FOOD SAFETY AND INSPECTION SERVICE

2008 FSIS National Residue Program Scheduled Sampling Plans

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

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Preface

The Food Safety and Inspection Service (FSIS) National Residue Program (NRP), *Blue Book* is a summary of the scheduled domestic and import sampling plans and includes a summary of adjustments to the 2007 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 import products 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) are also provided: 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 FSIS NRP should be directed to the USDA-FSIS Risk Assessment and Residue Division (RARD), Residue Branch, 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 Food Safety and Inspection Service (FSIS), the U.S. Department of Agriculture's public health regulatory agency, works with the Environmental Protection Agency (EPA) and the Department of Health and Human Services' Food and Drug Administration (FDA), to control veterinary drug, pesticide, and environmental contaminant residues in meat, poultry, and egg products. Residue control is a cooperative effort. EPA^{*} and FDA^{**} have statutory authority for establishing residue tolerances or action levels, and FSIS, through the National Residue Program (NRP) tests animal tissues and egg products to verify that tolerances or action levels are not violated.

FDA, under the Federal Food, Drug, and Cosmetic Act, establishes tolerances or action levels for veterinary drugs, food additives, and unavoidable environmental contaminants. EPA, through the Federal Insecticide, Fungicide and Rodenticide Act (as modified by the Food Quality Protection Act), sets tolerance levels for registered pesticides. For cancelled pesticides, action levels (similar to tolerances, but less formal) are established by FDA based on recommendations that EPA published in the Federal Register. FDA and EPA also have the authority to ensure compliance with established tolerances or action levels.

FSIS collects samples of meat, poultry, and egg products at federally inspected establishments and analyzes the samples at FSIS laboratories for chemical residues of veterinary drugs, pesticides, and environmental contaminants. Laboratory findings that exceed established tolerances and action levels are shared with FDA and EPA. This authority is provided under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. FSIS regulations are published in Title 9 of the Code of Federal Regulations (9 CFR), chapter III.

Since 1967, FSIS has administered the NRP to collect data on chemical residues in domestic and imported meat, poultry, and egg products. The NRP is designed to provide: (1) a structured process for identifying and evaluating compounds of concern by production class; (2) the capability to analyze for compounds of concern; (3) appropriate regulatory follow-up of reports of violative tissue residues; and (4) collection, statistical analysis, and reporting of the results of these activities.

With the implementation of the Hazard Analysis and Critical Control Points (HACCP) inspection system, another important component of the NRP is to provide verification of residue control in HACCP systems. As part of the HACCP regulation, slaughter and production establishments are required to identify all chemical residue hazards that are reasonably likely to occur, and develop systems to guard against them. A vigilant chemical residue prevention program is essential to foster the prudent use of veterinary drugs and pesticides in food animals. In 1999, the NRP was modified to make residue evaluation more consistent with risk assessment principles.

^{*} Tolerance levels established by EPA are published in Title 40 CFR.

^{**} Tolerance levels established by FDA are published in Title 21 CFR.

The NRP includes a variety of sampling plans to identify violative levels of chemical residues and to reduce consumers' exposure to chemical contaminants. The range of chemical compounds evaluated for inclusion in the various NRP sampling plans is comprehensive. It includes approved (legal) and unapproved (illegal) veterinary drugs, pesticides that may appear in meat, poultry, and egg products, and other xenobiotic and naturally occurring compounds that may pose a potential human health hazard.

A violation in a production class (food animal or egg product) occurs when a chemical residue is detected and the residue is in excess of an established tolerance or action level. The collection of samples is either scheduled from FSIS Headquarters (scheduled sampling) or initiated by the inspector-in-charge (inspector generated sampling). In scheduled sampling, samples are collected from healthy appearing animals and the findings provide exposure assessment data. The majority of the NRP sampling is conducted under inspector generated sampling. These samples are collected in establishments from suspect animals; their carcasses are subject to retention and condemnation if a violative level of chemical residue is found. FSIS notifies FDA of the violation and assists in obtaining the names of producers and, in the case of food animal products, other parties involved in offering the animals for sale.

FDA and cooperating state agencies will follow-up on known violators with educational visits. If a problem is not corrected, subsequent FDA visits could result in enforcement action, including prosecution. FSIS posts a Repeat Violator List on its web site, listing the names and addresses of parties FDA has determined are responsible for more than one veterinary drug, pesticide, or other chemical residue violation in a 12-month period. The list provides helpful information to processors and producers working to avoid illegal levels of residues, serves as a deterrent for violators, and enables FSIS to make better use of resources.

Data gathered in the NRP are used to verify the safety of meat, poultry, and egg products in the United States. The program helps FSIS, FDA, and EPA enforce Federal laws and regulations, and assists in the design of programs to enhance the nation's residue control programs.

SAMPLING PLANS OF THE NATIONAL RESIDUE PROGRAM

The National Residue Program (NRP) consists of two sampling plans: domestic and import. These plans are further divided 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 healthy appearing food animals. Scheduled sampling plans are generated from FSIS Headquarters using the FSIS Form 10,210-3. The development of scheduled sampling plans is a process that proceeds in the following manner: 1) determine which compounds are of food safety concern; 2) use algorithms to rank the selected compounds; 3) pair these compounds with appropriate production classes; and 4) establish sample sizes. The Surveillance Advisory Team (SAT) at its annual meeting determines the compound/production class pairs. The FSIS Residue Branch staff determines the sample sizes by employing statistical analysis techniques to calculate sample numbers. In the 2006 NRP, FSIS started using sample sizes of either 230 or 300 animals for each compound/production class pair. Statistically, applying sampling rates of 230 and 300 per production class population assures a 90 percent and 95 percent probability, respectively, to detect residue violations if the violation rate in the population is equal to or greater than one percent. Residue Branch has adopted a sample size of 300 as a public health standard. This sample size and resulting violation data are used to verify two different types of process control. The first is to verify that industry's process controls meet this public health standard for the compound/production class pairs being tested. The second is to verify that establishments' HACCP plans for residues are in control. Finally, reviews and final adjustments to these sampling plans are made by FSIS Senior Management, FSIS laboratory staff, FDA, and EPA. The following types of assessments are being scheduled:

Exposure Assessments

Exposure Assessments are used:

- By FSIS, FDA, and EPA to determine the prevalence of residues in the Nation's meat, poultry, and egg products;
- By FSIS to condemn carcasses with violative levels of residue;
- By FDA to regulate producers when a sample contains violative levels of residues;
- By industry to retain product until the sample has been tested; and
- By industry to recall product that was not retained while the sample was tested, and found to contain violative levels of residue.

Exploratory Assessments

Exploratory Assessments are designed by Residue Branch:

- To reinvestigate animal populations from ongoing or previous exposure assessments if the violation rate is confirmed at one percent or greater;
- To investigate animal populations when the compounds in question have no established tolerances; and
- To respond to intelligence reports from the field.

Inspector Generated Sampling

Inspector generated sampling is conducted by in-plant Public Health Veterinarians (PHVs) using FSIS Form 10,000-2. This occurs when the in-plant PHV suspects that an animal may have violative level of chemical residues. Currently, inspector generated sampling targets *individual suspect animals* and *suspect populations of 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. These criteria include but are not limited to the following: 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 either an antibiotic or sulfonamide drug in an animal, then he or she can perform the in-plant screening test: Fast Antimicrobial Screening Test (FAST). If the result of a screening test is positive, then the sample is sent to an FSIS laboratory

for confirmation. If the IIC does not have FAST 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 an FSIS regulation, directive (e.g., FSIS Directive 10,800.1), or notice (e.g., as in the case of show animals and bob veal).

IMPORT REINSPECTION SAMPLING PLAN

Imported meat, poultry, and egg products are sampled at U.S. ports of entry to detect chemical residues. Port-of-Entry Reinspection is a monitoring program conducted to verify the equivalence of inspection systems in exporting countries. The chemical residue sampling program is one of several Types Of Inspection (TOI) conducted during FSIS reinspection of imported products. All imported products are subject to reinspection and one or more TOIs are conducted on every lot of product before it enters the United States. The following are the three levels of chemical residue reinspection:

- Normal sampling is defined as random sampling from a lot;
- Increased sampling is defined as above the normal sampling as the result of an Agency management decision; and
- Intensified sampling is 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.

Summary Table I Status of the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) Prohibited Drugs 2008 FSIS NRP – Domestic and Import Sampling

AMDUCA ¹ Prohibited Drug	Scheduled Samples		
AMDUCA Pronibited Drug	Domestic	Import	Total
Avoparcin (glycopeptide)	Not in the 2008 NRP.	Not in the 2008 NRP.	0
Chloramphenicol	300, 300, 300, 300, and 300 samples are scheduled for bob veal, heifers, mature chickens, mature turkeys, and steers, respectively.	96, 90, 16, and 16 samples are scheduled for fresh beef, veal, turkey, and chicken, respectively	1,718
Clenbuterol ²	230, 300, and 90 samples are scheduled for goats, market hogs, and non-formula fed veal, respectively.	90 and 96 samples are scheduled for fresh veal and pork, respectively.	806
Diethylstilbestrol ³	Not in the 2008 NRP.	Not in the 2008 NRP.	0
Fluoroquinolones ⁴	300, 300, 230, 230, 45, 300, 90, 95, 300, 230, 300, 300, 300, 90, 45, 300, 60, 230, and 300 samples are scheduled for bulls, boars/stags, bob veal, dairy cows, ducks, formula-fed veal, goats, heavy calves, heifers, lambs, market hogs, mature chickens, mature turkeys, non-formula-fed veal, rabbits, roaster pigs, sheep, sows, and steers, respectively.	300, 8, 230, 90, 16, 16, 16 and 8 samples are scheduled for cattle, horse, pigs, chicken, turkey and varied combination fresh	4,729
Nitrofurans ⁵	230, 300, and 300 samples are scheduled for dairy cows, market hogs, and sows, respectively.	No samples are scheduled for 2008 NRP	830
Nitroimidazoles ⁶	300 samples are scheduled for young chickens.	16 samples are scheduled for fresh chicken	316

Summary Table I (continued) Status of the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) Prohibited Drugs 2008 FSIS NRP – Domestic and Import Sampling

	2000 I DID I (IKI Domestic and Imp	A	
AMDUCA ¹ Prohibited Drug	Scheduled Samples		
AMDUCA Tromblied Drug	Domestic	Import	Total
Phenylbutazone ⁷	No samples are scheduled for 2008 NRP	No samples are scheduled for 2008 NRP	0
Ronidazole	Not in the 2008 NRP.	Not in the 2008 NRP.	0
Vancomycin	Not in the 2008 NRP.	Not in the 2008 NRP.	0

² beta-Agonist method is applicable to clenbuterol, salbutamol, cimaterol, zilpaterol and ractopamine.

