Testing Information on Violations (01/01/2000 to 12/31/2009)

The two methods used to calculate violation rate scores are based on violation rate data from a random sampling of animals entering the food supply.

Method A: Maximum Violation Rate
Identify the production class exhibiting the highest average violation rate (i.e., the number of violations over the period from 1999 to 2008 divided by the total number of samples analyzed).

The results were attributed a score as follows:

4 = > 0.70%

3 = 0.31% - 0.70 %

2 = 0.15% - 0.30%

1 = < 0.15%

NT = Not tested by FSIS

NA = Tested by FSIS, but violation information does not apply

Note that the above violation rate criteria are different from those used in planning the 1998 to 2002 NRPs. For previous NRPs, the criteria were identified as follows: 4 = > 1.0%; 3 = 0.50% to 1.0%; 2 = 0.15% to 0.49%; and 1 = < 0.15%. The new cutoffs permit FSIS to better distinguish between "high-violation" and "low-violation" slaughter classes.

Method B: Violation Rate Weighted by Size of Production Class
For each production class analyzed, multiply the average violation rate (defined above) by the relative consumption value for that class (i.e., weighted annual U.S. production for that class divided by total production for all classes for which FSIS has regulatory responsibility). Add together the values for all production classes.

The results were attributed a score as follows:

4 = > 0.15%

3 = 0.076% to 0.15%

2 = 0.01% to 0.075%

1 = < 0.01%

NT = Not tested by FSIS

NA = Tested by FSIS, but violation information does not apply

A final score is determined by assigning the greater score from either Method A and Method B to each veterinary drug or veterinary drug class.

Method A identifies those veterinary drugs that are of regulatory concern because they exhibit high violation rates, independent of the relative consumption value of the production class in which the violations have occurred. Method B identifies those veterinary drugs that may not have the highest violation rates, but are of concern because they exhibit moderate violation rates in a relatively large proportion of the U.S. meat supply. By employing methods A and B together, and assigning a final score based on the highest score received from each, both of the above concerns are captured.

Regulatory Concern

Based on regulatory intelligence information (e.g., FDA on farm investigations) about possible misuse, FSIS makes professional judgments about the likelihood of occurrence of violations. 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 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." For each veterinary drug in the production class for which it is approved, the conditions of use specify the dosing regimen and the withdrawal time. The withdrawal time is the number of days that must pass between completion of the dosing regimen and the time of slaughter. The withdraw time provides sufficient time for the concentration of the veterinary drug in the animal to decrease below the tolerance. Approved veterinary drugs were scored as follows:

4 = when the withdrawal time is greater than 14 days

3 = when the withdrawal time is between 8 and 14 days

2 = when the withdrawal time is between 1 and 7 days

1 = when there is a zero-day withdrawal time

For unapproved veterinary drugs, scores in this category were assigned based on estimates of the veterinary drug's half-life.

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 veterinary drug resistance patterns of human pathogenic organisms.

3 = Limited scientific information is available to suggest or document public health risk, but 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 on doses sold, as well as surveys of treatment practices in animal populations that are representative of national feedlot, dairy, poultry, and swine production.

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.

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.

Acute or Chronic Toxicity Concerns

The toxicity of the compound and the severity associated with the compound's toxic endpoint are scored as follows:

4 = Compound is a carcinogen, potentially life threatening, or has significant acute effects, including the 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 = 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
2011 U.S. NRP Domestic Scheduled Sampling

Compound / Compound Class	Historical Testing Info. on Violations (FSIS) (V)[1]	Regulatory Concern (CVM) (R)[2]	Withdrawal Time (CVM) (W)[3]	Relative Number Animals Treated (CVM) (N)[4]	Predicted V V= 0.25(R*N)[5]	Impact New and Existing Human Disease (CDC) (D)[6]	Acute or Chronic Toxicity Concerns (CVM) (T)[7]	Relative Public Health Concern Score = V*[(D+3*T)/4]
Antibiotics quantitated by the FSIS Bioassay MRM[8]	4	4	4	4	4.0	4	4	**16.0**
Carbadox (antimicrobial)	4	4	4	3	4.0	3	4	**15.0**
Avermectins in FSIS MRM (incl. doramectin, ivermectin, moxidectin) (antiparasitics)	4	3	4	4	4.0	2	4	**14.0**
Sulfonamides (antimicrobials, some are coccidiostats)	4	4	3	4	4.0	4	3	**13.0**
Xenobiotic hormones (zeranol, trenbolone)	4	4	1	3	4	3	3	**12.0**
Flunixin	4	4	2	3	4	1	3	**10.0**
Florfenicol (chloramphenicol derivative)	NT[9]	3	4	4	3	4	3	**9.75**
Hormones (naturally occurring)	NT	4	1	4	4	2	2	**8.0**
Arsenicals (detected as As)	3	4	2	4	3	3	2	**6.75**
Dexamethasone (glucocorticoid)	NA[10]-O	4	2	2	2	1	3	**5.0**
Methyl prednisone (glucocorticoid)	NT	4	2	2	2	1	3	**5.0**
Eprinomectin (avermectin)	NT	2	2	3	1.5	2	3	**4.13**

[1] Scores for historical testing for residue violations, V, are information are provided by USDA's Food Safety and Inspection Service (FSIS)
[2] Scores for regulatory concern, R, are provided by FDA's Center for Veterinary Medicine (CVM)
[3] Scores for withdrawal time, W, are provided by FDA's Center for Veterinary Medicine (CVM)
[4] Scores for relative number of animals treated, N, are provided by FDA's Center for Veterinary Medicine (CVM)
[5] 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.
[6] Scores on impact new and existing human diseases, D, are provided by Center for Disease Control and Prevention
[7] Scores for acute or chronic toxicity concerns, T, are provided by Center for Disease Control and Prevention
[8] MRM = Multi Residue Method
[9] NT = Not tested by FSIS
[10] NA = Tested by FSIS, but violation information does not apply

Table 1 *(continued)*
Scoring Table for Veterinary Drugs
2011 U.S. NRP Domestic Scheduled Sampling

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	1.0	3	3	**3.0**
Berenil (antiprotazol, histomonas)	NT	4	4	1	1	2	3	**2.75**
beta agonists (ractopamine, zilapterol, cimaterol, salbutamol)	1	4	2	3	1.0	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	2.0	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 2009 Animal and Egg Production Data
2011 U.S. NRP Domestic Scheduled Sampling Plan

Production Class	Number of Head Slaughtered[1]	Pounds per Animal (dressed weight)[2]	Total Pounds (dressed weight)	Percent Estimated Relative Consumption
Bulls	583,728	878	512,513,184	0.470%
Beef cows	3,331,889	610	2,032,452,290	1.865%
Dairy cows	2,826,637	610	1,724,248,570	1.582%
Heifers	9,739,581	782	7,616,352,342	6.988%
Steers	16,290,325	847	13,797,905,275	12.660%
Bob veal	520,783	75	39,058,725	0.036%
Formula-fed veal	370,454	245	90,761,230	0.083%
Non-formula-fed veal	15,999	350	5,599,650	0.005%
Heavy calves	29,453	400	11,781,200	0.011%
SUBTOTAL, CATTLE	**33,708,849**		**25,830,672,466**	**23.700%**
Market hogs	108,206,020	203	21,965,822,060	20.154%
Roaster pigs	753,423	70	52,739,610	0.048%
Boars/Stags	449,713	199	89,492,887	0.082%
Sows	3,352,852	306	1,025,972,712	0.941%
SUBTOTAL, SWINE	**112,762,008**		**23,134,027,269**	**21.225%**
Sheep	2,159,338	70	151,153,660	0.139%
Lambs	154,153	64	9,865,792	0.009%
Goats	651,783	50	32,589,150	0.030%
SUBTOTAL, OVINE	**2,965,274**		**193,608,602**	**0.178%**
Bison	53,510	610	32,641,100	0.030%
TOTAL, ALL LIVESTOCK	**149,489,641**		**49,190,949,437**	**45.133%**
Young chickens	8,544,285,285	Not Reported	47,776,488,239	43.835%
Mature chickens	138,692,395	Not Reported	796,037,624	0.730%
Young turkeys	245,590,672	Not Reported	7,099,906,243	6.514%
Mature turkeys	1,810,634	Not Reported	47,820,431	0.044%
Ducks	22,896,447	Not Reported	153,923,719	0.141%
Geese	178,434	Not Reported	2,489,307	0.002%
Other fowl (includes squab)	2,953,823	Not Reported	2,923,171	0.003%
SUBTOTAL, POULTRY	**8,956,407,690**		**55,879,588,734**	**51.269%**
Rabbits	271,415	Not Reported	1,287,878	0.001%
Egg products	Not Applicable	Not Applicable	3,920,140,000	**3.597%**
GRAND TOTAL in POUNDS, ALL PRODUCTION CLASSES			**105,075,746,189**	**100%**

The purpose of this table is 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. These estimates were made 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 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).*

[1] Number of heads is obtained from the Animal Disposition Reporting System (ADRS).
[2] Average dressed weights are obtained from the publication: "Livestock Slaughter 2009 Summary," National Agricultural Statistics Service (NASS), March 2010. In instances when the average weight is not available, an average weight based on previous calendar year's data was imputed.

Table 3
Veterinary Drug/Production Class Pairs, Sorted by Sampling Priority Score
2011 U.S. NRP Domestic Scheduled Sampling Plan

Veterinary Drug or Drug Class	*Compound Priority Rating (P)*	*Production Class*	*Relative Percent Consumption in 2009(C)*	*Sampling Priority Score (P * C)*	*Unadjusted Number of Samples*
Antibiotics (7-Plate Bioassay)	16.0	Young chickens	43.835	701.36	300
Antibiotics (7-Plate Bioassay)	16.0	Market hogs	20.154	322.46	300
Carbadox	15.0	Market hogs	20.154	302.31	300
Arsenicals	6.75	Young chickens	43.835	295.89	300
Sulfonamides	13.0	Market hogs	20.154	262.00	300
Antibiotics (7-Plate Bioassay)	16.0	Steers	12.660	202.56	300
Avermectins	14.0	Steers	12.660	177.24	300
Sulfonamides	13.0	Steers	12.660	164.58	300
Arsenicals	6.75	Market hogs	20.154	136.04	300
Florfenicol	9.75	Steers	12.660	123.44	300
Antibiotics (7-Plate Bioassay)	16.0	Heifers	6.988	111.81	300
Antibiotics (7-Plate Bioassay)	16.0	Young turkeys	6.514	104.22	300
Sulfonamides	13.0	Heifers	6.988	90.84	300
Beta-Agonists	2.75	Market hogs	20.154	55.42	300
Sulfonamides	13.0	Egg products	3.597	46.76	300
Arsenicals	6.75	Young turkeys	6.514	43.97	300

Table 3 *(continued)*
Veterinary Drug/Production Class Pairs, Sorted by Sampling Priority Score
2011 U.S. NRP Domestic Scheduled Sampling Plan

Veterinary Drug or Drug Class	*Compound Priority Rating (P)*	*Production Class*	*Relative Percent Consumption in 2009(C)*	*Sampling Priority Score (P * C)*	*Unadjusted Number of Samples*
Beta-Agonists	2.75	Steers	12.660	34.82	300
Antibiotics (7-Plate Bioassay)	16.0	Beef cows	1.865	29.84	300
Avermectins	14	Beef cows	1.825	26.11	300
Antibiotics (7-Plate Bioassay)	16.0	Dairy cows	1.582	25.31	300
Arsenicals	6.75	Egg products	3.597	24.28	300
Sulfonamides	13.0	Beef cows	1.865	24.25	300
Avermectins	14	Dairy cows	1.582	22.15	300
Sulfonamides	13.0	Dairy cows	1.582	20.57	300
Beta-Agonists	2.75	Heifers	6.988	19.22	300
Flunixin	10	Beef cows	1.865	18.65	300
Flunixin	10	Dairy cows	1.582	15.82	300
Antibiotics (7-Plate Bioassay)	16.0	Sows	0.941	15.06	300
Sulfonamides	13.0	Sows	0.941	12.23	300
Antibiotics (7-Plate Bioassay)	16.0	Mature chickens	0.730	11.68	300
Sulfonamides	13.0	Mature chickens	0.730	9.49	300
Antibiotics (7-Plate Bioassay)	16.0	Bulls	0.470	7.52	300

Table 3 *(continued)*
Veterinary Drug/Production Class Pairs, Sorted by Sampling Priority Score
2011 U.S. NRP Domestic Scheduled Sampling Plan

Veterinary Drug or Drug Class	*Compound Priority Rating (P)*	*Production Class*	*Relative Percent Consumption in 2009(C)*	*Sampling Priority Score (P * C)*	*Unadjusted Number of Samples*
Avermectins	14.0	Bulls	0.470	6.58	300
Sulfonamides	13.0	Bulls	0.470	6.11	300
Antibiotics (7-Plate Bioassay)	16.0	Ducks	0.141	2.26	300
Antibiotics (7-Plate Bioassay)	16.0	Mature sheep	0.139	2.22	300
Avermectins	14	Mature sheep	0.139	1.95	300
Antibiotics (7-Plate Bioassay)	16.0	Formula-fed veal	0.083	1.33	300
Antibiotics (7-Plate Bioassay)	16.0	Boars/stags	0.082	1.31	300
Avermectins	14.0	Formula-fed veal	0.083	1.16	300
Avermectins	14.0	Boars/stags	0.082	1.15	300
Sulfonamides	13.0	Formula-fed veal	0.083	1.01	300
Sulfonamides	13.0	Boars/stags	0.082	1.07	300
Flunixin	10.0	Formula-fed veal	0.083	0.83	300
Florfenicol	9.75	Formula-fed veal	0.083	0.81	300
Antibiotics (7-Plate Bioassay)	16.0	Roaster pigs	0.048	0.77	300
Carbadox	15.0	Roaster pigs	0.048	0.72	300
Antibiotics (7-Plate Bioassay)	16.0	Mature turkeys	0.044	0.70	300

Table 3 *(continued)*
Veterinary Drug/Production Class Pairs, Sorted by Sampling Priority Score
2011 U.S. NRP Domestic Scheduled Sampling Plan