³ Xenobiotic hormone.

¹ Drugs banned by FDA from extralabel use under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) 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.

⁴ The fluoroquinolones, enrofloxacin and danofloxacin, are approved for use steers and heifers.

⁵ Furazolidone and nitrofurazone; antimicrobials.

⁶ Nitroimidazoles in the FSIS multi residue method (MRM) are dimetridazole and ipronidazole; antiprotozoal

⁷ Although not in the FSIS Scheduled sampling plan for 2008, testing for phenylbutazone will be conducted for inspector generated samples found FAST positive.

Summary Table II Rank and Status of Veterinary Drugs 2008 FSIS NRP – Domestic and Import Scheduled Sampling

Rank	Veterinary Drug	Score	Scheduled Samples		Total
капк		Score	Domestic	Import	Totai
1	Antibiotics ¹	15.1	300, 300, 230, 230, 45, 300, 90, 95, 300, 230, 300, 300, 300, 90, 45, 300, 60, 230, and 300 samples are scheduled for bulls, boars/stags, bob veal, dairy cows, ducks, formula-fed veal, goats, heavy calves, heifers, lambs, market hogs, mature chickens, mature turkeys, non-formula-fed veal, rabbits, roaster pigs, sheep, sows, and steers, respectively.	300, 8, 230, 90, 16, 16, 16 and 8 samples are scheduled for cattle, horse, pigs, chicken, turkey and varied combination fresh, respectively	4,729
2	Avermectins ²	14.1	300, 300, 230, 135, 300, 230, 90, 45, 300, and 300 samples are scheduled for bulls, boars/stags, goats, heavy calves, lambs, mature sheep, non-formula-fed veal, rabbits, roaster pigs, and sows, respectively.	300, 60, 90, 90 and 24 samples are scheduled for fresh beef, processed beef, fresh veal, fresh lamb and mutton, and fresh goat, respectively	2,794
3	Carbadox ³	12.4	300 and 300samples are scheduled for market hogs and roaster pigs, respectively.	No samples are scheduled for the 2008 NRP.	600
4	Florfenicol ⁴	12.1	230, 230, and 90 samples are scheduled for beef cows, mature chickens, and non-formula fed veal, respectively.	88 samples are scheduled for fresh beef.	638
5	Sulfonamides ⁵	12.0	230, 230, 300, 230, 135, 300, 230, 300, 90, 230, 300, 230, and 300 samples are scheduled for bob veal, dairy cows, egg products, goats, heavy calves, heifers, market hogs, mature chickens, non-formula-fed veal, roaster pigs, sows, steers, and young chickens, respectively.	300, 60, 8, 230, 64, 16, 8, 8, 16, and 90 are scheduled for fresh beef, processed beef, fresh horse, fresh pork, processed pork, fresh turkey, processed turkey, fresh varied combo, processed varied combo, and fresh veal, respectively.	3,905
6	Arsenicals ⁶	6.8	300, 300 and 300 samples are scheduled for beef cows, egg products, and mature turkeys, respectively ⁷ .	96, 16, 16, 8, and 8 samples are scheduled for fresh pork, fresh turkey, fresh chicken, processed chicken, and processed turkey, respectively.	1,044

Rank	Veterinary Drug	Seene	Scheduled Sam	0	Total
Канк	Velerinary Drug	Score	Domestic	Import	Totat
7	Thyreostats ⁸	5.9	300 samples are scheduled for beef cows	90 samples are scheduled for fresh veal	390
8	Dipyrone ⁹	5.5	Not in the 2008 NRP	Not in the 2008 NRP	0
9	ß-Agonists	5.5	230, 300, and 90 samples are scheduled for goats, market hogs, and non-formula fed veal, respectively.	90 and 96 samples are scheduled for fresh veal and pork, respectively.	806
10	Flunixin ¹⁰	5.3	90 and 90 samples are scheduled for bulls and dairy cows, respectively.	88 samples re scheduled for fresh beef.	268
11	Berenil ¹¹	5.2	Not in the 2008 NRP	Not in the 2008 NRP	0
12	Trenbolone	5.1	90 and 90 samples are scheduled for formula-fed veal and non-formula-fed veal, respectively.	No samples are scheduled for the 2008 NRP.	180
13	Zeranol ¹²	5.1	90 and 90 samples are scheduled for formula-fed veal and non-formula-fed veal, respectively.	90 samples are scheduled for fresh veal.	270
14	Methyl prednisone ¹³	4.7	Not in the 2008 NRP	Not in the 2008 NRP	0

Rank	ank Veterinary Drug Score Score			<u> </u>	Total
Канк	velerinary Drug	score	Domestic	Import	10101
15	Dexamethasone ¹⁴	4.7	Not in the 2008 NRP	Not in the 2008 NRP	0
16	Thiamphenicol ¹⁵	4.6	Not in the 2008 NRP	Not in the 2008 NRP	0
17	Eprinomectin	4.5	Not in the 2008 NRP	Not in the 2008 NRP	0
18	Clorsulon ¹⁶	4.5	Not in the 2008 NRP	Not in the 2008 NRP	0
19	Amprolium ¹⁷	4.2	Not in the 2008 NRP	Not in the 2008 NRP	0
20	Halofuginone ¹⁸	4.0	Not in the 2008 NRP	Not in the 2008 NRP	0
21	Benzimidazoles ¹⁹	3.9	Not in the 2008 NRP	Not in the 2008 NRP	0
22	Lasalocid ²⁰	3.8	Not in the 2008 NRP	Not in the 2008 NRP	0

Rank	Vataningm, Duug	Score	Scheduled Samples				
канк	Veterinary Drug	score	Domestic	Import	Total		
23	Prednisone ²¹	3.8	Not in the 2008 NRP	Not in the 2008 NRP	0		
24	Etodolac ²²	3.8	Not in the 2008 NRP	Not in the 2008 NRP	0		
25	Hormones (naturally- occurring) ²³	3.8	Not in the 2008 NRP	Not in the 2008 NRP	0		
26	Melengesterol acetate ²⁴ (MGA)	3.0	300 samples are scheduled for heifers.	No samples are scheduled for the 2008 NRP.	0		
27	Levamisole ²⁵	3.0	Not in the 2008 NRP	Not in the 2008 NRP	0		
28	Morantel and pyrantel	2.5	Not in the 2008 NRP	Not in the 2008 NRP	0		
29	Nicarbazin ²⁶	1.9	Not in the 2008 NRP	Not in the 2008 NRP	0		
30	Veterinary tranquilizers ²⁷	1.9	Not in the 2008 NRP Not in the 2008 NRP		0		

¹ <u>Tetracyclines :</u> tetracycline, oxytetracycline, chlortetracycline (HPLC for identification, quantitation by bioassay). <u>Aminoglycosides:</u> spectinomycin, hygromycin, streptomycin, dithydrostreptomycin, amikacin, kanamycin, apramycin, gentamycin, tobramycin (LC/MS/MS for confirmation, quantitation of streptomycin, dihydrostreptomycin,

gentamycin, and neomycin by bioassay). <u>Macrolides :</u> lincomycin, pirlymycin, clindamycin, tilmicosin, erythromycin, and tylosin. All macrolides are confirmed by LC/MS/MS. Tilmicosin is also quantitated by HPLC. Erythromycin and tylosin are quantitated by the bioassay. <u>Beta Lactams :</u> 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). <u>Fluroquinolones:</u> ciprofloxacin, norfloxacin, errofloxacin, sarafloxacin, difloxacin, desethylene diprofloxacin, desmethyl danofloxacin (LC/MS/MS for confirmation).

² Doramectin, ivermectin, and moxidectin; Antiparasitic.

³ Antimicrobial.

⁴ Chloramphenicol derivative.

⁵ Sulfonamides in the FSIS multi-residue method (MRM): Sulfapyridine, sulfadiazine, sulfathiazole, sulfamerazine, sulfamethazine, sulfachloropyridazine, sulfadoxine, sulfamethoxypyridazine, sulfadimethoxine, sulfadimethoxine, sulfacetamide, sulfamethoxazole, sulfamethizole, sulfamilamide, sulfaguanidine, sulfabromomethazine, sulfasalazine, sulfatethoxypyridazine, sulfaphenazole, and sulfatroxazole; Antimicrobials, some are coccidiostats;

FDA has not set a tolerance for the following sulfonamides: sulfapyridine, sulfadiazine, sulfadoxine, sulfamethoxypyridazine, sulfasoxazole, sulfacetamide, sulfamethoxazole, sulfamethizole, sulfanilamide, sulfaguanidine, sulfasalazine, sulfaphenazole, and sulfatroxazole.

⁶ Detected as As

⁷ Beef cows, market hogs, roaster pigs, boars and stags, sows, mature chickens, and mature turkeys have a 0% violation rate for arsenic for the 3 year period (2001-2003). These production classes were rotated back into the scheduled sampling program for 2006 based on the expert opinion of the Surveillance Advisory Team (SAT). Samples from beef cows and mature turkeys are scheduled for the 2008 NRP.

⁸ Includes 2- thiouracil, 6-methyl-2-thiouracil, 6-propyl-2-thiouracil, 2-mercapto-1-methylimidazole, 2- mercaptobenzimidazole

⁹ Non-Steroidal Anti-Inflammatory Drug (NSAID).

¹⁰ Non-Steroidal Anti-Inflammatory Drug (NSAID). Although not in the FSIS Scheduled sampling plan for 2008, testing forflunixin will be conducted for inspector generated samples found FAST positive.

¹¹ Antiprotozoal.

- ¹² Xenobiotic hormone
- ¹³ Glucocorticoid.
- ¹⁴ Glucocorticoid.
- ¹⁵ Chloramphenicol derivative
- ¹⁶ Anthelmintic, Trematodes

¹⁷ Coccidiostat

¹⁸ Antiprotozoal, coccidiostat

¹⁹ 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); Anthelmintics

²⁰ Coccidiostat

²¹ Glucocorticoid

²² Non-Steroidal Anti-Inflammatory Drug (NSAID).

²³ 17-Estradiol, testosterone, and progesterone

²⁴ Xenobiotic hormone

²⁵ Anthelmintic

²⁶ Coccidiostat

²⁷ Azaperone and its metabolite azaperol, xylazine, haloperidol, acetopromazine, propionylpromazine, and chlorpromazine

Summary Table III Rank and Status for Pesticides 2008 FSIS NRP, Domestic Scheduled Sampling Plan

Rank	Compound / Compound Class ¹	Score	Status in the 2008 NRP		Total
Канк	Compound / Compound Class		Domestic	Import	10101
1	Chlorinated hydrocarbons (CHCs) and chlorinated organophosphates (COPs) – those compounds in the FSIS multi-residue method (MRM) ² including formerly registered pesticides: DDT and coumaphos, and registered pesticides such as endosulfan	16.0	300, 230, 300, 230, 135, 300, 300, 230, and 230 samples are scheduled for beef cows, boars/stags, dairy cows, goats, heavy calves, heifers, lambs, mature sheep, and sows, respectively	300, 79, 230, 64, 90, 24, 16, 16, 8, 8, 16, 8, and 16 samples are scheduled fresh beef, processed beef, fresh pork, processed pork, fresh lamb/mutton, fresh goat, fresh turkey, fresh chicken, processed chicken, processed turkey, other fowl fresh, fresh varied combo, processed varied combo, respectively	3,130
2	Chlorinated organophosphates (COPs) and organo phosphates (OPs) - those compounds not in FSIS COP and OP multi-residue method (MRM) ³	16.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0
3	Imazalil	16.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0
4	Triazines – those compounds not in FSIS triazine multi- residue method (MRM) ⁴	15.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0
5	Carbamates – those compounds in the FSIS carbamate triazine multi-residue method (MRM) ⁵	14.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0
6	Synthetic Pyrethroids – those compounds in the FSIS synthetic pyrethrin (pyrethroids) multi-residue method (MRM) ⁶	14.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0
7	1-(2,4-Dichlorophenyl)-2-(1H-imidazole-1-yl)-1- ethanol ⁷	14.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0

Summary Table III (continued) Rank and Status for Pesticides 2008 FSIS NRP, Domestic Scheduled Sampling Plan

Rank	Compound / Compound Class ¹	Score	Status in the 2008 NRP		- Total	
капк	Compouna / Compouna Class		Domestic	Import	10101	
8	1,1-(2,2-Dichloroethylidene)bis(4-methoxybenzene) ⁸	14.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0	
9	1-Methoxy-4-(1,2,2,2-tetrachloroethyl)benzene) ⁹	14.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0	
10	3-(1-(2,4-Dichlorophenyl)-2-(1H-imidazole-1-yl) ethoxy)-1,2-propane diol ¹⁰	14.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0	
11	Cyhalothrin, lambda	14.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0	
12	Fipronil ¹¹	14.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0	
13	MB 45950	14.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0	
14	MB 46513	14.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0	
15	Methoxychlor olefin	14.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0	

Summary Table III (continued) Rank and Status for Pesticides 2008 FSIS NRP, Domestic Scheduled Sampling Plan

Rank	Compound / Compound Class ¹	Score	Status in the 2008 NRP		– Total
капк	Compouna / Compouna Class		Domestic	Import	
16	Triazines – compounds in FSIS triazine multi-residue method (MRM) ¹²	13.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0
17	Arsanilic acid	13.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0
18	Etoxazole	13.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0
19	Indoxacarb	13.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0
20	Metconazole	13.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0
21	Prothioconazole	13.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0
22	Tetraconazole	13.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0
23	Triflumizole	13.0	Not in the 2008 NRP.	Not in the 2008 NRP.	0

Summary Table III (continued) Rank and Status for Pesticides 2008 FSIS NRP, Domestic Scheduled Sampling Plan

² 2,2',4,4',5,5'-hexabromobiphenyl (HBB), Aldrin, BHC alpha, BHC beta, BHC delta, chlordane-cis (-alpha), chlordane-trans, chlorfenvinphos, Chlorpyrifos, Chlorpyrifos methyl, Coumaphos O-analog (oxon), Coumaphos S, Dieldrin, Endosulfan I, Endosulfan sulfate, endrin, halowaxes, Heptachlor, Heptachlor epoxide A, Heptachlor epoxide B, Hexachlorobenzene, Lindane, Methoxychlor, Mirex, o,p'-DDE (2,4), o,p'-DDT, o,p'-TDE (DDD), p,p'-DDE (4,4), p,p'-DDT, p,p'-TDE (DDD), Phosalone, polybrominated biphenyls (PBBs), polychlorinated biphenyls (aroclors 1254, 1260) (PCBs), tetrachlorvinphos (stirofos), Toxaphene, and trans-nonachlor.

³ Regulatory method is needed: Azinphos-methyl, azinphos-methyl oxon, chlorpyrifos, coumaphos, coumaphos oxon, diazinon, diazinon oxon, diazinon met G-27550, dichlorvos, dimethoate, dimethoate oxon, dioxathion, ethion monooxon, fenthion, fenthion oxon, fenthion oxon sulfone, fenthion oxon sulfoxide, fenthion sulfoxide, malathion, malathion oxon, naled, phosmet, phosmet oxon, pirimiphos-methyl, trichlorfon, tetrachlorvinphos, tetrachlorvinphos-4 metabolites, acephate, methamidophos, chlorpyrifos-methyl, fenamiphos sulfoxide,fenamiphos sulfoxide,fenamiphos sulfoxide desisopropyl, fenamiphos sulfore desisopropyl, isofenphos oxon, isofenphos desisopropyl, isofenphos oxon desisopropyl, methidathion, ODM, parathion (ethyl), parathion oxon, parathion methyl, parathion methyl oxon, phorate oxon, phorate oxon sulfone, phorate oxon sulfoxide, phorate sulfoxide, profenofos, sulprofos oxon, sulprofos oxon sulfoxide, sulprofos sulfone, sulprofos sulfoxide, tribufos (DEF).

⁴ Regulatory method is needed: Atrazine chloro metabolites, metribuzin, metribuzin DADK, metribuzin DA, metribuzin DK, amitraz, amitraz 2,4-DMA metabs., desdiethyl simazine, desethyl simazine, simazine chloro metabolites.

⁵ Regulatory method is needed: Aldicarb, aldicarb sulfoxide, aldicarb sulfone, carbaryl, carbofuran, carbofuran, 3-hydroxy.

⁶ Cypermethrin, *cis*-permethrin, *trans*-permethrin, fenvalerate, *zeta*-cypermethrin.

⁷ Regulatory method is needed.

⁸ Regulatory method is needed.

⁹ Regulatory method is needed.

¹⁰ Regulatory method is needed.

¹¹ Regulatory method is needed.

¹² Atrazine, simazine, propazine, terbuthylazine

¹ Only those pesticides that have been designated as representing a broad potential public health risk are included in this summary table. For a complete list of pesticides that were considered for the 2008 NRP, see Table 27.

Summary Table IV Rank and Status of Unavoidable Contaminants 2008 FSIS NRP, Domestic and Import Scheduled Sampling

Unavoidable Contaminant ¹	Scheduled Samples				
Unavoladore Contaminani	Domestic	Import	Total		
Lead and cadmium	300 samples are scheduled for beef cows.	No samples are scheduled for the 2008 NRP.	300		

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

Overview of the National Residue Program Design

The USDA's Food Safety and Inspection Service (FSIS) obtains information on the occurrence of residues in meat, poultry, and egg products from two principal sources: the domestic and import scheduled sampling plans. The design of the domestic and import sampling plans begins with the generation of a list of residues that may occur in meat, poultry, and egg products and that are of concern to human health. To develop this list, FSIS coordinates a meeting of the Surveillance Advisory Team (SAT). The SAT is an interagency committee comprised of members from the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Agricultural Marketing Service (AMS), the Agricultural Research Service (ARS), and FSIS. The SAT identifies the priority compounds of public health concern, and provides FSIS with detailed information about each compound. FSIS then combines this information with its historical data on compound violation rates to develop the domestic scheduled sampling and the import reinspection plan. These sampling plans guide the allocation of FSIS laboratory and inspection resources.