Veterinary Drug or Drug Class	*Compound Priority Rating (P)*	*Production Class*	*Relative Percent Consumption in 2009(C)*	*Sampling Priority Score (P * C)*	*Unadjusted Number of Samples*
Sulfonamides	13.0	Roaster pigs	0.048	0.62	300
Antibiotics (7-Plate Bioassay)	16.0	Bob veal	0.036	0.58	300
Antibiotics (7-Plate Bioassay)	16.0	Goats	0.030	0.48	300
Sulfonamides	13.0	Bob veal	0.036	0.47	300
Avermectin	14.0	Goats	0.030	0.42	300
Flunixin	10.0	Bob veal	0.036	0.36	300
Arsenicals	6.75	Mature turkeys	0.044	0.30	300
Beta-Agonists	2.75	Formula-fed veal	0.083	0.23	300
Antibiotics (7-Plate Bioassay)	16.0	Heavy calves	0.011	0.18	300
Avermectins	14.0	Heavy calves	0.011	0.15	300
Antibiotics (7-Plate Bioassay)	16.0	Lambs	0.009	0.14	300
Sulfonamides	13.0	Heavy calves	0.011	0.14	300
Flunixin	10.0	Heavy calves	0.011	0.11	300
Beta-Agonists	2.75	Goats	0.030	0.08	300
Antibiotics (7-Plate Bioassay)	16.0	Non- formula-fed veal	0.005	0.08	300
Avermectins	14.0	Non- formula-fed veal	0.005	0.07	300

Table 3 *(continued)*
Veterinary Drug/Production Class Pairs, Sorted by Sampling Priority Score
2011 U.S. NRP Domestic Scheduled Sampling Plan

Veterinary Drug or Drug Class	*Compound Priority Rating (P)*	*Production Class*	*Relative Percent Consumption in 2009(C)*	*Sampling Priority Score (P * C)*	*Unadjusted Number of Samples*
Sulfonamides	13.0	Non- formula-fed veal	0.005	0.07	300
Florfenicol	9.75	Non- formula-fed veal	0.005	0.05	300
Antibiotics (7-Plate Bioassay)	16.0	Geese	0.002	0.03	300
Antibiotics (7-Plate Bioassay)	16.0	Rabbits	0.001	0.02	300
Beta-Agonists	2.75	Non-formula-fed veal	0.005	0.01	300

Table 4
Number of Scheduled Samples for Veterinary Drug/Production Class Pairs
2011 U.S. NRP Domestic Scheduled Sampling

Veterinary Drug (or drug class)	*Production Class*	*Priority Score*[1]	*Number of Samples*[2]	*% Violation*[3]	*% Violation*[4]	*Unadjusted Number of Samples*[5]	*Adjustment for Violations*[6]	*Adjustment for Minor Species*[7]	*Adjustment for Lab Capacity*[8]	*Adjustment for Production Facilities*[9]	*Final*[10]
Antibiotics[11]	Beef cows	29.84	2781	0.11	N/A	300	300	300	300	300	300
Antibiotics[11]	Boars/stags	1.312	2235	0.18	N/A	300	300	300	300	300	300
Antibiotics[11]	Bob veal	0.576	2897	3.31	<1	300	300	300	300	300	300
Antibiotics[11]	Bulls	7.520	1457	0	N/A	300	300	300	300	300	300
Antibiotics[11]	Dairy cows	25.312	3969	0.63	N/A	300	300	300	300	300	300
Antibiotics[11]	Ducks	2.256	1142	0	N/A	300	300	300	300	300	300
Antibiotics[11]	Formula-fed veal	1.328	3990	0.45	N/A	300	300	45	45	45	45
Antibiotics[11]	Geese	0.032	35	0	N/A	300	300	300	300	300	300
Antibiotics[11]	Goats	0.480	1056	0.09	N/A	300	300	30	30	30	30
Antibiotics[11]	Heavy calves	0.176	1446	0.69	N/A	300	300	300	90	90	90
Antibiotics[11]	Heifers	111.808	3902	0.05	N/A	300	300	300	90	90	90
Antibiotics[11]	Lambs	0.144	2037	0.05	N/A	300	300	300	300	300	300
Antibiotics[11]	Market hogs	322.464	4122	0.15	N/A	300	300	300	300	300	300
Antibiotics[11]	Mature chickens	11.680	1560	0.06	N/A	300	300	300	300	300	300
Antibiotics[11]	Mature turkeys	0.704	995	0	N/A	300	300	300	300	300	300
Antibiotics[11]	Non-formula-fed veal	0.080	1351	2.15	>1	300	300	300	300	300	300
Antibiotics[11]	Rabbits	0.016	652	2.30	N/A	300	300	300	90	90	90
Antibiotics[11]	Roaster pigs	0.768	1521	0.33	N/A	300	300	30	30	30	30
Antibiotics[11]	Sheep	2.224	818	0	N/A	300	300	300	300	300	300
Antibiotics[11]	Sows	15.056	2731	0.48	N/A	300	300	300	300	300	300
Antibiotics[11]	Steers	202.560	2339	0.09	<1	300	300	300	300	300	300
Antibiotics[11]	Young chickens	701.360	3308	0.06	N/A	300	300	300	230	230	230
Antibiotics[11]	Young turkeys	104.224	2970	0	N/A	300	300	300	300	300	300
Totals						**6,900**					**5,405**
Arsenicals	Egg products	24.279	1434	0		300	300	300	300	300	300
Arsenicals	Market hogs	136.039	2119	0		300	300	300	300	300	300
Arsenicals	Mature turkeys	0.297	617	0		300	300	300	300	300	300
Arsenicals	Young chickens	295.886	6110	0.07		300	300	300	300	300	300
Arsenicals	Young turkeys	43.969	2265	0.04		300	300	300	300	300	300
Totals						**1,500**					**1,500**
Avermectins	Beef cows	26.11	1765	0.06	N/A	300	300	300	300	300	300
Avermectins	Boars/stags	1.148	662	0.15	N/A	300	300	300	300	300	300
Avermectins	Bulls	6.58	2747	0.33	<1	300	300	300	230	230	230
Avermectins	Dairy cows	22.148	1305	0	N/A	300	300	300	300	300	300

Table 4 *(continued)*
Number of Scheduled Samples for Veterinary Drug/Production Class Pairs
2011 U.S. NRP Domestic Scheduled Sampling

Veterinary Drug (or drug class)	*Production Class*	*Priority Score*[1]	*Number of Samples*[2]	*% Violation*[3]	*% Violation*[4]	*Unadjusted Number of Samples*[5]	*Adjustment for Violations*[6]	*Adjustment for Minor Species*[7]	*Adjustment for Lab Capacity*[8]	*Adjustment for Production Facilities*[9]	*Final*[10]
Avermectins	Formula fed veal	1.162	1050	0	N/A	300	300	300	300	300	300
Avermectins	Goats	0.420	2525	1.90	>1	300	300	300	230	230	230
Avermectins	Heavy calves	0.154	1678	0.48	N/A	300	300	300	90	90	90
Avermectins	Mature sheep	1.946	1216	0.33	N/A	300	300	300	300	300	300
Avermectins	Non-formula fed veal	0.07	1122	0.45	N/A	300	300	300	90	90	90
Avermectins	Steers	177.24	3632	0.06	N/A	300	300	300	300	300	300
Totals						**3,000**					**2,440**
ß-Agonists	Formula fed veal	0.228	1194	0	N/A	300	300	300	230	230	230
ß-Agonists	Goats	0.082	270	0	N/A	300	300	300	90	90	90
ß-Agonists	Heifers	19.217	603	0	N/A	300	300	300	300	300	300
ß-Agonists	Market hogs	55.423	1820	0	N/A	300	300	300	300	300	300
ß-Agonists	Non-formula fed veal	0.0137	1026	0.1	N/A	300	300	300	90	90	90
ß-Agonists	Steers	34.815	2444	0	N/A	300	300	300	300	300	300
Totals						**1,800**					**1,310**
Carbadox	Market hogs	302.31	1042	0.10	0	300	300	300	300	300	300
Carbadox	Roaster pigs	0.72	1120	0.71	>1	300	300	300	230	230	230
Totals						**600**					**530**
Chloramphenicol	Mature chickens	N/A	820	0	N/A	300	300	300	300	300	300
Chloramphenicol	Mature turkeys	N/A	800	0	N/A	300	300	300	300	300	300
Chloramphenicol	Youing chickens	N/A	1113	0	N/A	300	300	300	300	300	300
Chloramphenicol	Young turkeys	N/A	813	0	N/A	300	300	300	300	300	300
Totals						**1,200**					**1,200**
Florfenicol	Formula fed veal	0.809	517	0.19	N/A	300	300	300	300	300	300
Florfenicol	Non formula fed veal	0.048	619	1.78	N/A	300	300	300	90	90	90
Florfenicol	Steers	123.435	0	0	N/A	300	300	300	300	300	300
Totals						**900**					**690**
Flunixin	Beef cows	18.650	522	0	N/A	300	300	300	300	300	300
Flunixin	Bob veal	0.360	85	0	N/A	300	300	300	300	300	300
Flunixin	Dairy cows	15.82	1498	0.93	N/A	300	300	300	300	300	300
Flunixin	Formula fed veal	0.830	0	0	N/A	300	300	300	300	300	300
Flunixin	Heavy calves	0.110	346	0	N/A	300	300	300	90	90	90

Table 4 *(continued)*
Number of Scheduled Samples for Veterinary Drug/Production Class Pairs
2011 U.S. NRP Domestic Scheduled Sampling

Veterinary Drug (or drug class)	*Production Class*	*Priority Score*[1]	*Number of Samples*[2]	*% Violation*[3]	*% Violation*[4]	*Unadjusted Number of Samples*[5]	*Adjustment for Violations*[6]	*Adjustment for Minor Species*[7]	*Adjustment for Lab Capacity*[8]	*Adjustment for Production Facilities*[9]	*Final*[10]
Totals						**1,500**					**1,290**
Nitrofurans	Dairy cows	N/A	989	0.30	<1	300	300	300	230	230	230
Nitrofurans	Market hogs	N/A	826	0	N/A	300	300	300	300	300	300
Nitrofurans	Roaster pigs	N/A	328	0	N/A	300	300	300	300	300	300
Totals						**900**					**830**
Nitroimidazoles	Young turkeys	N/A	905	0	N/A	300	300	300	300	300	300
Totals						**300**					**300**
Sulfonamides	Beef cows	24.245	2611	0.15	<1	300	300	300	300	300	300
Sulfonamides	Bob veal	0.468	2895	0.62	N/A	300	300	300	300	300	300
Sulfonamides	Boars/stags	1.066	1483	0.13	N/A	300	300	300	300	300	300
Sulfonamides	Bulls	6.11	2624	0.11	<1	300	300	300	230	230	230
Sulfonamides	Dairy cows	20.566	2532	0.39	N/A	300	300	300	300	300	300
Sulfonamides	Egg products	46.761	1589	0	N/A	300	300	300	300	300	300
Sulfonamides	Formula-fed veal	1.092	1895	0.26	<1	300	300	300	300	300	300
Sulfonamides	Heavy calves	0.143	1888	0.37	>1	300	300	300	90	90	90
Sulfonamides	Heifers	90.844	1931	0.05	N/A	300	300	300	300	300	300
Sulfonamides	Market hogs	262.002	3664	0.60	<1	300	300	300	300	300	300
Sulfonamides	Mature chickens	9.49	1355	0	N/A	300	300	300	300	300	300
Sulfonamides	Non-formula-fed veal	0.065	1483	0.47	N/A	300	300	300	90	90	90
Sulfonamides	Roaster pigs	0.624	1596	1.32	>1	300	300	300	230	230	230
Sulfonamides	Sows	12.223	1769	0.11	N/A	300	300	300	300	300	300
Sulfonamides	Steers	164.58	3255	0.15	N/A	300	300	300	300	300	300
Totals						**4,500**					**3,940**

[1] For an explanation of this score, see Table 3.
[2] Number of Samples (2000-2009) analyzed by the FSIS Scheduled Sampling Plan.
[3] The percent of samples with residue concentrations exceeding the tolerance or action level (or, for a drug whose use was not permitted in the production class in which it was detected, the percent of samples with any detectable residue), for the 10- year period, 2000-2009.

Table 4 *(continued)*
Number of Scheduled Samples for Veterinary Drug/Production Class Pairs
2011 U.S. NRP Domestic Scheduled Sampling

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[4] The percent of samples with residue concentrations exceeding the tolerance or action level (or, for a drug whose use was not permitted in the production class in which it was detected, the percent of samples with any detectable residue) for CY 2009 based on the guideline that one violation within 300 samples represents a violation rate equal or greater than 1%, see Statistical Table in Appendix III. * Incomplete set of data, less than 230 samples were collected and analyzed.
[5] The number obtained from the last column of Table 4.
[6] If the violation rate for a compound-production class pair was determined to be 0% for the 3- year period (2007-2009), it was rotated out of the program and no samples were scheduled. Note that, SAT can, based on new intelligence or professional judgment, rotate a compound-production class pair back into the FSIS scheduled sampling program at any time.
[7] The following minor species have been rotated out of the FSIS scheduled sampling plan: bison, squab, and ratites.
[8] Change is based on the analytical capabilities of the FSIS Laboratories.
[9] For this adjustment, FSIS considered the total number of production facilities (USDA Inspected Establishments for 2005) for each production class. If the total number of production facilities for a production class was found to be low relative to other production classes, the total number of scheduled samples was reduced for that production class. The number of samples selected for the reduction is based on FSIS professional judgment. If the number of facilities is less than 100, the number of scheduled samples was adjusted down by one level (if 300 were assigned initially, decrease to 230 samples).
[10] Final numbers were obtained following an assessment of laboratory capacity, production volume, and violation rate data.
[11] Antibiotics in the 7-plate Bioassay

Design of the Import Reinspection Sampling Plan for Veterinary Drugs

I. Selecting and Ranking Candidate Compounds

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 using the same ranking scores as the domestic scheduled sampling plan. If FSIS believes that a compound is being misused in a foreign country, then the compound/country pair will be added to the IRSP.

II. Prioritizing Candidate Veterinary Drugs

FSIS selects compound classes for sampling from the list of ranked veterinary drugs, based on the relative public health concern. FSIS and SAT focused on compounds and compound classes that are a potential public health concern for inclusion in the 2011 U.S. NRP.

After identifying high-priority compounds and compound classes, FSIS applied other practical considerations to determine the compounds for sampling. The principal considerations include 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 are included in the 2011 scheduled sampling plan.