Factors taken into consideration in developing the domestic and import scheduled sampling plans are:

- The overall estimated relative public health risk associated with each compound or compound class in meat, poultry, and egg products;
- The production classes in which each compound or compound class is likely to be of concern;
- The availability of analytical methods, which determines which compounds or compound classes can be analyzed; and
- The analytical capacity of the FSIS laboratories, which determines how many analyses of each compound or compound class can be performed.

The process used to design the import plan is similar to that of the domestic plans, with two important exceptions. First, since many countries ship processed products only, it is often not possible to test raw product at the U.S. port-of-entry. Further, even when raw product is shipped, it often consists of muscle tissue only. By contrast, domestic residue testing often is targeted towards organ tissues (typically kidney and liver). This is because many residues concentrate in organs, which makes them easier to detect. Because of this concentration effect, FDA often bases its tolerances for veterinary drugs upon the levels found in kidney or liver. Second, while countries are required to identify the animal species used in each product, they are not required to identify the production class. Testing on imported meat and poultry is subdivided by animal species (e.g., chicken vs. pig), and cannot be further subdivided within a species (e.g., steer vs. heifer vs. dairy cow. vs. formula-fed veal). Egg products, however, can be distinguished as a separate category.

Because different countries have different approved compounds and different use practices, 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

The candidate veterinary drugs of concern selected by members of the Surveillance Advisory Team (SAT) are presented below and in Table 1. Some veterinary drugs are grouped together because they are (or are likely to be) detected by the same analytical methodology. 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 bioassay¹)

<u>Tetracyclines</u>: tetracycline, oxytetracycline, chlortetracycline (HPLC for identification, quantitation by bioassay). <u>Aminoglycosides</u>: spectinomycin, hygromycin, streptomycin, dithydrostreptomycin, amikacin, kanamycin, apramycin, gentamycin, neomycin, tobramycin (LC/MS/MS for confirmation, quantitation of streptomycin, dihydrostreptomycin, gentamycin, and neomycin by bioassay). <u>Macrolides</u>: Lincomycin, pirlymycin, clindamycin, tilmicosin, erythromycin, and tylosin are confirmed by LC/MS/MS. Tilmicosin is also quantitated by HPLC. Erythromycin and tylosin are quantitated by the bioassay. <u>Beta-Lactams</u>: amoxicillin, ampicillin, cloxacillin, naficillin, cefazolin, DCCD, dicloxacillin, penicillin G and ampicillin). <u>Fluoroquinolones</u>: ciprofloxacin, norfloxacin, 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 MRM: doramectin, ivermectin, and moxidectin)
- Benzimidazoles (classification: anthelmintics; compounds in FSIS MRM: thiabendazole and its 5hydroxythiabendazole 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: NSAID²)
- Eprinomectin (classification: antiparasitic; avermectin)
- Etodolac (classification: NSAID)

¹ FSIS quantitates most antibiotics using a 7-plate bioassay that measures microbial inhibition. The pattern of inhibition (i.e., the combination of plates showing inhibition) is used to identify the antibiotic. There are some antibiotics, however, that share the same pattern of inhibition. For these antibiotics, it is necessary to undertake follow-up testing (High Performance Liquid Chromatography or mass spectrometry) to establish their identities, where such follow-up methodologies are available.

² NSAID = *non*-steroidal anti-inflammatory drug

- 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, sulfascetamide, sulfamethoxazole, sulfamethizole, sulfanilamide, sulfaguanidine,
- sulfabromomethazine, sulfasalazine, sulfaethoxypyridazine, sulfaphenazole, and sulfatroxazole)
- Sulfanitran (classification: antibacterial, coccidiostat)³
- Thyreostats (compounds: 2-thiouracil, 6-methyl-2-thiouracil, 6-proply-2-thiouracil, 2-mercapto-1methylimidazole (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)

Drugs Banned from Extralabel use under AMDUCA

FDA has advised FSIS that drugs banned from extralabel use under AMDUCA, called AMDUCA prohibited, are of high public health concern. Therefore, these AMDUCA prohibited drugs are not evaluated for inclusion using the ranking formula presented below. Instead, all AMDUCA drugs are automatically assigned a high sampling priority, and are included in the NRP if methodologies and resources are available. AMDUCA prohibited drugs are listed in Summary Table I, *Status of AMDUCA Prohibited Drugs (page 2)*.

³ FSIS, in consultation with FDA, rotated sulfanitran out of the NRP beginning in the 2005 NRP.

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 drug classes in each of the following categories:

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

Definitions of each of these categories, and the criteria used for scoring, appear at the end of this section in the *Scoring Key for Veterinary Drugs*, 2008 Domestic Residue Program.

The results of the compound scoring process are presented in Table 1, *Scoring Table for Veterinary Drugs*.

Compound Ranking

1. Background

As stated above, FSIS employs risk assessment techniques and principles to obtain a ranking of the relative public health concern represented by each of the above candidate compounds or compound classes.

If FSIS were 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 could be combined with consumption data to estimate exposure. By combining these exposure data with toxicity information, risk is estimated for each compound or compound class from the following:

	Equation 1
=	Exposure x Toxicity Consumption x Residue Levels x Toxicity Consumption x Risk per Unit of Consumption

FSIS does not currently attempt to associate different degrees of risk with different amounts or percentages by which the tolerance or action level is exceeded. FSIS instead determined that the best available method for the measurement of relative toxicity is 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.*

The category, (see *FSIS Historical Testing Information on Violations*, Table 1) is based on the percent of tested carcasses found to have residues in excess of the tolerance or action level. This percentage is determined from data obtained from the FSIS domestic scheduled sampling plan. Drug compounds were scored by two methods: (a) the maximum violation rate seen in any production class (averaged over 1997-2006); and (b) the maximum, for any production class, of the violation rate (again, averaged over 1997-2006), but weighted by the size of the production class. The final score for each drug was assigned based

on the higher of these two scores.⁴ Therefore, it can be seen from *Equation 1* that the violation rate scores assigned in Table 1 represent a rough overall estimate of *relative* risk per unit of consumption.⁵ However, for the many candidate compounds or compound classes of concern that have never been included in the FSIS NRP, data on violation rates are not available. It was therefore necessary to generate an estimate of the overall violation rate for each these untested compounds and compound classes.

2. Estimating the Violation Rate

"Regulatory Concern," "Withdrawal Time," and "Relative Number of Animals Treated" were chosen as scoring categories to estimate the violation rate because they are expected to be positively correlated with the violation rate. Therefore, categories are expected to serve as predictors of violations in those compounds or compound classes for which no reliable historical testing information was available. As indicated in the *Scoring Key for Veterinary Drugs* (see page 27), the category, "Regulatory Concern," was designed to predict the "likelihood of occurrence of violations, based on regulatory intelligence information about possible misuse." The category, "Withdrawal Time," is expected to correlate with "FSIS Historical Testing Information on Violations" because a longer withdrawal time is less likely to be properly observed. When a withdrawal time for a 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 drug would not have passed. The category, "Relative Number of Animals Treated," is expected to correlate with "FSIS 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. Using the scores assigned to these compounds and compound classes, it was possible to evaluate how well the above criteria correlate. In an effort to impute values for the missing data, a linear regression model was applied. The dependent variable in this model is the category, "FSIS 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."

Nine compounds or compound classes for which current, reliable data were available to score the category "FSIS Historical Testing Information on Violations," and 21 compounds or compound classes for which there were no data are listed in Table 1. A least squares linear regression model, using the value of the independent variable from the nine (9) scored compounds or compound classes, was then used to predict scores in the category "FSIS Historical Testing Information on Violations" for the 21 compounds for which this information is not available. The following equation was derived:

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 "FSIS 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, in Phase IV, using Equation 6; the results are presented in Table 5.

 $Equation \ 2$ Vp = 1.157 + 0.18 (W*N) $Vp = Predicted \ score \ for "FSIS \ Historical \ Testing \ Information \ on \ Violations"$ $W = score \ for "Withdrawal \ Time$ $N = Score \ for "Relative \ Number \ of \ Animals \ Treated"$ $W*N = Product \ of \ W \ and \ N.$

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
- W²
- N²
- 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 an overall model p-value of 0.09 and a regression value (R^2) of 0.52, which explains a 52% variability in the data.

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, "FSIS 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 drug or 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. The general form of the calculation is given in Equation 3 and the scores for relative public health concern are summarized in Table 1 (see page 31).

Equation 3

- Relative Public Health Concern = *Predicted* or *Actual* score for "FSIS 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 drug violation means that a compound was found at a level where the likelihood of a toxic effect exceeds the Food and Drug Administration's (FDA's) standards. However, this does not address the *severity* of the effect associated with the toxic endpoint. To capture this concern FSIS has added the category "Acute or Chronic Toxicity Concerns." Compounds in this category that have the highest degree of human toxicity 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 category, "Lack of FSIS Testing Information on Violations," has been removed from the expression for relative public health concern beginning with the planning of the 2006 NRP. SAT and other residue experts observed that the scores for the category lacked variability and, therefore, did not result in significant variability in the relative public health concern for a residue.

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 that were considered differed principally in the relative weights given to the categories, "Acute or Chronic Toxicity Concerns" versus "Impact on New and Existing Human Disease." FSIS selected the formula shown in the column for "Relative Public Health Concern Score" in Table 1. The selection is based on a consensus by the SAT about the relative importance of each category, and how much each category should be allowed to alter the underlying risk-based score, "V," in Equation 4. In this formula, the score for "FSIS 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. The selected formula formalizes the basis of FSIS's judgment for relative public health concern for each compound and enables others to observe and understand the adjustments that were made. It also ensures consistency in how these adjustments were applied across a wide range of compounds. Equation 4 summarizes the way final adjustments were made.

Equation 4

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

$$\begin{split} R &= V((D+3T)/4) \\ V &= Predicted \text{ or } Actual \text{ score for "FSIS Historical Testing Information on Violations"} \\ D &= \text{ score for "Impact on New and Existing Human Disease"} \\ T &= \text{ score for "Acute or Chronic Toxicity Concerns"} \end{split}$$

In this formula, the category, "Acute or Chronic Toxicity Concerns," was given 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.

The formulas used in this section for the veterinary drugs and in the section for the 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. However, as a result of the normalization, 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.

In Summary Table II, *Rank and Status for Veterinary Drugs* (page 3), the drugs are ranked by their rating scores, as generated using the above weighting formula. The scores presented in the Summary Table II enable FSIS to bring consistency, grounded in formal risk-based considerations, to its efforts to differentiate among a very diverse range of drugs and drug 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, when relative exposure values for each compound/production class (C/PC) pair are estimated.

II. Prioritizing Candidate Drugs

Once the ranking of the veterinary drugs was completed, the ranking scores for relative public health concern were used as criteria for selecting compounds and compound classes to include in the 2008 NRP and to determine which compounds and compound classes to include in the 2008 NRP based on the availability of laboratory resources.

The consensus of FSIS and FDA was that those compounds and compound classes that have rankings of 1-10, 12, and 13 (out of a total of 30) represent a potential public health concern sufficient to justify their inclusion in the 2008 NRP. In addition, FSIS is performing limited testing on MGA (ranked 26th).

Once the high-priority compounds and compound classes had been identified, it was necessary for FSIS to apply practical considerations to determine the compounds for which the Agency would sample. The principal consideration was the availability of laboratory resources, especially the availability of appropriate analytical methods within the FSIS laboratories. Based on these considerations, FSIS plans to schedule the following veterinary drugs in the 2008 NRP for domestic sampling:

- Antibiotics (7-plate bioassay)
- Arsenicals
- Avermectins
- *beta*-Agonists
- Carbadox
- Chloramphenicol
- Florfenicol
- Flunixin
- Melengestrol acetate (MGA)
- Nitrofurans
- Nitroimidazoles
- *Phenylbutazone*, Note that phenylbutazone will not be scheduled in the 2008 NRP. However, FAST positive samples will be tested for phenylbutazone.
- Sulfonamides
- Thyreostats
- Xenobiotic hormones

In the 2008 NRP, FSIS will employ a number of analytical methodologies to characterize (identify and quantitate) veterinary drug residues. The methodologies are effective for the analysis of individual compounds and there are also multi residue methods (MRMs) for antibiotics, avermectins, *beta*-agonists, and sulfonamides that distinguish individual compounds in a compound class.

Summary Table II (see page 3) lists all of the original candidate veterinary drugs in rank order. This table specifies individual compounds and compound classes that will be scheduled for domestic sampling in the 2008 NRP. For each highly ranked compound or compound class that is not included for domestic sampling in the 2008 NRP, a brief explanation of the reason for its exclusion is provided. This table will be used to identify future method development needs for veterinary drugs for the FSIS NRP.

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

The SAT participants identify the production classes of concern for each of the drugs and drug classes to be included in the 2008 NRP. These determinations were based upon professional judgment of the likelihood of finding violations within each production class (information examined included use approvals, extent of use, evidence of misuse and, if available, past violation history), combined with the proportion of total domestic meat consumption each production class represented. The results are presented in Table 3, *Production Classes Considered for Each Veterinary Drug/Drug Class* (see page 37). Compound/Production Class pairs included in the 2008 NRP are designated by a "●." Those C/PC pairs that are of regulatory concern, but that could not be included in the 2008 NRP because of laboratory resource constraints, are marked with a "○."

Production class nomenclature:

- Beef cows are mature female cattle bred for muscle development, ordinarily having given birth to one or more calves.
- Boars are mature swine showing male sexual characteristics.
- 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.
- Ducks are birds of both sexes and any age.
- Egg products are yolks, whites, or whole eggs after breaking and are processed as dried, frozen, or liquid.
- Geese are birds of both sexes and any age.
- Goats are animals of both sexes and any age.
- Heifers are young, female cattle that have not yet given birth to a calf.
- Lambs are generally defined as sheep younger than 14 months and having a break joint in at least one leg.
- Market hogs are swine usually marketed near six months of age and 200 to 300 pounds live weight.
- 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 livestock include bison, deer, elk, etc.

- Other poultry include ratites (typically ostriches, emus and rheas), guineas, squabs (young, unfledged pigeons), adult pigeons, pheasants, grouse, partridge, quail, etc.
- Rabbits are any of several lagomorph mammals of both sexes and any age.
- Roaster pigs are animals of both sexes and any age that are marketed with the carcass unsplited and with the head on.
- Sheep are mature animals of both sexes.
- 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.
- Steers are male cattle castrated before sexual maturity.
- 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 8 months of age.
- Young turkeys include fryer/roaster birds that are of both sexes and usually less than 12 weeks of age, and include turkeys that are birds of both sexes usually less than 6 months of age.

IV. Allocation of Sampling Resources

"Full-Resource" Sampling

Table 3 lists the estimated consumption of each production class as a percentage of the total consumption of all the production classes in the table. To obtain these estimates, production data for animals (and egg products) that were presented for slaughter (or processing) in federally inspected establishments during calendar year 2006 were employed as a surrogate for consumption. The production data for calves were collected, collated and reported by FSIS, using the Automated Data Reporting System. 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. As shown in Equation 5, the estimated relative percent of consumption represented by each production class was obtained by dividing the estimated total annual U.S. domestic production (pounds dressed weight) for that class by the total poundage for all production classes that are listed in Table 3:

Equation 5 Percent Estimated Relative Percent of Domestic Consumption (ERC)

> ERC = AP/TP x 100 AP = Annual Production (dressed weight in pounds) TP = Total Annual Production of all Production Classes

All calculations and results are presented in Table 3, *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 4 and as presented in Table 3). The resulting priority score for compound-production class pairs is shown in tables 4 and 5 and is calculated as follows (Equation 6):

Equation 6

Priority Score (PS)

PS = CP x 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 C/PC pair, and thus can be used to prioritize FSIS analytical sampling resources according to the latter. Note that the risk ranking provided by Equation 6 is based upon average consumption across the entire U.S. population, rather than upon maximally exposed individuals.

In Table 4, Veterinary Drug Compound-Production Class Pairs, Sorted by Sampling Priority Score, "Full Resource" Sampling, the calculation shown in Equation 6 has been carried out for the antibiotics, arsenicals, avermectins, and sulfonamides, MGA, florfenicol, flunixin, xenobiotic hormones, carbadox, *beta*-agonists, and thyreostats for each production class in which the specified drug might appear (as indicated in Table 5). Initially, the compound-production class pairs were sorted by their sampling priority scores (see Table 4). Then, the compound-production class pairs were assigned sampling numbers of 300. These priority scores were combined with historical violation rate information for each individual compound-production class pair, information on laboratory sampling capacity, and the number of slaughter facilities to select, for each pairing the final number of samples to be scheduled for each analysis. 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, 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 typically done for larger production classes, since these represent a larger potential consumer exposure).

Beginning in the 2006 NRP, minor species, rabbits, ratites, squab, geese, ducks, and bison, have not be scheduled for the domestic sampling program. The reason is that minor species are low production animals. Not scheduling the minor species allows FSIS to focus those resources on the development of methodologies in areas that are of high public health concern. However, based on field reports, FDA expressed interest in performing limited testing for antibiotics in ducks and rabbits, and for avermectins in rabbits in the 2008 NRP.

Adjusting Relative Sampling Numbers

Adjusting for historical data on violation rates of individual C/PC pairs

As described above, FSIS uses "FSIS Historical Testing Information on Violations" as a critical factor in ranking the various veterinary drugs and drug classes according to their relative public health concern. Because this information is available for each production class individually, it can also be used to further refine the relative priority of sampling each C/PC pair. Table 5, *Number of Scheduled Samples for Veterinary Drug/Production Class Pairs, 2008 NRP Domestic Scheduled Sampling*, lists the number of analyses assigned to each C/PC pair in Table 4. Table 5 also reports the total number of samples analyzed in the FSIS scheduled sampling plan for the period 01/01/1997-12/31/2006, and 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) for each compound-production class pair. Using these data, the following rules were applied to adjust the sampling numbers:

- If less than 300 samples (i.e., 230 samples) were tested in the FSIS scheduled sampling plan for a compound-production class pair for the period of 01/01/1997-12/31/2006, maintain the sampling level (if 300 were assigned initially, maintain 300 samples).
- If the number of samples tested in the FSIS scheduled sampling plan for a compound-production class pair for the period 01/01/1997-12/31/2006 was 300 samples, and violations were found during CY 2007, or the violation rate greater than or equal to 0.70% (≥ 0.70%) during 01/01/1997-12/31/2006, decrease the sampling level using Statistical Table in Appendix III.
- If 300 samples were tested in the FSIS scheduled sampling plan for a compound-production class pair for the period 01/01/1997-12/31/2006, and no violations were found during CY 2007, maintain the sampling level.
- If at least 300 samples tested in the FSIS scheduled sampling plan for a compound-production class pair (for the period 01/01/2004-12/31/2006), and a violation rate of 0.00% was found, rotate the C/PC pair out of the NRP.⁶
- The maximum number of samples to be scheduled for testing is 300.