- Antibiotics: (7-plate bioassay[1])
  Tetracyclines: tetracycline, oxytetracycline, chlortetracycline (HPLC for identification, quantitation by bioassay). Aminoglycosides: spectinomycin, hygromycin, streptomycin, dihydrostreptomycin, amikacin, kanamycin, apramycin, gentamicin, neomycin, tobramycin, paromomycin (LC/MS/MS for confirmation, quantitation of streptomycin, dihydrostreptomycin, gentamicin, and neomycin by bioassay).
  Macrolides: Lincomycin, pirlymycin, clindamycin, tilmicosin, erythromycin, tulathromycin, and tylosin are confirmed by LC/MS/MS. Tilmicosin is also quantitated by HPLC. Erythromycin and tylosin are quantitated by the bioassay. 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). HPLC quantitative analysis for ceftiofur. Fluoroquinolones: ciprofloxacin, norfloxacin, danofloxacin, enrofloxacin, sarafloxacin, difloxacin, desethylene diprofloxacin, desmethyl danofloxacin (LC/MS/MS for confirmation).

Other Veterinary drugs:

- Arsenicals (detected as elemental arsenic)
- Avermectins (classification: anthelmintics; compounds in FSIS MRM: doramectin, ivermectin, and moxidectin)
- β-Agonists (ractopamine,cimaterol, zilpaterol and salbutamol; growth promotants)
- Florfenicol (classification: antibiotic; chloramphenicol derivative)
- Flunixin (classification: NSAID)
- Sulfonamides (classification: antimicrobials, and some are coccidiostats; compounds in FSIS MRM:

[1] FSIS quantifies most antibiotics using a 7-plate bioassay that measures microbial inhibition. Scientists use the pattern of inhibition (i.e., the combination of plates showing inhibition) to identify the antibiotic. Some antibiotics share the same pattern of inhibition. For these antibiotics, it is necessary to undertake follow-up testing (e.g., HPLC or mass spectrometry, when available) to establish their identities.

sulfapyridine, sulfadiazine, sulfathiazole, sulfamerazine, sulfamethazine, sulfachloropyridazine, sulfadoxine, sulfamethoxypyridazine, sulfaquinoxaline, sulfadimethoxine, sulfisoxazole, sulfamethoxazole, sulfaethoxypyridazine, sulfaphenazole, and sulfatroxazole)

Veterinary drugs prohibited from extra-label use under AMDUCA
AMDUCA veterinary drugs prohibited from extra-label use by 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 automatically 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.

- **Chloramphenicol** (classification: antibiotic; AMDUCA- prohibited)
- **Clenbuterol** (classification: β-Agonists; AMDUCA- prohibited)
- **Nitroimidazoles** (classification: antiprotozoals; AMDUCA- prohibited in food animals; compounds in FSIS MRM: dimetridazole, ipronidazole)

III. Identifying Compound/Production Class (C/PC) Pairs

FDA SAT participants identified the veterinary drugs and veterinary drug classes of concern scheduled for inclusion in the 2011 U.S. NRP.

IV. Allocation of Sampling Resources

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 ten 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.[2]

Animal product classes

Table 7 lists the estimated amount and percentage of all the product classes imported into the United States. The data for the product classes were obtained from the Automated Import Information System. The percent of each product class imported annually is calculated using Equation 7:

Equation 7

$$\%\ \text{Product Class Imported } (P_C) = \frac{\text{Amount Product Class Imported}}{\text{All Meat, Poultry, Egg Imports}} \times 100$$

[2] This paragraph explains FSIS policies on imported egg product testing; however, no imported egg products were tested in 2011.

Equation 8 calculates the relative sampling priority by multiplying the percent product class imported (P_C) by the veterinary drug scores obtained in Phase I.

Equation 8

$$\text{Relative Sampling Priority (RSP)} = (P_C) \times \text{Veterinary Drug Score}$$

Based on the scores, one of the following sampling options is chosen: (1) high regulatory concern (300 samples/year), (2) moderate regulatory concern (230 samples/year), and (3) low regulatory concern (90 samples/year). These data are presented in Table 8.

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 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; and
(h) processed varied combination products from Canada.

Allocation of samples among exporting countries

The manner in which samples are allocated among the exporting countries depends on whether the relative imported amount of the product class (P_C) is more or less than one percent of all imports.

Allocation of samples in product classes where P_C is less than one percent

If a product class represents less than one percent (by weight) of total combined U.S. imports of meat, poultry, and egg products, then the total number of samples analyzed for any compound or compound class is eight times the number of countries from which that product is imported. For example, if fresh veal is imported from only three countries and the amount imported is 0.50 % relative to the total U.S. import, 24 samples will be taken for each analysis, eight samples for each country (3 countries × 8 samples).

Allocation of samples in product classes where P_C is greater than one percent

For major product classes, the number of samples is allocated to each country depending upon the relative amount of product imported from that country. Table 6 lists the amount of product imported from each country. The percent of a product class imported from a country is calculated using Equation 9 and listed in Table 7.

Equation 9

$$\text{Percent Product Class Imported per Country } (P_{C/C}) = \frac{\text{Amount of Product Class from Country}}{\text{Total Amount of Product Class}} \times 100$$

Equation 10 calculates the number of samples taken at the port-of-entry based on the relative amount of product class imported per country. The results are listed in the column labeled "Unadjusted Samples" in Tables 9 to 25.

Equation 10

$$\text{Unadjusted Number of Samples per Country } (U_{C/S}) = \text{Total Number of Samples} \times (P_{C/C})/100$$

A country with fewer than eight samples is assigned eight samples, indicated in the column labeled "1st Adjustment" in Tables 9 to 25. If this causes the total number of samples for a product class to exceed the unadjusted number of samples, a second adjustment is performed according to Equation 11.

Equation 11

$$\text{Number of Samples after 2nd Adjustment} = (U_{C/S}) - \frac{(N \times P_{C/C})}{(P_{T/C})}$$

where,

N = (total number of samples after 1st adjustment) - (total number of samples initially allocated)
$P_{T/C}$ = total percentage of product class from countries with more than eight samples after 1st adjustment
$P_{C/C}$ = percent product class imported per country
$U_{C/S}$ = unadjusted number of samples

The final number of products sampled for each country is indicated in Tables 9 to 25 in the column labeled "Final." After the allocation of samples among different countries, the final number of samples for each compound/product class pair is determined and is listed in Table 8. The numbers in the table may vary slightly because of the rounding upwards or downwards of the samples.

Notes:

The candidate veterinary drugs of concern for the IRSP are the same as those listed in the domestic sampling plan.

Import reinspection sampling for pesticides is discussed in the section *Design of the Import Reinspection Plan for Pesticides*.

Table 5
Estimated Annual Amount of Product Imported
2011 U.S. NRP Import Reinspection Sampling Plan

Product	Amount imported (in pounds)	% of all imported product
Beef, fresh	1,820,408,942	54.282%
Beef, processed	199,494,621	5.949%
Veal, fresh	36,694,262	1.094%
Veal, processed	73,315	0.002%
Horse, fresh	1,248,224	0.037%
Pork, fresh	739,291,412	22.045%
Pork, processed	150,533,390	4.489%
Lamb/Mutton, fresh	155,915,815	4.649%
Lamb/Mutton, processed	420,796	0.013%
Goat, fresh	27,652,902	0.825%
Chicken, fresh	108,309,679	3.230%
Chicken, processed	72,305,578	2.156%
Turkey, fresh	19,173,462	0.572%
Turkey, processed	3,955,523	0.118%
Ratite, fresh	134,948	0.004%
Other Fowl, fresh	2,869,986	0.086%
Other Fowl, processed	398,636	0.012%
Varied combination, fresh	25,526	0.001%
Varied combination, processed	14,708,828	0.439%
Total	3,353,615,845	100.000%

Table 6
Estimated Annual Amount (in pounds) of Product Imported per Country
2011 U.S. NRP Import Reinspection Sampling Plan

Production Class	Argentina	Australia	Austria	Brazil	Canada	Chile	Costa Rica
Beef, fresh	-	606,734,393	-	-	645,345,667	1,511,375	17,290,377
Beef, processed	27,014,226	2,108,179	-	113,026,919	45,951,148	-	43
Veal, fresh	-	3,398,494	-	-	18,453,935	-	-
Veal, processed	-	17	-	-	73,283	-	-
Horse, fresh	-	-	-	-	1,248,224	-	-
Pork, fresh	-	75,553	-	-	635,879,783	2,775,055	-
Pork, processed	-	-	128,097	-	112,317,247	-	-
Lamb/Mutton, fresh	-	109,813,373	-	-	238,852	-	-
Lamb/Mutton, processed	-	164,756	-	-	148,692	-	-
Goat, fresh	-	27,103,114	-	-	-	-	-
Chicken, fresh	-	-	-	-	92,869,505	15,357,450	-
Chicken, processed	-	-	-	-	60,455,343	-	-
Turkey, fresh	-	-	-	-	17,285,880	1,887,582	-
Turkey, processed	-	-	-	-	915,066	-	-
Ratite, fresh	-	129,712	-	-	-	-	-
Other Fowl, fresh	-	-	-	-	2,782,791	-	-
Other Fowl, processed	-	-	-	-	350,275	-	-
Varied comb., fresh	-	-	-	-	25,526	-	-
Varied comb., processed	-	7,916	-	-	10,553,699	-	-
Total lbs/country	27,014,226	749,535,507	128,097	113,026,919	1,644,894,916	21,531,462	17,290,420

Continued on next page.

Table 6 *(continued)*
Estimated Annual Amount (in pounds) of Product Imported per Country
2011 U.S. NRP Import Reinspection Sampling Plan

Production Class	Croatia	Denmark	Finland	France	Germany	Honduras	Hungary
Beef, fresh	-	-	-	-	-	3,548,961	-
Beef, processed	-	-	-	-	-	-	-
Veal, fresh	-	-	-	-	-	-	-
Veal, processed	-	-	-	-	-	-	-
Horse, fresh	-	-	-	-	-	-	-
Pork, fresh	-	78,562,208	2,010,326	-	-	-	-
Pork, processed	244,415	6,864,173	-	22,626	779,311	-	342,982
Lamb/Mutton, fresh	-	-	-	-	-	-	-
Lamb/Mutton, processed	-	-	-	-	-	-	-
Goat, fresh	-	-	-	-	-	-	-
Chicken, fresh	-	-	-	-	-	-	-
Chicken, processed	-	-	-	-	-	-	-
Turkey, fresh	-	-	-	-	-	-	-
Turkey, processed	-	-	-	-	-	-	-
Ratite, fresh	-	-	-	-	-	-	-
Other Fowl, fresh	-	-	-	87,195	-	-	-
Other Fowl, processed	-	-	-	48,361	-	-	-
Varied comb., fresh	-	-	-	-	-	-	-
Varied comb., processed	-	-	-	669	-	-	-
Total lbs/country	244,415	85,426,381	2,010,326	158,851	779,311	3,548,961	342,982

Continued on next page.

Table 6 *(continued)*
Estimated Annual Amount (in pounds) of Product Imported per Country
2011 U.S. NRP Import Reinspection Sampling Plan

Production Class	Iceland	Ireland	Israel	Italy	Japan	Mexico	Netherlands
Beef, fresh	-	-	-	-	156,378	53,475,019	-
Beef, processed	-	-	-	-	-	2,713,027	-
Veal, fresh	-	-	-	-	-	-	-
Veal, processed	-	-	-	-	-	-	-
Horse, fresh	-	-	-	-	-	-	-
Pork, fresh	-	3,177,196	-	-	-	5,482,280	4,274,814
Pork, processed	-	-	-	8,373,043	-	1,992,137	303,563
Lamb/Mutton, fresh	155,357	-	-	-	-	41,585	-
Lamb/Mutton, processed	-	-	-	-	-	-	-
Goat, fresh	-	-	-	-	-	108,012	-
Chicken, fresh	-	-	-	-	-	82,724	-
Chicken, processed	-	-	914,235	-	-	10,936,000	-
Turkey, fresh	-	-	-	-	-	-	-
Turkey, processed	-	-	1,156,096	-	-	1,884,361	-
Ratite, fresh	-	-	-	-	-	-	-
Other Fowl, fresh	-	-	-	-	-	-	-
Other Fowl, processed	-	-	-	-	-	-	-
Varied comb., fresh	-	-	-	-	-	-	-
Varied comb., processed	-	-	-	-	-	4,146,544	-
Total lbs/country	155,357	3,177,196	2,070,331	8,373,043	156,378	80,861,689	7,545,707

Continued on next page.

Table 6 *(continued)*
Estimated Annual Amount (in pounds) of Product Imported per Country
2011 U.S. NRP Import Reinspection Sampling Plan

Production Class	New Zealand	Nicaragua	N. Ireland	Poland	Spain	Sweden	UK	Uruguay
Beef, fresh	366,766,023	67,797,845	-	-	-	-	-	57,782,904
Beef, processed	5,740,243	-	-	-	-	-	-	2,940,836
Veal, fresh	14,841,833	-	-	-	-	-	-	-
Veal, processed	15	-	-	-	-	-	-	-
Horse, fresh	-	-	-	-	-	-	-	-
Pork, fresh	-	-	1,998,192	1,908,463	39,461	882,126	2,225,955	-
Pork, processed	-	-	-	17,673,902	1,491,894	-	-	-
Lamb/Mutton, fresh	45,666,648	-	-	-	-	-	-	-
Lamb/Mutton, processed	107,348	-	-	-	-	-	-	-
Goat, fresh	441,776	-	-	-	-	-	-	-
Chicken, fresh	-	-	-	-	-	-	-	-
Chicken, processed	-	-	-	-	-	-	-	-
Turkey, fresh	-	-	-	-	-	-	-	-
Turkey, processed	-	-	-	-	-	-	-	-
Ratite, fresh	5,236	-	-	-	-	-	-	-
Other Fowl, fresh	-	-	-	-	-	-	-	-
Other Fowl, processed	-	-	-	-	-	-	-	-
Varied comb., fresh	-	-	-	-	-	-	-	-
Varied comb., processed	-	-	-	-	-	-	-	-
Total lbs/country	433,569,122	67,797,845	1,998,192	19,582,365	1,531,355	882,126	2,225,955	60,723,740

Table 7
Estimated Relative Annual Amount (%) of Product Imported per Country
2011 U.S. NRP Import Reinspection Sampling Plan

Percentages add up to 100% across each row.