All of the above adjustments were applied, and the sampling numbers obtained following these adjustments are listed in Table 5 under the heading "Initial Adjustment" (initial adjusted number of samples).

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

An adjustment to the total number of scheduled samples was made based on the number of production facilities. For this adjustment, FSIS considered the total number of production facilities (USDA Inspected Establishments for 2006) 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

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

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 1 level (if 300 were assigned initially, decrease to at least 230 samples).

Adjustment for a zero percent (0%) violation rate for the three year period, 2004 – 2006

FSIS historical violation data were examined for the 2004-2006 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

The total number of scheduled samples for compound-production class pairs were obtained following adjustments for laboratory capacity, production, and violation rate data are listed in Table 5, under the heading "Final Adjustment."

"Limited Resource" Sampling

The 2008 NRP includes a number of compounds for which FSIS does not have extensive sampling data. FSIS is concerned with obtaining information on their occurrence in production classes where it is suspected they 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 2008 NRP, selection of production classes for the limited resource sampling for compounds (Table 5) was made as follows:

- Flunixin is of concern in bulls, dairy cows, beef, cows, and heavy calves. The analytical capacity is 260 samples for flunixin in the domestic 2008 NRP. FSIS will schedule 180 analyses for flunixin in bulls, and dairy cows for domestic sampling and 88 fresh beef samples for the import program for a total of 258 samples.
- Nitrofurans (furazolidone and furaltadone) are of concern in dairy cows, market hogs and sows. The analytical capacity for nitrofurans in the 2008 NRP is 830 samples. FSIS will schedule 830 analyses for nitrofurans in dairy cows, market hogs and sows for domestic sampling in the 2008 NRP. No import samples are scheduled for nitrofurans.
- Nitroimidazoles (dimetridazole and ipronidazole) are of concern in young chickens. The analytical capacity for nitroimidazoles in the 2008 domestic NRP is 300 samples. FSIS will schedule 300 analyses for nitroimidazoles for young chickens in the 2008 NRP and will also schedule 16 fresh chicken import samples for a total of 316 nitroimidazole samples.

- Phenylbutazone is of concern in bulls, dairy cows, and beef cows for the 2008 domestic NRP; the analytical capacity for phenylbutazone is limited. FSIS will not schedule samples for the domestic 2008 domestic or import program. However, testing for phenylbutazone will be conducted for inplant FAST positive samples.
- Thyreostats are of concern beef cows for the 2008 domestic NRP; the analytical capacity for thyreostats is 300 samples. FSIS will schedule 300 analyses in beef cows for domestic sampling and 90 fresh veal samples for import sampling for a total of 390 samples.
- Trenbolone is of concern in formula-fed veal and non-formula-fed veal for the 2008 NRP; the analytical capacity for trenbolone is 180 samples in 2007 domestic NRP. FSIS will schedule 180 samples in formula-fed veal and non-formula-fed veal for domestic sampling. No samples will be scheduled for the import program.
- Zeranol is of concern in formula-fed veal and non-formula-fed veal for the 2008 NRP; the analytical capacity for zeranol is 270 samples in the domestic 2007 NRP. FSIS will schedule 180 samples in formula-fed veal and non-formula-fed veal for domestic sampling .FSIS will also schedule 90 fresh veal import samples for a total of 270 samples.

The above information is presented in tabular format at the end of the section, "Summary of Domestic and Import Sampling," in Table 50, *Combined Summary, 2008 FSIS NRP, Domestic and Import Scheduled Sampling, and Exploratory Assessments.*

V. Scoring Key

FSIS Historical Testing Information on Violations (01/01/1997 - 12/31/2006)

Violation rate scores were calculated by two different methods (see below), 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 (the number of violations over the period from 1997 - 2006, divided by the total number of samples analyzed). Score as follows:

 $\begin{array}{l} 4 = > 0.70\% \\ 3 = 0.31\% - 0.70\% \\ 2 = 0.15\% - 0.30\% \\ 1 = < 0.15\% \\ NT = & Not tested by FSIS \\ NA = & Tested by FSIS, but violation information does not apply \end{array}$

Note that the above violation rate criteria are different from those used in planning the 1998 - 2002 NRP's. For previous NRP's the criteria were as follows: 4 = > 1.0%; 3 = 0.50% - 1.0%; 2 = 0.15% - 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 (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. Score as follows:

 $\begin{array}{ll} 4 = > 0.15\% \\ 3 = 0.076\% - 0.15\% \\ 2 = 0.01\% - 0.075\% \\ 1 = < 0.01\% \\ NT = & \text{Not tested by FSIS} \\ NA = & \text{Tested by FSIS, but violation information does not apply} \end{array}$

A final score is determined by assigning, to each drug or drug class, the greater of the scores from Method A and Method B.

It can be seen that Method A identifies those 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 drugs that may not have the highest violation rates, but would nevertheless be 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

This consists of professional judgments made about the likelihood of occurrence of violations, based on regulatory intelligence information about possible misuse. Due to the public health significance of 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 not approved for use in food animals in the U.S.
- 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 drugs are required to follow approved "conditions of use." For each drug, in each production class in 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. This allows sufficient time for the concentration of drug in the animal to decrease below the tolerance. For approved drugs, the following scores were used:

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

For unapproved drugs, scores in this category were assigned based on estimates of their half-lives.

Impact on New and Existing Human Disease

This represents the extent to which the use or misuse of a drug may contribute to new and existing human disease by changing the patterns of antibiotic resistance in human pathogens. A score for impact on new and existing human disease is determined as follows:

- 4= Scientific information gathered from a variety of reliable sources indicates that possible widespread use of this compound might significantly modify drug resistance patterns of human pathogenic organisms.
- 3 = Limited scientific information is available to suggest or document public health risk but 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

These 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 drug fall within the top third of those administered to animals treated within a particular category and dosage form of active ingredient.
- 3 = Products containing this drug fall within the middle third of those administered to animals treated within a particular category and dosage form of active ingredient.
- 2 = Products containing this drug fall within the bottom 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," as defined below).
- 1 = Products containing this drug are estimated to have extremely limited usage.

Note: Where data were unavailable, scores were estimated, based on comparison to related drugs with known usage levels. Numbers estimated in this way are in parentheses.

Acute or Chronic Toxicity Concerns

This represents a combination of the toxicity of the compound and the severity associated with the compound's toxic endpoint.

- 4 = Compound is a carcinogen, or potentially life threatening, or has significant acute effects including the anaphylactic response to an allergen.
- 3 = Systemic No Observed Effect Levels (NOEL's) seen at intermediate to low doses in laboratory test animals. Antimicrobial effects with a high potential to alter intestinal microflora.
- 2 = Systemic NOEL's seen at high oral doses in laboratory test animals. 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 1Scoring Table for Veterinary Drugs2008 FSIS NRP, Domestic Scheduled Sampling

Compound / Compound Class	Historical Testing for Violations ¹ (V)	Regulatory Concern ² (R)	Withdrawal Time ³ (W)	Relative Number Treated ⁴ (N)	$\begin{array}{c} Predicted \ V \\ (V = 1.157 \ + \\ 0.18 \ (W^*N))^5 \end{array}$	Impact New & Existing Human Disease ⁶ (D)	Acute or Chronic Toxicity Concerns ⁷ (T)	Relative Public Health Concern Score (P = V[(D+3T)/4])
Antibiotics ⁸	4	4	4	4	4.0	3	4	15.1
Avermectins ⁹	4	3	4	4	4.0	2	4	14.1
Carbadox ¹⁰	3	4	4	3	3.0	3	4	12.4
Florfenicol	NA-3 ¹¹	3	4	4	4.0	3	3	12.1
Sulfonamides ¹²	4	4	3	4	4.0	3	3	12.0
Arsenicals ¹³	3	4	2	4	3.0	3	2	6.8
Thyreostats ¹⁴	NA-0 ¹⁵	4	3	1	1.7	2	4	5.9
Dipyrone ¹⁶	Not Tested	4	3	1	1.7	1	4	5.5
Ractopamine ¹⁷	2	4	2	3	2.0	2	3	5.5
Flunixin	3	4	2	3	3.0	1	2	5.3
Berenil ¹⁸	NA-2 ¹⁹	4	4	1	1.9	2	3	5.2
Trenbolone ²⁰	NA-2 ²¹	4	1	3	1.7	3	3	5.1
Zeranol ²²	NA-2 ²³	3	1	3	1.7	3	3	5.1
Methyl prednisone	Not Tested	4	2	2	1.9	1	3	4.7
Dexamethasone	NA-O ²⁴	4	2	2	1.9	1	3	4.7
Thiamphenicol	Not Tested	3	2	1	1.5	3	3	4.6
Eprinomectin	Not Tested	2	2	3	2.2	2	2	4.5
Clorsulon ²⁵	Not Tested	2	3	2	2.2	2	2	4.5
Amprolium ²⁶	Not Tested	4	2	2	1.9	3	2	4.2
Halofuginone ²⁷	NA-1 ²⁸	1	2	2	2.0	2	2	4.0

Table 1 (continued)Scoring Table for Veterinary Drugs2008 FSIS NRP, Domestic Scheduled Sampling

Compound / Compound Class	Historical Testing for Violations ¹ (V)	Regulatory Concern ² (R)	Withdrawal Time ³ (W)	Relative Number Treated ⁴ (N)	Predicted V (V = 1.157 + 0.18 (W*N)) ⁵	Impact New & Existing Human Disease ⁶ (D)	Acute or Chronic Toxicity Concerns ⁷ (T)	Relative Public Health Concern Score (P = V[(D+3T)/4])
Benzimidazoles ²⁹	Not Tested	1	3	2	2.2	1	2	3.9
Lasalocid ³⁰	Not Tested	2	1	3	1.7	3	2	3.8
Prednisone	Not Tested	2	2	1	1.5	1	3	3.8
Etodolac ³¹	Not Tested	3	2	1	1.5	1	3	3.8
Hormones, endogenous	Not Tested	2	1	4	1.9	2	2	3.8
Melengesterol acetate (MGA) ³²	1	3	1	4	1.0	3	3	3.0
Levamisole ³³	NA-1 ³⁴	3	3	2	3.0	1	1	3.0
Morantel and pyrantel ³⁵	Not Tested	1	1	2	2.0	2	1	2.5
Nicarbazin ³⁶	Not Tested	2	2	1	1.5	2	1	1.9
Veterinary tranquilizers	Not Tested	4	2	2	1.9	1	1	1.9

¹ Scores for historical testing information for residue violations, *V*, 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 the section on *Compound Rankings, Estimating Violation Rates*. Note that the predicted value is used unless *V* is known.