Production Class	Argentina	Australia	Austria	Brazil	Canada	Chile	Costa Rica
Beef, fresh	-	33.3	-	-	35.5	0.1	0.9
Beef, processed	13.5	1.1	-	56.7	23.0	-	<0.1
Veal, fresh	-	9.3	-	-	50.3	-	-
Veal, processed	-	<0.1	-	-	100.0	-	-
Horse, fresh	-	-	-	-	100.0	-	-
Pork, fresh	-	<0.1	-	-	86.0	0.4	-
Pork, processed	-	-	0.1	-	74.6	-	-
Lamb/Mutton, fresh	-	70.4	-	-	0.2	-	-
Lamb/Mutton, processed	-	39.2	-	-	35.3	-	-
Goat, fresh	-	98.0	-	-	-	-	-
Chicken, fresh	-	-	-	-	85.7	14.2	-
Chicken, processed	-	-	-	-	83.6	-	-
Turkey, fresh	-	-	-	-	90.2	9.8	-
Turkey, processed	-	-	-	-	23.1	-	-
Ratite, fresh	-	96.1	-	-	-	-	-
Other Fowl, fresh	-	-	-	-	97.0	-	-
Other Fowl, processed	-	-	-	-	87.9	-	-
Varied comb., fresh	-	-	-	-	100.0	-	-
Varied comb., processed	-	0.1	-	-	71.8	-	-

Continued on next page.

Table 7 *(continued)*
Estimated Relative Annual Amount (%) of Product Imported per Country
2011 U.S. NRP Import Reinspection Sampling Plan

Percentages add up to 100% across each row.

Production Class	Croatia	Denmark	Finland	France	Germany	Honduras	Hungary
Beef, fresh	-	-	-	-	-	0.2	-
Beef, processed	-	-	-	-	-	-	-
Veal, fresh	-	-	-	-	-	-	-
Veal, processed	-	-	-	-	-	-	-
Horse, fresh	-	-	-	-	-	-	-
Pork, fresh	-	10.6	0.3	-	-	-	-
Pork, processed	0.2	4.6	-	<0.1	0.5	-	0.2
Lamb/Mutton, fresh	-	-	-	-	-	-	-
Lamb/Mutton, processed	-	-	-	-	-	-	-
Goat, fresh	-	-	-	-	-	-	-
Chicken, fresh	-	-	-	-	-	-	-
Chicken, processed	-	-	-	-	-	-	-
Turkey, fresh	-	-	-	-	-	-	-
Turkey, processed	-	-	-	-	-	-	-
Ratite, fresh	-	-	-	-	-	-	-
Other Fowl, fresh	-	-	-	3.0	-	-	-
Other Fowl, processed	-	-	-	12.1	-	-	-
Varied comb., fresh	-	-	-	-	-	-	-
Varied comb., processed	-	-	-	<0.1	-	-	-

Continued on next page.

Table 7 *(continued)*
Estimated Relative Annual Amount (%) of Product Imported per Country
2011 U.S. NRP Import Reinspection Sampling Plan

Percentages add up to 100% across each row.

Production Class	Iceland	Ireland	Israel	Italy	Japan	Mexico	Netherlands
Beef, fresh	-	-	-	-	<0.1	2.9	-
Beef, processed	-	-	-	-	-	1.4	-
Veal, fresh	-	-	-	-	-	-	-
Veal, processed	-	-	-	-	-	-	-
Horse, fresh	-	-	-	-	-	-	-
Pork, fresh	-	0.4	-	-	-	0.7	0.6
Pork, processed	-	-	-	5.6	-	1.3	0.2
Lamb/Mutton, fresh	0.1	-	-	-	-	<0.1	-
Lamb/Mutton, processed	-	-	-	-	-	-	-
Goat, fresh	-	-	-	-	-	0.4	-
Chicken, fresh	-	-	-	-	-	0.1	-
Chicken, processed	-	-	1.3	-	-	15.1	-
Turkey, fresh	-	-	-	-	-	-	-
Turkey, processed	-	-	29.2	-	-	47.6	-
Ratite, fresh	-	-	-	-	-	-	-
Other Fowl, fresh	-	-	-	-	-	-	-
Other Fowl, processed	-	-	-	-	-	-	-
Varied comb., fresh	-	-	-	-	-	-	-
Varied comb., processed	-	-	-	-	-	28.2	-

Continued on next page.

Table 7 *(continued)*
Estimated Relative Annual Amount (%) of Product Imported per Country
2011 U.S. NRP Import Reinspection Sampling Plan

Percentages add up to 100% across each row.

Production Class	New Zealand	Nicaragua	N. Ireland	Poland	Spain	Sweden	UK	Uruguay
Beef, fresh	20.1	3.7	-	-	-	-	-	3.2
Beef, processed	2.9	-	-	-	-	-	-	1.5
Veal, fresh	40.4	-	-	-	-	-	-	-
Veal, processed	<0.1	-	-	-	-	-	-	-
Horse, fresh	-	-	-	-	-	-	-	-
Pork, fresh	-	-	0.3	0.3	<0.1	0.1	0.3	-
Pork, processed	-	-	-	11.7	1.0	-	-	-
Lamb/Mutton, fresh	29.3	-	-	-	-	-	-	-
Lamb/Mutton, processed	25.5	-	-	-	-	-	-	-
Goat, fresh	1.6	-	-	-	-	-	-	-
Chicken, fresh	-	-	-	-	-	-	-	-
Chicken, processed	-	-	-	-	-	-	-	-
Turkey, fresh	-	-	-	-	-	-	-	-
Turkey, processed	-	-	-	-	-	-	-	-
Ratite, fresh	3.9	-	-	-	-	-	-	-
Other Fowl, fresh	-	-	-	-	-	-	-	-
Other Fowl, processed	-	-	-	-	-	-	-	-
Varied comb., fresh	-	-	-	-	-	-	-	-
Varied comb., processed	-	-	-	-	-	-	-	-

Table 8
Number of Veterinary Drug Samples per Production Class
2011 U.S. NRP Import Reinspection Sampling Plan

No. of Countries	Product Class	% of Imports	Drug	Score	RSP*	Samples Allocated	Samples Final
10	Beef, fresh	54.3%	Antibiotics	16	869	300	300
13	Pork, fresh	22.0%			353	230	230
3	Chicken, fresh	3.2%			52	90	90
3	Veal, fresh	1.1%			18	90	90
2	Turkey, fresh	0.6%			9	16	16
2	Other fowl, fresh	0.1%			1	16	16
1	Horse, fresh	<0.1%			1	8	8
1	Varied comb., fresh	<0.1%			0	8	8
13	Pork, fresh	22.0%	Arsenic	6.8	150	90	104
3	Chicken, fresh	3.2%			22	90	90
3	Chicken, processed	2.2%			15	90	8
2	Turkey, fresh	0.6%			4	16	16
3	Turkey, processed	0.1%			1	16	16
10	Beef, fresh	54.3%	Avermectins	14	760	300	300
8	Beef, processed	5.9%			83	90	63
5	Lamb/Mutton, fresh	4.6%			65	90	90
3	Veal, fresh	1.1%			15	90	90
3	Goat, fresh	0.8%			12	24	24
3	Lamb/Mutton, processed	<0.1%			0	0	0
13	Pork, fresh	22.0%	B-agonist	2.8	62	90	104
3	Veal, fresh	1.1%			3	90	90
10	Beef, fresh	54.3%	Chloramphenicol	0	0	90	91
3	Chicken, fresh	3.2%			0	90	90
2	Turkey, fresh	0.6%			0	16	16
3	Veal, fresh	1.1%			0	90	89
10	Beef, fresh	54.3%	Florfenicol	9.8	532	90	90
10	Beef, fresh	54.3%	Flunixin	10	543	90	90
3	Chicken, fresh	3.2%	Nitroimidazole	0	0	90	90
10	Beef, fresh	54.3%	Sulfonamides	13	706	300	300
13	Pork, fresh	22.0%			287	230	230
8	Beef, processed	5.9%			77	90	63
12	Pork, processed	4.5%			58	90	48
3	Veal, fresh	1.1%			14	90	90
2	Turkey, fresh	0.6%			7	16	16
4	Varied comb., processed	0.4%			6	24	24
3	Turkey, processed	0.1%			2	16	16
3	Veal, processed	<0.1%			0	24	0
1	Horse, fresh	<0.1%			0	8	8
1	Varied comb., fresh	<0.1%			0	8	8
						Total:	**3,112**

*RSP = Relative Sample Priority

Tables 9-25: Allocation of Veterinary Drug Samples to Importing Countries
2011 U.S. NRP, Import Reinspection Sampling Plan

Table 9: Beef, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Antibiotics	% Product per Country (Pc/c)	Unadjusted Samples 300*(Pc/c)/100	Number of Samples	
			1st Adjustment	Final
Australia	33.3	100	100	90
Canada	35.5	106	106	96
Chile	0.1	0	8	8
Costa Rica	1.0	3	8	8
Honduras	0.2	1	8	8
Japan	<0.1	0	8	8
Mexico	2.9	9	9	8
New Zealand	20.2	60	60	55
Nicaragua	3.7	11	11	10
Uruguay	3.2	10	10	9
Total	**100.0**	**300**	**328**	**300**
Avermectins	**% Product per Country (Pc/c)**	**Unadjusted Samples 300*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Australia	33.3	100	100	90
Canada	35.5	106	106	96
Chile	0.1	0	8	8
Costa Rica	1.0	3	8	8
Honduras	0.2	1	8	8
Japan	<0.1	0	8	8
Mexico	2.9	9	9	8
New Zealand	20.2	60	60	55
Nicaragua	3.7	11	11	10
Uruguay	3.2	10	10	9
Total	**100.0**	**300**	**328**	**300**
Chloramphenicol	**% Product per Country (Pc/c)**	**Unadjusted Samples 90*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Australia	33.3	30	30	13
Canada	35.5	32	32	14
Chile	0.1	0	8	8
Costa Rica	1.0	1	8	8
Honduras	0.2	0	8	8
Japan	<0.1	0	8	8
Mexico	2.9	3	8	8
New Zealand	20.2	18	18	8
Nicaragua	3.7	3	8	8
Uruguay	3.2	3	8	8
Total	**100**	**90**	**136**	**91**

This table is continued on the next page.

Table 9: Beef, Fresh *(continued)*
2011 U.S. NRP Import Reinspection Sampling Plan

Florfenicol	**% Product per Country (Pc/c)**	**Unadjusted Samples 90*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Australia	33.3	30	30	13
Canada	35.5	32	32	14
Chile	0.1	0	8	8
Costa Rica	1.0	1	8	8
Honduras	0.2	0	8	8
Japan	<0.1	0	8	7
Mexico	2.9	3	8	8
New Zealand	20.2	18	18	8
Nicaragua	3.7	3	8	8
Uruguay	3.2	3	8	8
Total	**100**	**90**	**136**	**90**
Flunixin	**% Product per Country (Pc/c)**	**Unadjusted Samples 90*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Australia	33.3	30	30	13
Canada	35.5	32	32	14
Chile	0.1	0	8	8
Costa Rica	1.0	1	8	8
Honduras	0.2	0	8	8
Japan	<0.1	0	8	7
Mexico	2.9	3	8	8
New Zealand	20.2	18	18	8
Nicaragua	3.7	3	8	8
Uruguay	3.2	3	8	8
Total	**100.0**	**90**	**136**	**90**
Sulfonamides	**% Product per Country (Pc/c)**	**Unadjusted Samples 300*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Australia	33.3	100	100	90
Canada	35.5	106	106	96
Chile	0.1	0	8	8
Costa Rica	1.0	3	8	8
Honduras	0.2	1	8	8
Japan	<0.1	0	8	8
Mexico	2.9	9	9	8
New Zealand	20.2	60	60	55
Nicaragua	3.7	11	11	10
Uruguay	3.2	10	10	9
Total	**100.0**	**300**	**328**	**300**

Table 10: Beef, Processed
2011 U.S. NRP Import Reinspection Sampling Plan

Avermectins	% Product per Country (Pc/c)	Unadjusted Samples 90*(Pc/c)/100	Number of Samples	
			1st Adjustment	Final
Argentina	13.5	12	12	12
Australia*	1.1	1	0	0
Brazil	56.7	51	51	51
Canada*	23.0	21	0	0
Costa Rica*	<0.1	0	0	0
Mexico*	1.4	1	0	0
New Zealand*	2.9	3	0	0
Uruguay*	1.5	1	0	0
Total	**100.0**	**90**	**63**	**63**
Sulfonamides	**% Product per Country (Pc/c)**	**Unadjusted Samples 90*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Argentina	13.5	12	12	12
Australia*	1.1	1	0	0
Brazil	56.7	51	51	51
Canada*	23.0	21	0	0
Costa Rica*	<0.1	0	0	0
Mexico*	1.4	1	0	0
New Zealand*	2.9	3	0	0
Uruguay*	1.5	1	0	0
Total	**100.0**	**90**	**63**	**63**

*Country exports fresh beef to the United States.

Table 11: Horse, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Antibiotics	% Product per Country (Pc/c)	Number of Samples	
Canada	100.0	8	"Horse, fresh" represents less than 1% of total imports to the United States. Each country is allocated 8 samples.
Total	**100.0**	**8**	
Sulfonamides	**% Product per Country (Pc/c)**	**Number of Samples**	
Canada	100.0	8	
Total	**100.0**	**8**	

Table 12: Veal Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Antibiotics	% Product per Country (Pc/c)	Unadjusted Samples 90*(Pc/c)/100	Number of Samples	
			1st Adjustment	Final
Australia	9.3	8	8	8
Canada	50.3	45	45	46
New Zealand	40.5	36	36	36
Total	**100.0**	**89**	**89**	**90**
Avermectins	**% Product per Country (Pc/c)**	**Unadjusted Samples 90*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Australia	9.3	8	8	8
Canada	50.3	45	45	46
New Zealand	40.5	36	36	36
Total	**100.0**	**89**	**89**	**90**
Beta-agonists	**% Product per Country (Pc/c)**	**Unadjusted Samples 90*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Australia	9.3	8	8	8
Canada	50.3	45	45	46
New Zealand	40.5	36	36	36
Total	**100.0**	**89**	**89**	**90**
Chloramphenicol	**% Product per Country (Pc/c)**	**Unadjusted Samples 90*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Australia	9.3	8	8	8
Canada	50.3	45	45	45
New Zealand	40.5	36	36	36
Total	**100.0**	**89**	**89**	**89**
Sulfonamides	**% Product per Country (Pc/c)**	**Unadjusted Samples 90*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Australia	9.3	8	8	8
Canada	50.3	45	45	46
New Zealand	40.5	36	36	36
Total	**100.0**	**89**	**89**	**90**

Table 13: Veal, Processed
2011 U.S. NRP Import Reinspection Sampling Plan

Sulfonamides	% Product per Country (Pc/c)	Number of Samples	
Australia*	<0.1	0	All countries exporting processed veal also export fresh veal to the United States.
Canada*	100.0	0	
New Zealand*	<0.1	0	
Total	**100.0**	**0**	

*Country exports fresh veal to the United States.

Table 14: Pork, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Antibiotics	% Product per Country (Pc/c)	Unadjusted Samples 230*(Pc/c)/100	Number of Samples	
			1st Adjustment	Final
Australia	<0.1	0	8	8
Canada	86.0	198	198	126
Chile	0.4	1	8	8
Denmark	10.6	24	24	16
Finland	0.3	1	8	8
Ireland	0.4	1	8	8
Mexico	0.7	2	8	8
Netherlands	0.6	1	8	8
Northern Ireland	0.3	1	8	8
Poland	0.3	1	8	8
Spain	<0.1	0	8	8
Sweden	0.1	0	8	8
UK	0.3	1	8	8
Total	**100.0**	**231**	**310**	**230**
Arsenicals	**% Product per Country (Pc/c)**	**Unadjusted Samples 90*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Australia	<0.1	0	8	8
Canada	86.0	77	77	8
Chile	0.4	0	8	8
Denmark	10.6	10	10	8
Finland	0.3	0	8	8
Ireland	0.4	0	8	8
Mexico	0.7	1	8	8
Netherlands	0.6	1	8	8
Northern Ireland	0.3	0	8	8
Poland	0.3	0	8	8
Spain	<0.1	0	8	8
Sweden	0.1	0	8	8
UK	0.3	0	8	8
Total	**100.0**	**89**	**175**	**104**
Beta-agonists	**% Product per Country (Pc/c)**	**Unadjusted Samples 90*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Australia	<0.1	0	8	8
Canada	86.0	77	77	8
Chile	0.4	0	8	8
Denmark	10.6	10	10	8
Finland	0.3	0	8	8
Ireland	0.4	0	8	8
Mexico	0.7	1	8	8
Netherlands	0.6	1	8	8
Northern Ireland	0.3	0	8	8
Poland	0.3	0	8	8
Spain	<0.1	0	8	8
Sweden	0.1	0	8	8
UK	0.3	0	8	8
Total	**100.0**	**89**	**175**	**104**

This table is continued on the next page.

Table 14: Pork, Fresh *(continued)*
2011 U.S. NRP Import Reinspection Sampling Plan

Sulfonamides	% Product per Country (Pc/c)	Unadjusted Samples 230*(Pc/c)/100	Number of Samples	
			1st Adjustment	Final
Australia	<0.1	0	8	8
Canada	86.0	198	198	126
Chile	0.4	1	8	8
Denmark	10.6	24	24	16
Finland	0.3	1	8	8
Ireland	0.4	1	8	8
Mexico	0.7	2	8	8
Netherlands	0.6	1	8	8
Northern Ireland	0.3	1	8	8
Poland	0.3	1	8	8
Spain	<0.1	0	8	8
Sweden	0.1	0	8	8
UK	0.3	1	8	8
Total	**100.0**	**231**	**310**	**230**

Table 15: Pork, Processed
2011 U.S. NRP Import Reinspection Sampling Plan

Sulfonamides	% Product per Country (Pc/c)	Unadjusted Samples 90*(Pc/c)/100	Number of Samples	
			1st Adjustment	Final
Austria	0.1	0	8	8
Canada*	74.6	67	0	0
Croatia	0.2	0	8	8
Denmark*	4.6	4	0	0
France	<0.1	0	8	8
Germany	0.5	0	8	8
Hungary	0.2	0	8	8
Italy	5.6	5	8	8
Mexico*	1.3	1	0	0
Netherlands*	0.2	0	0	0
Poland*	11.7	11	0	0
Spain*	1.0	1	0	0
Total	**100.0**	**89**	**48**	**48**

*Country exports fresh pork to the United States.

Table 16: Lamb/Mutton, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Avermectins	% Product per Country (Pc/c)	Unadjusted Samples 90*(Pc/c)/100	Number of Samples	
			1st Adjustment	Final
Australia	70.4	63	63	47
Canada	0.2	0	8	8
Iceland	0.1	0	8	8
Mexico	<0.1	0	8	8
New Zealand	29.3	26	26	19
Total	**100.0**	**89**	**113**	**90**

Table 17: Lamb/Mutton, Processed
2011 U.S. NRP Import Reinspection Sampling Plan

Avermectins	% Product per Country (Pc/c)	Number of Samples	
Australia*	39.2	0	All countries exporting processed lamb/mutton also export fresh lamb/mutton to the United States.
Canada*	35.3	0	
New Zealand*	25.5	0	
Total	**100.0**	**0**	

*Country exports fresh lamb/mutton to the United States.

Table 18: Goat, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Avermectins	% Product per Country (Pc/c)	Number of Samples	
Australia	98.0	8	"Goat, fresh" represents less than 1% of total imports to the United States. Each country is allocated 8 samples.
Mexico	0.4	8	
New Zealand	1.6	8	
Total	**100.0**	**24**	

Table 19: Chicken, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Antibiotics	% Product per Country (Pc/c)	Unadjusted Samples 90*(Pc/c)/100	Number of Samples	
			1st Adjustment	Final
Canada	85.7	77	77	70
Chile	14.2	13	13	12
Mexico	0.1	0	8	8
Total	**100.0**	**90**	**98**	**90**
Arsenicals	**% Product per Country (Pc/c)**	**Unadjusted Samples 90*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Canada	85.7	77	77	70
Chile	14.2	13	13	12
Mexico	0.1	0	8	8
Total	**100.0**	**90**	**98**	**90**
Chloramphenicol	**% Product per Country (Pc/c)**	**Unadjusted Samples 90*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Canada	85.7	77	77	70
Chile	14.2	13	13	12
Mexico	0.1	0	8	8
Total	**100.0**	**90**	**98**	**90**
Nitroimidazole	**% Product per Country (Pc/c)**	**Unadjusted Samples 90*(Pc/c)/100**	**Number of Samples**	
			1st Adjustment	**Final**
Canada	85.7	77	77	70
Chile	14.2	13	13	12
Mexico	0.1	0	8	8
Total	**100.0**	**90**	**98**	**90**

Table 20: Chicken, Processed
2011 U.S. NRP Import Reinspection Sampling Plan

Arsenicals	% Product per Country (Pc/c)	Unadjusted Samples 90*(Pc/c)/100	Number of Samples	
			1st Adjustment	Final
Canada*	83.6	75	0	0
Israel	1.3	1	8	8
Mexico*	15.1	14	0	0
Total	**100.0**	**90**	**8**	**8**

*Country exports fresh chicken to the United States.

Table 21: Turkey, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Antibiotics	**% Product per Country (Pc/c)**	**Number of Samples**	
Canada	90.2	8	
Chile	9.8	8	
Total	**100.0**	**16**	
Arsenicals	**% Product per Country (Pc/c)**	**Number of Samples**	
Canada	90.2	8	"Turkey, fresh" represents less than 1% of total imports to the United States. Each country is allocated 8 samples.
Chile	9.8	8	
Total	**100.0**	**16**	
Chloramphenicol	**% Product per Country (Pc/c)**	**Number of Samples**	
Canada	90.2	8	
Chile	9.8	8	
Total	**100.0**	**16**	
Sulfonamides	**% Product per Country (Pc/c)**	**Number of Samples**	
Canada	90.2	8	
Chile	9.8	8	
Total	**100.0**	**16**	

Table 22: Turkey, Processed
2011 U.S. NRP Import Reinspection Sampling Plan

Arsenicals	**% Product per Country (Pc/c)**	**Number of Samples**	
Canada*	23.1	0	
Israel	29.2	8	
Mexico	47.6	8	"Turkey, processed" represents less than 1% of total imports to the United States. Each country is allocated 8 samples.
Total	**100.0**	**16**	
Sulfonamides	**% Product per Country (Pc/c)**	**Number of Samples**	
Canada*	23.1	0	
Israel	29.2	8	
Mexico	47.6	8	
Total	**100.0**	**16**	

*Country exports fresh turkey to the United States.

Table 23: Other Fowl, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Antibiotics	% Product per Country (Pc/c)	Number of Samples	"Other fowl, fresh" represents less than 1% of total imports to the United States. Each country is allocated 8 samples.
Canada	97.0	8	
France	3.0	8	
Total	**100.0**	**16**	

Table 24: Varied Combination, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Antibiotics	% Product per Country (Pc/c)	Number of Samples	"Varied combination, fresh" represents less than 1% of total imports to the United States. Each country is allocated 8 samples.
Canada	100.0	8	
Total	**100.0**	**8**	
Sulfonamides	**% Product per Country (Pc/c)**	**Number of Samples**	
Canada	100.0	8	
Total	**100.0**	**8**	

Table 25: Varied Combination, Processed
2011 U.S. NRP Import Reinspection Sampling Plan

Sulfonamides	% Product per Country (Pc/c)	Number of Samples	"Varied combination, processed" represents less than 1% of total imports to the United States. Each country is allocated 8 samples.
Australia	0.1	8	
Canada*	71.8	0	
France	<0.1	8	
Mexico	28.2	8	
Total	**100.0**	**24**	

*Country exports fresh varied combination to the United States.

Design of the Domestic Scheduled Sampling Plan for Pesticides

I. Selecting and Ranking Candidate Pesticides

EPA SAT members reviewed more than 290 compound/compound classes before selecting the candidate pesticides of concern for the 2011 U.S. NRP, which are presented in Table 26. FSIS prioritizes analyses by grouping compounds detected using the same analytical method together.

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
- Toxicity

Category definitions and scoring criteria appear in the section "*Scoring Key for Pesticides*" and scoring results are presented in Table 26. The score assigned to each category, including compounds grouped together, is the highest score for all members of the group.

Compound Ranking

1. Background

Using *Equation 1*[1]:

Risk = Exposure × Toxicity
= Consumption × Residue Levels × Toxicity
= Consumption × "Risk per Unit of Consumption"

FSIS employed risk assessment techniques and principles to obtain a ranking of the relative public health concern represented by each of the candidate compounds or compound classes. Unlike veterinary drugs, FSIS does not have historical data on a sufficient range of different pesticide compounds or compound classes to predict violation scores (e.g., risk per unit of consumption) using a regression equation. SAT employed a slightly different approach, but related, to the veterinary drugs, to estimate the "Risk per Unit of Consumption" term.

2. Rating the Pesticides According to Relative Public Health Concern

The categories, "Regulatory Concern," "Pre-slaughter Interval," and "Bioconcentration Factor," were employed as predictors of 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. EPA expects the "Withdrawal Time" category for veterinary drugs and the "Pre-slaughter Interval" category to correlate with residue level, because longer pre-slaughter intervals are less likely to be observed properly. When the pre-slaughter interval is

[1] See the section, "Design of the Domestic Scheduled Sampling Plan for Veterinary Drugs."

not observed, the carcass may contain violative levels of residues, because the time necessary for sufficient metabolism and/or elimination of the pesticide may not have passed. Bioconcentration is a measure of 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. The numerical value assigned to toxicity is independent of other parameters and it can be used directly as a term in Equation 12.

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, as shown in Equation 12.

Equation 12

Relative Public Health Concern

= Estimated relative risk per unit of consumption × *modifier for* "Lack of FSIS Testing Information on Violations"
= Estimated relative exposure × Relative toxicity × *modifier for* "Lack of FSIS Testing Information on Violations"
= Weighted average of {"Regulatory Concern," "Pre-slaughter Interval," "Bioconcentration factor"} × "Toxicity"

Comparing Equation 12 to Equation 3, it can be seen that 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'. "Endocrine Disruption" was not included in Equation 12 because scores for this category were not available for most of the pesticides.

The pesticide ratings presented in Table 26 are based on their relative public health concern, which was determined by combining the scoring categories presented in Equation 12 with a weighting formula. The formula is presented in Equation 13 and the results appear in Table 26. FSIS selected this formula because of the relative importance of each modifier and the degree each modifier should be allowed to alter the underlying risk-based score for Relative Public Health Concern. The formula enables others to observe and understand the adjustments that were made and it ensures consistency in how these adjustments were applied across a wide range of compounds.

Equation 13

Relative public health concern rating, pesticides = $((2\times R+P+B)/4)) \times T$

Where: R = score for "Regulatory Concern"
P = score for "Pre-slaughter Interval"
B = score for "Bioconcentration Factor"
T = score for "Toxicity"

The variable for regulatory concern (R) in Equation 13 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.

Equation 13 uses variables that are derived from terms (scoring categories) that are not the same as the terms used in Equation 4. Therefore, scores for pesticides and veterinary drugs cannot be reliably compared. However, Equation 13 for pesticides and Equation 4 for veterinary drugs have been normalized to provide a rough comparison between these two different categories 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 due to differences in overall consumption. Data on relative consumption are applied subsequently, in Phase IV, after estimation of relative exposure values for each compound/production class (C/PC) pair.

II. Prioritizing Candidate Pesticides

After ranking the pesticides according to their relative public health concern, SAT used the ranking scores to select compounds for the 2011 U.S. NRP. 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 2011 U.S. NRP.

After identifying the high-priority compounds and compound classes, FSIS considered the availability of its laboratory resources, especially appropriate analytical methods. The following compounds were included in the 2011 U.S. NRP for the months of January through May.

- Chlorinated Hydrocarbons and Chlorinated Organophosphates (CHC/COP): Aldrin, BHC alpha, BHC beta*, BHC delta*, carbophenothion*, chlordane-cis (-alpha), chlordane-trans, chlordene*, chlorfenvinphos, Chlorpyrifos, Chlorpyrifos methyl*, Coumaphos O*, Coumaphos S, Dichlorfenthion*, Fenchlorphos (Ronnel), Heptachlor, Hexachlorobenzene (HCB), Lindane, Mirex, trans-nonachlor, o,p'-DDE (2,4)*, o,p'-DDT*, p,p'-DDE (4,4), p,p'-DDT, o,p'-TDE* (DDD), p,p'-TDE (DDD), Phosalone*, tetrachlorvinphos (stirofos), and Toxaphene
- Organochlorides (OC): Captan*, Dieldrin, Endosulfan I*, Endosulfan II, Endosulfan sulfate, Endrin, Endrin Ketone, Heptachlor epoxide A, Heptachlor epoxide B, Kepone*, Linuron*, Methoxychlor and Oxychlordane
- Environmental Contaminants: 2,2',4,4',5,5'-hexabromobiphenyl (HBB), halowaxes*, polybrominated biphenyls*, and polychlorinated biphenyls (aroclors 1254, 1260) (PCBs)

*compound/compound class identified, but not quantified.