⁶ Scores impact on new and existing human disease, *D*, are provided by FDA's Centers for Disease Control (CDC).

⁷ Scores for acute or chronic toxicity concerns, *T*, are provided by FDA's Center for Veterinary Medicine (CVM).

⁸ Antibiotics in the 7-Plate Bioassay.

⁹ Avermectins in the FSIS MRM are doramectin, ivermectin, moxidectin.

¹⁰ Antimicrobial.

¹¹ NA-3 = The data are preliminary. Data have been collected for only 1-2 years for 2 or more production classes.

¹² Antimicrobials and some are coccidiostats.

¹³ Detected as As.

¹⁴ Includes 2-thiouracil, 6-methyl-2-thiouracil, 6-proply-2-thiouracil, 2-mercapto-1-methylimidazole (tapazole), 6-phenyl-2-thiouracil, and 2-mercaptobenzimidazole

Table 1 (continued)Scoring Table for Veterinary Drugs2008 FSIS NRP, Domestic Scheduled Sampling

¹⁵ NA-O = The data are preliminary. Data have been collected for only one year for 2 or more production classes. ¹⁶ NSAID. ¹⁷ Historical testing data for Ractopamine violations is used to determine the Relative Public Concern score for beta-Agonists. ¹⁸ Antiprotozoal, histomonas. ¹⁹ NA-2 = Scheduled sampling data have been collected for a single production class and for a limited time period. ²⁰ Xenobiotic hormone. 21 NA-2 = Scheduled sampling data have been collected for a single production class and for a limited time period. ²² Xenobiotic hormone. 23 NA-2 = Scheduled sampling data have been collected for a single production class and for a limited time period. Not included in regression analysis. ²⁴ NA-1 = Scheduled sampling data have not been collected in the past 3-5 years; therefore, the data are not current enough to be considered reliable for calculating a value for V. ²⁵ Anthelmintic, Trematodes. ²⁶ Coccidiostat. ²⁷ Antiprotozoal, coccidiostat. 28 NA-1 = Scheduled sampling data have not been collected in the past 3-5 years; therefore, the data are not current enough to be considered reliable for calculating a value for V. ²⁹ Anthelmintics. ³⁰ Coccidiostat. ³¹ NSAID. ³² Xenobiotic hormone; FDA decreased the score for regulatory concern for melengestrol acetate (MGA) from 3 (2005 NRP) to 2 for the 2006 NRP. ³³ Anthelmintic, Nematodes. ³⁴ NA-1 = Scheduled sampling data have not been collected in the past 3-5 years; therefore, the data are not current enough to be considered reliable for calculating a value for V. ³⁵ Anthelmintics. ³⁶ Coccidiostat.

Table 2A Production Classes Considered for each Veterinary Drug and Drug Class 2008 FSIS NRP, Domestic Scheduled Sampling

			Animal Medicinal Dr	ug Use Clarification A	ct of 1994 (AMDU	CA) Prohibited Drugs	ii
ERC ⁱ	Production Class	<i>Clenbuterolⁱⁱⁱ</i>	Chloramphenicol	Fluoroquinolones	Nitrofurans	Nitroimidazoles	Phenylbutazone ^{iv} (ELISA method)
1.753	Beef cows			ĺ			0
0.086	Boars/Stags						
0.015	Bob veal			•			
0.455	Bulls						0
1.388	Dairy cows			•	●		0
0.180	Ducks						
3.364	Egg products						
0.108	Formula-fed veal						
0.027	Goats			•			
0.011	Heavy calves						
7.099	Heifers						
0.160	Lambs						
18.552	Market hogs						
0.694	Mature chickens						
0.007	Mature sheep						
0.080	Mature turkeys						
0.003	non-Formula-fed veal						
0.001	Rabbits						
0.052	Roaster pigs						
1.008	Sows				\bullet		
13.719	Steers						
44.495	Young chickens						
6.665	Young turkeys						

 \bullet = Compound/Production Class Pairs included in the 2008 NRP.

O = Compound/Production Class Pairs that are of regulatory concern, but are not included in the 2008 NRP because of laboratory resource constraints.

ⁱ ERC = Estimated relative percent of domestic consumption, calendar year 2006. This was derived by estimating the total annual U.S. domestic production (pounds dressed weight) for each production class, and dividing by the total poundage for all production classes on this list (see Table 4).

ⁱⁱ AMDUCA Drug Use Clarification Act of 1994 (AMDUCA) drugs are considered high priority in the NRP; for this reason, they do not receive a ranking score.

ⁱⁱⁱ Clenbuterol is analyzed using the beta-Agonist methodology that includes ractopamine, clenbuterol, cimaterol, zilpaterol, and salbutamol.

^{iv} Phenylbutazone will not be scheduled in the 2008 NRP; however, FAST positive samples will be tested for phenylbutazone (ELISA method).

Table 2BProduction Classes to be Considered for each Veterinary Drug and Drug Class2008 FSIS NRP, Domestic Scheduled Sampling

		Veterinary Drug and Priority Rating							
ERC^{i}	Production Class	Antibiotics ⁱⁱ	Arsenicals	Avermectins			Flunixin	Melengestrol Acetate (MGA)	
		15.1	6.8	14.1	12.4	12.1	5.3	3.0	
1.753	Beef cows		•			•	0		
0.086	Boars/Stags	•		•		0			
0.015	Bob veal	•				0			
0.455	Bulls	•		•		0			
1.388	Dairy cows					0			
0.180	Ducks								
3.364	Egg products								
0.108	Formula-fed veal	•							
0.027	Goats	•		•					
0.011	Heavy calves	•		•			0		
7.099	Heifers	•			6			•	
0.160	Lambs	•		•					
18.552	Market hogs	•			•	0			
0.694	Mature chickens	•				•			
0.007	Mature sheep			•					
0.080	Mature turkeys	•				0			
0.003	non-Formula-fed veal	•		•		•			
0.001	Rabbits								
0.052	Roaster pigs			•	•	0			
1.008	Sows			•		0			
13.719	Steers	•		1					
44.495	Young chickens]	1	0			
6.665	Young turkeys]					

Table 2B (continued) Production Classes Considered for each Veterinary Drug and Drug Class 2008 FSIS NRP, Domestic Scheduled Sampling

	Production Class		Veterinary Drug	g and Priority	Rating	
ERC		beta-Agonists ⁱⁱⁱ	Sulfonamides	Thyreostats	Trenbolone	Zeranol
		5.5	12.0	5.9	5.1	5.1
1.753	Beef cows					
0.086	Boars/Stags					
0.015	Bob veal					
0.455	Bulls					
1.388	Dairy cows					
0.180	Ducks					
3.364	Egg products					
0.108	Formula-fed veal					
0.027	Goats					
0.011	Heavy calves					
7.099	Heifers					
0.160	Lambs					
18.552	Market hogs					
0.694	Mature chickens					
0.007	Mature sheep					
0.080	Mature turkeys					
0.003	non-Formula-fed veal					
0.001	Rabbits					
0.052	Roaster pigs					
1.008	Sows					
13.719	Steers					
44.495	Young chickens					
6.665	Young turkeys					

 \bullet = Compound/Production Class Pairs included in the 2008 NRP.

O = Compound/Production Class Pairs that are of regulatory concern, but are not included in the 2008 NRP because of laboratory resource constraints.

■ = Compound/Production Class Pairs that have been suspended from testing by FSIS in the 2008 NRP.

ⁱⁱ Antibiotics in the 7-Plate Bioassay

ⁱ ERC = Estimated relative percent of domestic consumption, calendar year 2006. This was derived by estimating the total annual U.S. domestic production (pounds dressed weight) for each production class, and dividing by the total poundage for all production classes on this list (see Table 3).

ⁱⁱⁱ *beta*-Agonists were ranked using the historical testing data on ractopamine violations.