In May 2011, FSIS went to a new multi-class pesticides method, screening in muscle rather than fat. The list of pesticides in the new method is found in Appendix II Table A IIb.

Table 26 provides the sampling status of each compound or compound class in the 2011 scheduled sampling plan. A brief explanation justifies the exclusion of each highly ranked compound or compound class not scheduled for inclusion in the 2011 U.S. NRP. A number of highly ranked pesticides could not be included in the 2011 U.S. NRP due to methodological limitations. FSIS will apply methodology capable of capturing chlorinated hydrocarbons and chlorinated and non-chlorinated organophosphates when such methodology can be implemented. Use Summary Table III to identify future method developments needed for pesticides.

III. Identifying the Compound/Production Class (C/PC) Pairs

The CHC/COP class includes pesticides that may be present in the foods animals eat, creating the potential for the occurrence of "secondary residues" (i.e., residues that are not the result of direct treatment) in all classes of animals. The animals may be exposed to other environmental contaminants within this class, such as the PCBs.

Since the 2006 U.S. NRP, FSIS has suspended scheduled sampling for CHCs and COPs for the following production classes: minor species (ducks, geese, ratites, rabbits, squab, and bison); young turkeys; bulls; mature turkeys; and bob veal. Not scheduling these species will allow FSIS to focus those resources on the development of methodologies in areas that are of high public health concern. FSIS will continue sampling for CHCs and COPs for the occurrence of accidental contamination incidents.

IV. Allocation of Sampling Resources

Equation 14 establishes a relative sampling priority for each C/PC pair by multiplying the ranking score for the CHC/COPs with the estimated relative percent of domestic consumption for each production class. This calculation is identical to Equation 6, which was used to calculate the relative sampling priorities for the veterinary drugs:

Equation 14

$$(\text{Relative sampling priority})_{C/PC} = (\text{Ranking score})_{C} \times (\text{Estimated relative \% domestic consumption})_{PC}$$

Equation 14 is analogous to the equation used to estimate risk in Equation 1. While the results of Equation 14 do not constitute an estimate of risk, it provides a numerical representation of the relative public health concern associated with each C/PC pair and can be used to prioritize FSIS analytical sampling resources. This risk ranking is based on average consumption across the entire U.S. population, rather than on maximally exposed individuals.

C/PC pairs within a single compound class are ranked using the estimated relative percent of domestic consumption for each production class. To maintain a rough parity between the sampling numbers assigned to the veterinary drugs and those assigned to the pesticides, all of the relative consumption figures were multiplied by the ranking score for the CHC/COP compound class. The initial sample number was chosen to be 300 animals, regardless of the priority score. This sampling level provides 95% confidence in detecting a residue violation if the violation rate is 1% or higher. The results are presented in Table 27.

Adjusting Relative Sampling Numbers

Adjusting for Historical Data on Violation Rates of Individual C/PC pairs

Extensive FSIS historical testing information on violations, subdivided by production class, is available for the CHC/COP compound class. This information refines the relative priority of sampling each C/PC pair. Table 27 lists the priority score calculated by multiplying the number of FSIS-analyzed samples in each production class under its scheduled sampling plan (i.e., random sampling only) for the period January 1, 2000 to December 31, 2009 to the percent of samples found to be violative (i.e., present at a level in excess of the action level or regulatory tolerance, or for those compounds that are prohibited,

present at any detectable level). Using these data, the following rules were applied to adjust the sampling numbers:

1. Fewer than 300 samples from the C/PC pair tested over the 10-year period: +1 level (i.e., increase sampling level by one, e.g. from 230 to 300 samples).
2. At least 300 samples tested over the 10-year period, violation rate and violations were found during the 2009 calendar year, or the violation rate is greater than or equal to 0.25% ($\geq$ 0.25%) during January 1, 2000 to December 31, 2009: decrease the sampling level using Statistical Table in Appendix III.
3. At least 300 samples tested over the 10-year period, violation rate = 0.00%: maintain the initial sampling level.
4. The maximum number of samples to be scheduled for testing is 300.

An exception to these rules is:

> For the 2011 U.S. NRP, FSIS has continued to suspend scheduled sampling for CHCs and COPs for the following production classes: minor species (ducks, geese, ratites, rabbits, squab, and bison); young turkeys; bulls; mature turkeys; and bob veal.

The sampling numbers obtained following these adjustments are listed in Table 27.

Adjusting for Laboratory Capacity

The 2011 U.S. NRP sampling levels for dairy cows, mature chickens, steer and sows were adjusted to 230 samples each for laboratory capacity.

Adjustment for the Number of Slaughter Facilities

No adjustment was necessary for number of slaughter facilities for 2011 U.S. NRP.

V. Scoring Key

U.S. NRP Historical Testing Information on Violations (January 1, 2000 to December 31, 2009)

Violation rate scores were calculated by two different methods using violation rate data from FSIS random sampling of animals entering the food supply.

Method A: Maximum Violation Rate
Identify the production class exhibiting the highest average violation rate, calculated by dividing the number of violations over the 2000 to 2009 period by the total number of samples analyzed.

Score as follows:

4 = > 0.5%

3 = 0.25% - 0.5 %

2 = 0.07% - 0.24%

1 = < 0.07%

NT = Not tested by FSIS.

NA = Tested by FSIS, but violation information does not apply.

Method B: Violation Rate Weighted by Size of Production Class
To calculate violation rate for each production class, we multiplied the average violation rate (defined above) by the relative consumption value for that class. We weighted each class by the annual U.S. production and divided this value by the total production for all classes under FSIS regulation. Add together the values for all production classes.

Score as follows:

4 = > 0.08%

3 = 0.035% - 0.08%

2 = 0.003% - 0.034%

1 = < 0.003%

NT = Not tested by FSIS.

NA = Tested by FSIS, but violation information does not apply.

The final score for each pesticide or pesticide class is determined by assigning the greater score from Method A and Method B.

Method A identifies those pesticides that are of regulatory concern, because they exhibit high violation rates, independent of the relative consumption value. Method B identifies those pesticides that may not have the highest violation rates, but are of concern because they exhibit moderate violation rates in a relatively large proportion of the U.S. meat, poultry, and egg products. By employing Methods A and B together and assigning a final score based on the highest score, both of the above concerns are captured.

Regulatory Concern

These scores represent 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 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 follows:

The Acute Reference Dose (Acute RfD) is an estimate (with uncertainty spanning an order of magnitude or greater) of 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) is an estimate (with uncertainty spanning an order of magnitude or greater) of 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[2] (NOAEL) or the Lowest Observed Adverse Effect Level[3] (LOAEL) by Uncertainty Factors, which 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 an additional Food Quality and 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 the lower of the Acute and 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

EPA assigns a numerical value of 1, 2, 3, or 4 to pesticides for the category "Pre-Slaughter Interval," presented in Summary Table III. Pesticides approved for direct dermal application requires a pre-slaughter interval 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

EPA assigns numerical value of 1, 2, 3, or 4 to pesticides for the category "Bioconcentration Factor," presented in Table 26. 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:

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

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

3 = the log $K_{o/w}$ is between 2 and 3

2 = the log $K_{o/w}$ is between 1 and 2

1 = the 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 26. Endocrine disruption is a measure of the extent to which the compound changes endocrine function and causes adverse effects to individual organisms, their progeny, or organism populations/ 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," presented in Table 26. 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 26
Scoring Table for Pesticides
2011 U.S. NRP Domestic Scheduled Sampling Plan

Compound /Compound Class	*Historical Testing for Violations (V)*	*Regulatory Concern[1] (R)*	*Pre-Slaughter Interval[2] (P)*	*Bioconcen-trations[3] (B)*	*Endocrine Disruption[4]*	*Toxicity[5] (T)*	*Relative public health concern rating(((2*R)+P+B)/4)*T*
Chlorinated hydrocarbons and chlorinated organophosphates (CHCs and COPs) – compounds in the FSIS CHC/COP MRM	3	4	4	4	Not Available	4	16.0
Chlorinated organophosphates and organophosphates (COPs and OPs) not in the FSIS CHC/COP MRM	Not Tested	4	4	4	Not Available	4	16.0
Beta-Cyfluthrin	Not Tested	4	4	4	Not Available	4	16.0
Cyfluthrin	Not Tested	4	4	4	Not Available	4	16.0
Imazalil	Not Tested	4	4	4	Not Available	4	16.0
Triazines – compounds not in the FSIS triazine MRM	Not Tested	4	4	3	4	4	15.0
Carbamates in FSIS Carbamate – compounds in the FSIS MRM	Not Tested	4	4	2	3	4	14.0
Synthetic Pyrethroids – compounds in the FSIS Synthetic Pyrethrin MRM	Not Tested	3	4	4	3	4	14.0
1-(2,4-dichlorophenyl)-2-(1H-imidazole-1-yl)-1-ethanol	Not Tested	3	4	4	Not Available	4	14.0
1,1-(2,2-dichloroethylidene) bis(4-methoxybenzene)	Not Tested	3	4	4	Not Available	4	14.0
1-methoxy-4-(1,2,2,2-tetrachloroethyl)benzene)	Not Tested	3	4	4	Not Available	4	14.0
3-(1-(2,4-dichlorophenyl)-2-(1H-imidazole-1-yl)ethoxy)-1,2-propane diol	Not Tested	3	4	4	Not Available	4	14.0
Cyhalothrin, lambda-	Not Tested	4	4	2	Not Available	4	14.0
Fipronil	Not Tested	3	4	4	Not Available	4	14.0
MB 45950	Not Tested	3	4	4	Not Available	4	14.0
MB 46513	Not Tested	3	4	4	Not Available	4	14.0
Methoxychlorolefin	Not Tested	3	4	4	4	4	14.0
Triazines – compounds in the FSIS triazine MRM[xi]	Not Tested	4	2	3	4	4	13.0

Table 26 *(continued)*
Scoring Table for Pesticides
2011 U.S. NRP Domestic Scheduled Sampling Plan

Compound /Compound Class	*Historical Testing for Violations (V)*	*Regulatory Concern[1] (R)*	*Pre-Slaughter Interval[2] (P)*	*Bioconcen-trations[3] (B)*	*Endocrine Disruption[4]*	*Toxicity[5] (T)*	*Relative public health concern rating(((2*R)+P+B)/4)*T*
Arsanilic acid	Not Tested	4	1	4	Not Available	4	13.0
Etoxazole	Not Tested	4	1	4	Not Available	4	13.0
Indoxacarb (DPX-MP062)	Not Tested	4	1	4	Not Available	4	13.0
Metconazole	Not Tested	4	1	4	Not Available	4	13.0
Prothioconazole	Not Tested	4	1	4	Not Available	4	13.0

[1] Scores for regulatory concern, *R*, are provided by EPA.
[2] Scores for withdrawal time, *P*, are provided by EPA.
[3] Scores for bioconcentration factor are provided by EPA.
[4] Scores for endocrine disruption are provided by EPA.
[5] Scores for toxicity are provided by EPA.

Table 27
Pesticide Compound/Production Class Pairs, Sorted by Sampling Priority Score
2011 U.S. NRP Domestic Scheduled Sampling Plan

Compound Class	Production Class	Priority Score	Unadjusted Number of Samples	First Adjustment 4	Second Adjustment 5	Third Adjustment 6	Final 7
Pesticides	Young chickens	701.36	300	300	300	300	300
Pesticides	Steers	202.56	300	300	230	230	230
Pesticides	Dairy cows	25.312	300	300	230	230	230
Pesticides	Sows	15.056	300	300	230	230	230
Pesticides	Mature chickens	11.680	300	300	230	230	230
Pesticides	Boars/stags	1.312	300	300	300	300	300
Pesticides	Roaster pigs	0.768	300	300	300	300	300
Totals			**2,100**				**1,820**

4 Adjustment based on FSIS Historical Testing Information. Sampling levels were decreased based on the rules described in the section, *Design of the Domestic Scheduled Sampling Plan for Pesticides*.
5 Adjustment for Laboratory Capacity as discussed in the section, *Design of the Domestic Scheduled Sampling Plan for Pesticides*
6 Adjustment for Production Volume as discussed in the section, *Design of the Domestic Scheduled Sampling Plan for Pesticides*
7 Final adjustment numbers were obtained following an assessment of laboratory capacity and production volume. In addition, FSIS has suspended scheduled sampling for CHCs/COPs in bob veal, horses, and minor species (ducks, ratites, geese, rabbits, and squab) since the 2006 U.S. NRP

Design of the Import Reinspection Sampling Plan for Pesticides

I. Selecting and Ranking Candidate Pesticides

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 on the same pesticides specified in the domestic sampling plan using 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/country pair will be added to the IRSP.

II. Prioritizing Candidate Pesticides

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 *Design of the Domestic Scheduled Sampling Plan for Pesticides* section details the compounds identified by the multi-residue method (MRM) used between January and May, 2011. A new multi-class screening method was implemented in May, 2011, including compounds listed in Appendix II Table A IIb.

III. Identifying the Compound/Production Class (C/PC) Pairs

As with the domestic scheduled sampling plan, the import reinspection sampling for pesticides monitors for incidents of accidental and environmental contamination.

IV. Allocation of Sampling Resources

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 ten 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.[1]

Animal product classes

Table 5 lists the estimated amount and percentage of all the product classes imported into the United States. The data for the product classes were obtained from the Automated Import Information System. The percent of each product class imported annually is calculated using Equation 15:

Equation 15

$$\%\ \text{Product Class Imported } (P_C) = \frac{\text{Amount Product Class Imported}}{\text{All Meat, Poultry, and Egg Imports}} \times 100$$

[1] This paragraph explains FSIS policies on imported egg product testing. However, in 2011 no imported egg products were tested.

Equation 16 calculates the relative sampling priority by multiplying the percent product class imported (P_C) by the pesticide scores.

Equation 16
Relative Sampling Priority (RSP) = (P_C) × Pesticide Score

The sampling options are based on the calculated scores.
(1) high regulatory concern (300 samples/year);
(2) moderate regulatory concern (230 samples/year); or
(3) low regulatory concern (90 samples/year).

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 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; and
(h) processed varied combination products from Canada.

Allocation of samples among exporting countries

The manner in which samples are allocated among the exporting countries depends on whether the relative imported amount of the product class (P_C) is more or less than one percent of all imports.

Allocation of samples in product classes where P_C is less than one percent

If a product class represents less than one percent (by weight) of total combined U.S. imports of meat, poultry, and egg products, then the total number of samples analyzed for any compound or compound class is eight times the number of countries from which that product is imported. For example, if fresh veal is imported from only three countries and the amount imported is 0.50 % relative to the total U.S. import, 24 samples will be taken for each analysis, eight samples for each country (3 countries × 8 samples).

Allocation of samples in product classes where P_C is greater than one percent

For major product classes, the number of samples is allocated to each country depending upon the relative amount of product imported from that country. Table 6 lists the amount of product imported from each country. The percent of a product class imported from a country is calculated using Equation 17 and listed in Table 7.

Equation 17

$$\text{Percent Product Class Imported per Country } (P_{C/C}) = \frac{\text{Amount of Product Class from Country}}{\text{Total Amount of Product Class}} \times 100$$

Equation 18 calculates the number of samples taken at the port-of-entry based on the relative amount of product class imported per country. The results are listed in the column labeled "Unadjusted Samples" in Tables 29 to 38.

Equation 18

$$\text{Unadjusted Number of Samples per Country } (U_{C/S}) = \text{Total Number of Samples} \times (P_{C/C})/100$$

A country with less than eight samples is assigned eight samples, indicated in the column labeled "1st Adjustment" in Tables 29 to 38. If this causes the total number of samples for a product class to exceed the unadjusted number of samples, a second adjustment is performed according to Equation 19.

Equation 19

$$\text{Number of Samples after 2nd Adjustment} = (U_{C/S}) - \frac{(N \times P_{C/C})}{(P_{T/C})}$$

where,

N = (total number of samples after 1st adjustment) - (total number of samples initially allocated)
$P_{T/C}$ = total percentage of product class from countries with more than eight samples after 1st adjustment
$P_{C/C}$ = percent product class imported per country
$U_{C/S}$ = unadjusted number of samples

The final number of products sampled for each country is indicated in Tables 29 to 38 in the column labeled "Final." After the allocation of samples among different countries, the final number of samples for each compound/product class pair is determined and is listed in Table 28. The numbers in the table may vary slightly because of the rounding upwards or downwards of the samples.

Table 28
Number of Pesticide Samples per Production Class
2011 U.S. NRP Import Reinspection Sampling Plan

No. of Countries	Product Class	% of Imports	Pesticide	Score	RSP*	Samples Allocated	Samples Final
10	Beef, fresh	54.3%	Pesticides	16	869	300	300
8	Beef, processed	5.9%			95	90	90
5	Lamb/Mutton, fresh	4.6%			74	90	90
3	Goat, fresh	0.8%			13	24	24
2	Turkey, fresh	0.6%			9	16	16
4	Varied comb., processed	0.4%			7	24	24
3	Turkey, processed	0.1%			2	16	16
2	Other fowl, fresh	<0.1%			1	16	16
1	Horse, fresh	<0.1%			1	8	8
1	Varied comb., fresh	<0.1%			0	8	8
						Total:	**592**

*RSP = Relative Sample Priority

Tables 29-38: Allocation of PesticideSamples to Importing Countries
2011 U.S. NRP, Import Reinspection Sampling Plan

Table 29: Beef, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Pesticides	% Product per Country (Pc/c)	Unadjusted Samples 300*(Pc/c)/100	Number of Samples 1st Adjustment	Number of Samples Final
Australia	33.3	100	100	90
Canada	35.5	106	106	96
Chile	0.1	0	8	8
Costa Rica	1.0	3	8	8
Honduras	0.2	1	8	8
Japan	<0.1	0	8	8
Mexico	2.9	9	9	8
New Zealand	20.2	60	60	55
Nicaragua	3.7	11	11	10
Uruguay	3.2	10	10	9
Total	**100.0**	**300**	**328**	**300**

Table 30: Beef, Processed
2011 U.S. NRP Import Reinspection Sampling Plan

Pesticides	% Product per Country (Pc/c)	Unadjusted Samples 90*(Pc/c)/100	Number of Samples	
			1st Adjustment	Final
Argentina	13.5	12	12	18
Australia*	1.1	1	0	0
Brazil	56.7	51	51	72
Canada*	23.0	21	0	0
Costa Rica*	<0.1	0	0	0
Mexico*	1.4	1	0	0
New Zealand*	2.9	3	0	0
Uruguay*	1.5	1	0	0
Total	**100.0**	**90**	**63**	**90**

*Country exports fresh beef to the United States.

Table 31: Horse, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Pesticides	% Product per Country (Pc/c)	Number of Samples	"Horse, fresh" represents less than 1% of total imports to the United States. Each country is allocated eight samples.
Canada	100.0	8	
Total	**100.0**	**8**	

Table 32: Lamb/Mutton, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Pesticides	% Product per Country (Pc/c)	Unadjusted Samples 90*(Pc/c)/100	Number of Samples	
			1st Adjustment	Final
Australia	70.4	63	63	47
Canada	0.2	0	8	8
Iceland	0.1	0	8	8
Mexico	<0.1	0	8	8
New Zealand	29.3	26	26	19
Total	**100.0**	**89**	**113**	**90**

Table 33: Goat, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Pesticides	% Product per Country (Pc/c)	Number of Samples	"Goat, fresh" represents less than 1% of total imports to the United States. Each country is allocated eight samples.
Australia	98.0	8	
Mexico	0.4	8	
New Zealand	1.6	8	
Total	**100.0**	**24**	

Table 34: Turkey, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Pesticides	% Product per Country (Pc/c)	Number of Samples	"Turkey, fresh" represents less than 1% of total imports to the United States. Each country is allocated eight samples.
Canada	90.2	8	
Chile	9.8	8	
Total	**100.0**	**16**	

Table 35: Turkey, Processed
2011 U.S. NRP Import Reinspection Sampling Plan

Pesticides	% Product per Country (Pc/c)	Number of Samples	"Turkey, processed" represents less than 1% of total imports to the United States. Each country is allocated eight samples.
Canada*	23.1	0	
Israel	29.2	8	
Mexico	47.6	8	
Total	**100.0**	**16**	

*Country exports fresh turkey to the United States.

Table 36: Other Fowl, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Pesticides	% Product per Country (Pc/c)	Number of Samples	"Other fowl, fresh" represents less than 1% of total imports to the United States. Each country is allocated eight samples.
Canada	97.0	8	
France	3.0	8	
Total	**100.0**	**16**	

Table 37: Varied Combination, Fresh
2011 U.S. NRP Import Reinspection Sampling Plan

Pesticides	% Product per Country (Pc/c)	Number of Samples	"Varied combination, fresh" represents less than 1% of total imports to the United States. Each country is allocated eight samples.
Canada	100.0	8	
Total	**100.0**	**8**	

Table 38: Varied Combination, Processed
2011 U.S. NRP Import Reinspection Sampling Plan

Pesticides	% Product per Country (Pc/c)	Number of Samples	"Varied combination, processed" represents less than 1% of total imports to the United States. Each country is allocated eight samples.
Australia	0.1	8	
Canada*	71.8	0	
France	<0.1	8	
Mexico	28.2	8	
Total	**100.0**	**24**	

*Country exports fresh varied combination to the United States.

Scheduled Sampling Plans for Environmental and Processing Contaminants

SAT members selected the following candidate environmental and processing contaminants of concern.

A. Environmental Contaminants

In 2011, FSIS will conduct an exploratory assessment for cadmium and lead in market hogs. This follows cadmium and lead sampling that began in 2003 for heifers and dairy cows and continued in 2004 for boars and stags, dairy cows, heifers, and mature chickens. Ensuing years examined steers (2005), mature chickens (2006, 2007), beef cows (2008), dairy cows (2009), and market hogs (2010). Sampling for 2011 is summarized in Table 39.

This exploratory assessment on the occurrence and levels of cadmium and lead was designed to address the growing concern on the dietary exposure to these metals. Currently no tolerances exist for lead and cadmium in meat, poultry or egg products; FDA recommended including such testing in the National Residue Program.

B. Processing Contaminants

- Nitrosamines
- Maillard reaction products (from charring)
- Compounds migrating from packaging
- Polyaromatic hydrocarbons
- Breakdown products of oils used in deep frying

No processing contaminants have been designated for analysis in year 2011. Should a contamination incident occur during the year, FSIS may initiate residue sampling as part of an exploratory assessment plan.

Table 39
Number of Scheduled Samples per Product Class for Lead and Cadmium
2011 U.S. NRP Domestic Specifically Designed Survey

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

Sampling Plan for Exploratory Assessments

EXPLORATORY ASSESSMENTS

No additional exploratory assessments were scheduled for the 2011 U.S. NRP, except for the heavy metals (i.e., lead and cadmium) noted under environmental contaminants.

2011 NRP Sampling Plan Adjustments

The following are the major adjustments to the 2010 U.S. NRP:

- Testing will not take place for thyreostats, trenbolone, and zeranol.
- For 2011, the pesticide method is under revision and the number of compounds/compound classes and matrices may change during the year. To implement the new multi-class method, FSIS has worked with EPA to rank individual pesticides as opposed to ranking general classes, like "CHCs", which is a more informative process. This resulted in the addition of the highest ranked individual compounds for the new method. The list of pesticides in the new multi-class method is found in Appendix II table A-IIb.
- Egg products will be tested for arsenic.

Appendix I
Tissues Required for Laboratory Analysis

Tissues Required for Laboratory Analysis

Table A-I lists the tissue, quantity required for analysis, and the laboratory to which the tissue is sent for analysis.

Table A-I

Residue	Tissue Analyzed	Quantity (lb)	Lab
Antibiotics	kidney, liver, muscle	1	ML[1]
Arsenicals	liver, muscle	1	EL[2]
Avermectins	liver, muscle	1	EL
β-Agonists	liver, muscle	1	WL[3]
Carbadox	liver	1	WL
Chloramphenicol	muscle	1	EL
Pesticides	fat, muscle	1	WL
Florfenicol	liver, muscle	1	EL
Flunixin	liver, muscle	1	ML
Lead and Cadmium	kidney, muscle	1	EL
Nitrofurans	liver	1	WL
Nitroimidazoles	muscle	1	EL
Sulfonamides	liver, muscle	1	EL

[1] FSIS Midwestern Laboratory
[2] FSIS Eastern Laboratory
[3] FSIS Western Laboratory

Appendix II
FSIS Laboratory Analytical Methods

Introduction to Analytical Methods

FSIS requires analytical methods for detecting, quantifying, and identifying residues that may be present in meat, poultry, and processed egg products. The Agency uses these methods for monitoring and surveillance activities to determine whether a product is adulterated and for human health risk assessment evaluations. The Agency uses available methodologies to take appropriate regulatory action against adulterated products, consistent with the reliability of the analytical data. This section describes the types of methods used by FSIS to conduct analyses.

Table A-IIa – Analytical Methods
2011 U.S. NRP

Compound Class	*Compound*	*Analytical Method*			*Minimum Level of Applicability*		
		Screen	*Determinative (quantitative)*	*Confirmatory (identification)*	*Screen*	*Determinative (quantitative)*	*Confirmatory (identification)*
Antibiotics	Carbadox		GC-ECD	GC/EI IT/MS		15 ppb	30 ppb
	Chloramphenicol	ELISA	GC-ECD	GC-MS	0.25 ppb	0.25 ppb (M)(B)(T)(catfish)	0.30 ppb (M)(B)(T) (catfish)
	Florfenicol		HPLC	GC/SIM-MS LC/MS/MS		0.3 ppm (L)(B) (catfish) 0.2 ppm (M)(B) 1.5 ppm (P)(L) 0.6 ppm (P)(M)	0.5 ppm (L)(B), 0.3 ppm (M)(B) 0.3 ppm (B)(L,M), 1.5 ppm (P)(L), 0.6 ppm (P)(M) and catfish
Antibiotics: β-Lactams	Amoxicillin	HPLC/MS-MS		HPLC/MS-MS	Same as confirmatory	TBD	TBD
	Ampicillin					0.05 ppm	10 ppb
	Cefazolin					TBD	50 ppb
	Cloxacillin					TBD	TBD
	Desacetyl Cephapirin					TBD	100 ppb
	Ceftiofur (Parent) Desfuroyl Ceftiofur (Marker residue for Quantiation) Desfuroylceftiofur cysteine disulfide (DCCD) (Metabolite For Confirmation)		HPLC-UV			0.10 ppm	50 ppb
	Dicloxacillin					TBD	50 ppb
	Nafcillin					TBD	20 ppb
	Penicillin-G		Bioassay			0.05 ppm	50 ppb
	Oxacillin					TBD	TBD
Antibiotics: Tetracyclines	Chlortetracycline	7-Plate Bioassay	Bioassay	HPLC		0.05 ppm	0.5 ppm
	Oxytetracycline					0.40 ppm	
	Tetracycline						

Table A-IIa – Analytical Methods *(continued)*
2011 U.S. NRP

Compound Class	*Compound*	*Analytical Method*			*Minimum Level of Applicability*		
		Screen	*Determinative (quantitative)*	*Confirmatory (identification)*	*Screen*	*Determinative (quantitative)*	*Confirmatory (identification)*
Antibiotics: Macrolides	Clindamycin	7-Plate Bioassay		HPLC/MS-MS			0.1 ppm
	Erythromycin		Bioassay			0.25 ppm	0.1 ppm
	Lincomycin						0.1 ppm
	Pirlimycin						0.1 ppm
	Tilmicosin		HPLC-Ion Pairing			300 ppb (M) 600 ppb (L,K)	0.1 ppm
	Tulathromycin						1 ppm
	Tylosin		Bioassay			1.0 ppm	0.1 ppm
Antibiotics: Aminoglycosides	Amikacin	7-Plate Bioassay		UHPLC-MS/MS (B) HPLC-MS/MS (P,S)			1.0 ppm (P,S,-L,K), 0.4 ppm (P,S-M) 0.05 ppm (B-L,K,M)
	Apramycin						0.4 ppm (P,S-L,), 0.1 ppm (P,S-K,M), 0.05 ppm (B-K), 0.20 ppm (B-L), 0.10 ppm (B-M)
	Dihydrostreptomycin		Bioassay			1.0 ppm	0.40 ppm (P,S,-L,K,M), 1.0 (B-L,K), 0.25 (B-M)
	Gentamicin		Bioassay			0.5 ppm	0.4 ppm (P,S,B-L,), 0.1 ppm (P,S,B-K,M),
	Hygromycin						1.0 ppm (P,S-L,K), 0.4 ppm (P,S-M) 0.1 ppm (B-K,), 0.2 ppm (B-M)
	Kanamycin						4.0 ppm (P,S-L,M), 2.0 ppm (P,S-K) 4.0 ppm (B-L) 0.05 ppm (B-M), 0.20 ppm (B-K)
	Neomycin		Bioassay			2.5 ppm	1.80 ppm (P,S-K), 0.4 ppm (P,S,B-L), 0.1 ppm (P,S-M), 3.6 ppm (B-K), 1.2 ppm (B-M)
	Spectinomycin						1.0 ppm (P,S-L), 0.4 ppm (P,S-K), 0.25 ppm (P,S-M) 2.0 ppm (B-K), 0.25 ppm (B-L), 0.125 ppm (B-M)
	Streptomycin		Bioassay			0.5 ppm	0.4 ppm (P,S-L,K,M), 1.0 ppm (B-K,L), 0.25 ppm (B-M)
	Paromomycin						0.1 ppm (B-K), 0.2 ppm (B-M,L)
	Tobramycin						1.0 ppm (P,S,B-L), 0.1 ppm (P,S,B-K,M)

Table A-IIa – Analytical Methods *(continued)*
2011 U.S. NRP

Compound Class	*Compound*	*Analytical Method*			*Minimum Level of Applicability*		
		Screen	*Determinative (quantitative)*	*Confirmatory (identification)*	*Screen*	*Determinative (quantitative)*	*Confirmatory (identification)*
Antibiotics: Fluroquinolones	Ciprofloxacin	7-Plate Bioassay		HPLC IT -MS^2/ MS^3			25 ppb
	Danofloxacin						
	Desethylene diprofloxacin						
	Desmethyl danofloxacin						
	Difloxacin						
	Enrofloxacin						
	Norfloxacin						
	Sarafloxacin						
Arsenicals	Arsenicals		AAS	AAS		0.2 ppm	0.2 ppm
Avermectins	Ivermectin		HPLC	HPLC/APCI-MS		7.5 ppb	25 ppb
	Doramectin						
	Moxidectin						
β-Agonists	Cimaterol	LC/MS/MS		LC/MS/MS	3 ppb		3 ppb
	Clenbuterol				3 ppb		3 ppb
	Ractopamine		HPLC		21 ppb	1 ppb (M),(S-L) 25 ppb (L)(B)	21 ppb
	Salbutamol				3 ppb		3 ppb
	Zilpaterol				6 ppb		6 ppb
Heavy metals	Cadmium			ICP/MS			10 ppb
	Lead						25 ppb
Hormones, synthetic	Diethylstilbesterol (DES)		GC-MS	GC-MS		0.5 ppb	1.0 ppb (L,M)
	Zeranol	ELISA	GC-MS	GC-MS	1.0 ppb	1.0 ppb	1.0 ppb (L,M)
	alpha-Trenbolone	ELISA		GC/MS-MS	5.0 ppb		5.0 ppb (L)
	beta-Trenbolone	ELISA		GC/MS-MS	5.0 ppb		5.0 ppb (M)
Nitrofurans	Furazolidone	LC/MS-MS		LC/MS-MS	5.0 ppb (L) 1.0 ppb (catfish)		5.0 ppb (L) 1.0 ppb (catfish)
	Furaltadone				5.0 ppb (L) 1.0 ppb (catfish)		5.0 ppb (L) 1.0 ppb (catfish)

Table A-IIa – Analytical Methods *(continued)*
2011 U.S. NRP

Compound Class	*Compound*	*Analytical Method*			*Minimum Level of Applicability*		
		Screen	*Determinative (quantitative)*	*Confirmatory (identification)*	*Screen*	*Determinative (quantitative)*	*Confirmatory (identification)*
Hormones, synthetic	Diethylstilbesterol (DES)		GC-MS	GC-MS		0.5 ppb	1.0 ppb (L,M)
	Zeranol	ELISA	GC-MS	GC-MS	1.0 ppb	1.0 ppb	1.0 ppb (L,M)
	alpha-Trenbolone	ELISA		GC/MS-MS	5.0 ppb		5.0 ppb (L)
	beta-Trenbolone	ELISA		GC/MS-MS	5.0 ppb		5.0 ppb (M)
Nitrofurans	Furazolidone	LC/MS-MS		LC/MS-MS	5.0 ppb (L) 1.0 ppb (catfish)		5.0 ppb (L) 1.0 ppb (catfish)
	Furaltadone				5.0 ppb (L) 1.0 ppb (catfish)		5.0 ppb (L) 1.0 ppb (catfish)
Nitroimidazoles	Hydoxydimetridazole		HPLC	HPLC/MS/MS	1 ppb (S) (M)		1 ppb (S) (M)
	Hydroxyipronidazole				1 ppb		1 ppb
Non-Steroidal Anti-Inflam-matory Drugs (NSAIDs)	Flunixin	ELISA	HPLC/ESI-MS-MS	HPLC/ESI-MS-MS	50 ppb	62.5 ppb (L) 12.5 ppb (M)	62.5 ppb (L) 12.5 ppb (M)

Table A-IIa – Analytical Methods *(continued)*
2011 U.S. NRP

Compound Class	*Compound*	*Analytical Method*			*Minimum Level of Applicability*		
		Screen	*Determinative (quantitative)*	*Confirmatory (identification)*	*Screen*	*Determinative (quantitative)*	*Confirmatory (identification)*
Sulfonamides	Sulfapyridine	TLC	LC/MS-MS	LC/MS-MS	0.05 ppm	0.05 ppm for all but 0.10 ppm SQX	0.05 ppm for all but 0.10 ppm SQX
	Sulfadiazine						
	Sulfathiazole						
	Sulfamerazine						
	Sulfamethazine						
	Sulfachloropyridazine						
	Sulfamethoxypryridazine						
	Sulfaquinoxaline (SQX)						
	Sulfadimethoxine						
	Sulfaethoxypyridazine						
	Sulfaphenazole						
	Sulfatroxazole						
	Sulfisoxazole						
	Sulfadoxine						
Thyreostats	2-Mercaptobenzimidazole			HPLC/MS-MS			25 ppb
	6-Methyl-2-thiouracil						
	2-Mercapto-1-methylimidazole						
	6-Phenyl-2-thiouracil						
	6-Propyl-2-thiouracil						
	2-Thiouracil						
CHCs/COPs/ OCs/Environmental Contaminants	Aldrin	GC-ECD	GC-ECD		0.10 ppm	0.10 ppm	
	alpha-BHC				0.10 ppm	0.10 ppm	
	beta-BHC				0.10 ppm		
	delta-BHC				0.10 ppm		
	Captan				0.04 ppm	0.04 ppm	
	Carbophenothion				0.06 ppm	0.06 ppm	
	Chlordene				0.10 ppm		
	Chlorfenvinphos				0.05 ppm	0.05 ppm	

Table A-IIa – Analytical Methods *(continued)*
2011 U.S. NRP

Compound Class	*Compound*	*Analytical Method*			*Minimum Level of Applicability*		
		Screen	*Determinative (quantitative)*	*Confirmatory (identification)*	*Screen*	*Determinative (quantitative)*	*Confirmatory (identification)*
CHCs/COPs/ OCs/Environmental Contaminants *(cont'd)*	Chlorpyrifos	GC-ECD	GC-ECD		0.10 ppm	0.10 ppm	
	Chlorpyrifos methyl				0.10 ppm		
	cis-chlordane				0.02 ppm	0.30 ppm	
	Coumaphos-O				0.40 ppm	0.20 ppm	
	Coumaphos-S				0.20 ppm	0.20 ppm	
	Dichlofenthion				0.1 ppm		
	Dieldrin				0.10 ppm	0.10 ppm	
	Endosulfan I				0.02 ppm	0.02 ppm	
	Endosulfan II				0.04 ppm	0.04 ppm	
	Endosulfan sulfate				0.10 ppm		
	Endrin				0.10 ppm	0.10 ppm	
	Endrin Ketone				0.10 ppm		
	2,2',4,4',5,5'-hexabromobiphenyl (HBB)				0.10 ppm		
	Hexachlorobenzene (HCB)				0.10 ppm	0.10 ppm	
	Heptachlor epoxides				0.10 ppm	0.10 ppm	
	Heptachlor				0.03 ppm	0.10 ppm	
	Kepone				0.06 ppm	0.06 ppm	
	Lindane				0.10 ppm	0.10 ppm	
	Linuron				0.50 ppm	0.50 ppm	
	Methoxychlor				0.50 ppm	0.50 ppm	
	Mirex				0.10 ppm	0.10 ppm	
	Trans-Nonachlor				0.15 ppm	0.15 ppm	
	o,p'-TDE				0.15 ppm		
	o,p'-DDT				0.15 ppm	0.15 ppm	
	o,p'-DDE				0.10 ppm		
	Oxychlordane				0.04 ppm	0.04 ppm	

Table A-IIa – Analytical Methods *(continued)*
2011 U.S. NRP

Compound Class	*Compound*	*Analytical Method*			*Minimum Level of Applicability*		
		Screen	*Determinative (quantitative)*	*Confirmatory (identification)*	*Screen*	*Determinative (quantitative)*	*Confirmatory (identification)*
CHCs/COPs/ OCs/Environmental Contaminants *(cont'd)*	p,p'-DDE	GC-ECD	GC-ECD		0.10 ppm	0.10 ppm	
	p,p'-DDT				0.10 ppm	0.15 ppm	
	p,p'-TDE				0.10ppm	0.15 ppm	
	PCB 1260				0.50 ppm	0.50 ppm	
	PCB 1254				0.50 ppm	0.50 ppm	
	Phosalone				0.02 ppm	0.02 ppm	
	Polybrominated biphenyls				0.10 ppm		
	Ronnel				0.03 ppm	0.03 ppm	
	Stirofos				0.04 ppm	0.06 ppm	
	Toxaphene				1.00 ppm	1.00 ppm	
	trans-chlordane				0.04 ppm	0.30 ppm	
Adulterant / Contaminant	Melamine		HPLC-MS-MS	HPLC-MS-MS		50 ppb ground beef 1 ppp RTE	50 ppb ground beef 1 ppp RTE

Key:
AAS = Atomic Absorption Spectroscopy
APCI = Atmospheric Pressure Chemical Ionization
B = Bovine
CHCs = Chlorinated Hydrocarbons
COPs = Chlorinated Organophosphates
ECD = Electron Capture Detection
ELISA = Enzyme Linked Immunosorbent Assay
GC = Gas Chromatoraphy
GPC = Gel Permeation Chromatography
HPLC = High Performance Liquid Chromatography
K = Kidney
L = Liver
M = Muscle
Minimum Level of Applicability = The lowest quantity of residue (or sample component) that can be reliably observed or found in the sample matrix by the analytical methodology used.
MS = Mass Spectroscopy
P = Poultry
PCBs = Polychlorinated Biphenyls
ppb = parts per billion
ppm = parts per million
RTE= Ready–to-eat
SIM = Selected Ion Mode
S = Swine
TBD = To Be Determined
TLC = Thin Layer Chromatography
T = Turkey
UHPLC = Ultra High Performance Liquid Chromatography

Table A-IIb Pesticides in New Analytical Method
2011 U.S. NRP

Methodology: LC/MS/MS and GC/MS/MS
Matrix: Muscle

Compound Number	*Analyte*	*Minimum Level of Applicability (ppb)*	*Compound Number*	*Analyte*	*Minimum Level of Applicability (ppb)*
1	Alachlor	10	30	Propachlor	10
2	Aldrin	25	31	Propanil	6
3	Azinphos methyl	10	32	Propiconazole	15
4	Bifenthrin	5	33	Tefluthrin	5
5	Boscalid	15	34	Tetrachlorvinphos	10
6	Carfentrazone ethyl	5	35	Tetraconazole	5
7	Chlordane cis	5	36	3-Hydroxycarbofuran	20
8	Chlordane trans	5	37	Acephate	10
9	Chlorpyrifos	5	38	Carbaryl	25
10	Chlorpyrifos methyl	5	39	Carbofuran	10
11	L-Cyhalortin	5	40	Clofentizine	25
12	Cypermethrin	15	41	Diflubenzuron	25
13	Deltamethrin	10	42	Diuron	80
14	Dichlorvos (DDVP)	15	43	Ethofumesate	20
15	Dieldrin	15	44	Imazalil	5
16	Difenoconazole	15	45	Imidacloprid	25
17	Endosulfan I	22.5	46	Indoxacarb	50
18	Endosulfan II	22.5	47	Linuron	25
19	Endosulfan sulfate	7.5	48	Metalaxyl	10
20	Fipronil	5	49	Methomyl	30
21	Heptachlor	25	50	Methoxyfenozide	10
22	Heptachlor epoxide, cis	25	51	Myclobutanil	10
23	Heptachlor epoxide, trans	25	52	Norflurazon	10
24	Mirex	10	53	Pyridaben	9
25	Nonachlor trans	5	54	Simazine	10
26	Oxychlordane	10	55	Tebufenozide	40
27	Permethrin (cis & trans)	15	56	Thiabendazole	15
28	Piperonyl butoxide	22.5	57	Thiamethoxam	10
29	Pronamide	5			

Appendix III
Statistical Table

Statistical Table

Table AIII indicates the number of samples required to ensure detection of a violation that affects a given percentage of the sampled population. For a binomial distribution with sample size "*n*" and violation rate "*v*" (in decimal number), where *v* is the true violation rate in the population and *n* is the number of samples, the probability, *p*, of finding at least one violation among the *n* samples (assuming random sampling) is: $p = 1-(1-v)^n$. Therefore, if the true violation rate is 1% (i.e., 0.01), the probabilities of detecting at least one violation with sampling levels of 230 and 300 are 0.90 and 0.95, respectively.

Table AIII
Statistical Table
2011 U.S. National Residue Program

Percentage % Violative in the Sample (*v*)	Probability (*p*) of detecting at least one violation in (*n*) samples			
	0.90	**0.95**	**0.99**	**0.999**
	Number of Samples required "*n*"			
10	22	29	44	66
5	45	59	90	135
1	230	300	459	688
0.5	460	598	919	1,379
0.1	2,302	2,995	4,603	6,905
0.05	4,605	5,990	9,209	13,813

Procedure to calculate the required number of samples

$1-p=(1-v)^n$ ← Subtract one from both sides of the equation.

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

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

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