Table 3

Estimated Relative Consumption, Domestically Produced Meat, Poultry, and Egg Products Based on 2006 Animal and Egg Production Data^A 2008 FSIS NRP, Domestic Scheduled Sampling Plan

Production Class	Number of Head Slaughtered ^B	Pounds per Animal (dressed weight) ^C	Total Pounds (dressed weight)	Percent Estimated Relative Consumption
Bulls	528,266	914	482,835,124	0.455
Beef cows	2,989,010	622	1,859,164,220	1.753
Dairy cows	2,366,281	622	1,471,826,782	1.388
Heifers	9,813,470	767	7,526,931,490	7.099
Steers	17,462,162	833	14,545,980,946	13.719
Bob veal	206,266	75	15,469,950	0.015
Formula-fed veal	465,270	245	113,991,150	0.108
Non-formula-fed veal	8,716	350	3,050,600	0.003
Heavy calves	27,943	400	11,177,200	0.011
SUBTOTAL, CATTLE	33,867,384		26,030,427,462	24.550
Market hogs	99,346,502	198	19,670,607,396	18.552
Roaster pigs	789,959	70	55,297,130	0.052
Boars/Stags	399,629	227	90,715,783	0.086
Sows	3,460,066	309	1,069,160,394	1.008
SUBTOTAL, SWINE	103,996,156		20,885,780,703	19.698
Sheep	115,243	67	7,721,281	0.007
Lambs	2,419,751	70	169,382,570	0.160
Goats	569,319	50	28,465,950	0.027
SUBTOTAL, OVINE	3,104,313		205,569,801	0.194
Horses	104,433	500	52,216,500	0.049
Bison	42,506	610	25,928,660	0.024
TOTAL, ALL LIVESTOCK	141,114,792		47,199,923,126	44.516
Young chickens	8,901,364,574	Not reported	47,177,232,242	44.495
Mature chickens	131,490,164	Not reported	736,344,918	0.694
Young turkeys	252,383,910	Not reported	7,066,749,480	6.665
Mature turkeys	3,412,675	Not reported	85,316,875	0.080
Ducks	28,026,675	Not reported	190,581,390	0.180
Geese	153,837	Not reported	1,999,881	0.002
Other fowl (includes squab)	1,338,642	Not reported	2,543,420	0.002
SUBTOTAL, POULTRY	9,318,170,477		55,260,768,206	52.119
Rabbits	310,093	Not reported	1,581,474	0.001
Egg products ^D	Not applicable	Not applicable	3,566,786,000	3.364
GRAND TOTAL in POUNDS ,	ALL PRODUCTION	N CLASSES	106,029,058,806	100

(A) 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. This was estimated 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 produce that is consumed, regardless of who consumes it (i.e., no distinction is made between domestic products consumed domestically and products that are exported).* (B) Number of heads is obtained from the Animal Disposition Reporting System (ADRS). (C) Average dressed weights are obtained from the publication: "Livestock Slaughter," National Agricultural Statistics Service (NASS), March 2006. In instances when the average weight is not available, an average weight based on previous calendar year's data was imputed. (D) For Fiscal Year 2006

Veterinary Drug or Drug Class	Compound Priority Rating (P)	Production Class	Relative Percent Consumption in 2006(C)	Sampling Priority Score (P * C)	Unadjusted Number of Samples
Sulfonamides	12.0	Young chickens	44.495	533.940	300
Antibiotics (7-Plate Bioassay)	15.1	Market hogs	18.552	280.135	300
Carbadox	12.4	Market hogs	18.552	230.045	300
Sulfonamides	12.0	Market hogs	18.552	222.624	300
Antibiotics (7-Plate Bioassay)	15.1	Steers			300
Sulfonamides	12.0	Steers	Steers 13.719 164.628		300
Antibiotics (7-Plate Bioassay)	15.1	Heifers	7.099	107.195	300
beta Agonists	5.5	Market hogs	18.552	102.036	300
Sulfonamides	12.0	Heifers	7.099	85.188	300
Sulfonamides	12.0	Egg products	3.364	40.368	300
Arsenicals	6.8	Egg products	3.364	22.875	300
MGA	3.0	Heifers	7.099	21.297	300
Florfenicol	12.1	Beef cows	1.753	21.211	300

Veterinary Drug or Drug Class	Compound Priority Rating (P)	Production Class	Relative Percent Consumption in 2006(C)	Sampling Priority Score (P * C)	Unadjusted Number of Samples
Antibiotics (7-Plate Bioassay)	15.1	Dairy cows	1.388	20.959	300
Sulfonamides	12.0	Dairy cows	1.388	16.656	300
Antibiotics (7-Plate Bioassay)	15.1	Sows	1.008	15.221	300
Avermectins	14.1	Sows	1.008	14.213	300
Sulfonamides	12.0	Sows 1.008 12.096		12.096	300
Arsenicals	6.8	Beef cows	1.753	11.920	300
Antibiotics (7-Plate Bioassay)	15.1	Mature chickens	0.694	10.479	300
Thyreostats	5.9	Beef cows	1.753	10.343	300
Florfenicol	12.1	Mature chickens	0.694	8.397	300
Sulfonamides	12.0	Mature chickens	0.694	8.328	300
Flunixin	5.3	Dairy cows	1.388	7.356	300
Antibiotics (7-Plate Bioassay)	15.1	Bulls	Bulls 0.455		300
Avermectins	14.1	Bulls	0.455	6.416	300

Veterinary Drug or Drug Class	Compound Priority Rating (P)	Production Class	Relative Percent Consumption in 2006(C)	Sampling Priority Score (P * C)	Unadjusted Number of Samples
Antibiotics (7-Plate Bioassay)	15.1	Ducks	0.18	2.718	300
Antibiotics (7-Plate Bioassay)	15.1	Lambs	0.16	2.416	300
Flunixin	5.3	Bulls	0.455	2.412	300
Avermectins	14.1	Lambs	0.16	2.256	300
Antibiotics (7-Plate Bioassay)	15.1	Formula-fed veal	0.108	1.631	300
Antibiotics (7-Plate Bioassay)	15.1	Boars/stags	0.086	1.299	300
Avermectins	14.1	Boars/stags	0.086	1.213	300
Antibiotics (7-Plate Bioassay)	15.1	Mature turkeys	0.08	1.208	300
Antibiotics (7-Plate Bioassay)	15.1	Roaster pigs	0.052	0.785	300
Avermectins	14.1	Roaster pigs	0.052	0.733	300
Carbadox	12.4	Roaster pigs	0.052	0.645	300
Sulfonamides	12.0	Roaster pigs	0.052	0.624	300
Trenbolone	5.1	Formula fed veal	0.108	0.551	300

Veterinary Drug or Drug Class	Compound Priority Rating (P)	Production Class	Relative Percent Consumption in 2006(C)	Sampling Priority Score (P * C)	Unadjusted Number of Samples
Zeranol	5.1	Formula fed veal	0.108	0.551	300
Arsenicals	6.8	Mature turkeys	0.08	0.544	300
Antibiotics (7-Plate Bioassay)	15.1	Goats	0.027	0.408	300
Avermectins	14.1	Goats	0.027	0.381	300
Sulfonamides	12.0	Goats 0.027 0.324		300	
Antibiotics (7-Plate Bioassay)	15.1	Bob veal	0.015	0.227	300
Sulfonamides	12.0	Bob veal	0.015	0.180	300
Antibiotics (7-Plate Bioassay)	15.1	Heavy calves	0.011	0.166	300
Avermectins	14.1	Heavy calves	0.011	0.155	300
beta Agonists	5.5	Goats	0.027	0.149	300
Sulfonamides	12.0	Heavy calves	0.011	0.132	300
Antibiotics (7-Plate Bioassay)	15.1	Mature sheep	0.007	0.106	300
Avermectins	14.1	Mature sheep	0.007	0.099	300

Veterinary Drug or Drug Class	Compound Priority Rating (P)	Production Class	Relative Percent Consumption in 2006(C)	Sampling Priority Score (P * C)	Unadjusted Number of Samples
Antibiotics (7-Plate Bioassay)	15.1	Non-formula-fed veal	0.003	0.045	300
Avermectins	14.1	Non-formula-fed veal	0.003	0.042	300
Florfenicol	12.1	Non-formula-fed veal 0.003 0.036		300	
Sulfonamides	12.0	Non-formula-fed veal	0.003	0.036	300
beta Agonists	5.5	Non-formula-fed veal	0.003	0.017	300
Trenbolone	5.1	Non-formula-fed veal	0.003	0.015	300
Zeranol	5.1	Non-formula-fed veal	0.003	0.015	300
Antibiotics (7-Plate Bioassay)	15.1	Rabbits	0.001	0.015	300
Avermectins	14.1	Rabbits	0.001	0.014	300

Table 5Number of Scheduled Samples for Veterinary Drug/Production Class Pairs2008 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	Boars/stags	1.299	2,043	0.29	< 1	300	300	300	300	300	300
Antibiotics ¹¹	Bob veal	0.227	3,628	2.89	> 1	300	230	230	230	230	230
Antibiotics ¹¹	Bulls	6.871	1,695	0.31	N/A	300	300	300	300	300	300
Antibiotics ¹¹	Dairy cows	20.959	4,547	0.00	> 1	300	230	230	230	230	230
Antibiotics ¹¹	Ducks	2.718	2,381	0.00	N/A	300	300	45	45	45	45
Antibiotics ¹¹	Formula-fed veal	1.631	4,338	0.67	< 1	300	300	300	300	300	300
Antibiotics ¹¹	Goats	0.408	1,842	0.11	N/A	300	300	90	90	90	90
Antibiotics ¹¹	Heavy calves	0.166	2,165	0.69	> 1	300	230	95	95	95	95
Antibiotics ¹¹	Heifers	107.195	4,120	0.07	< 1	300	300	300	300	300	300
Antibiotics ¹¹	Lambs	2.416	2,532	0.04	N/A	300	300	230	230	230	230
Antibiotics ¹¹	Market hogs	280.135	4,948	0.16	N/A	300	300	300	300	300	300
Antibiotics ¹¹	Mature chickens	10.479	1,993	0.05	N/A	300	300	300	300	300	300
Antibiotics ¹¹	Mature turkeys	1.208	1,184	0.03	N/A	300	300	300	300	300	300
Antibiotics ¹¹	Non-formula-fed veal	0.045	1,648	1.94	> 1	300	230	90	90	90	90
Antibiotics ¹¹	Rabbits	0.015	1,203	3.24	N/A	300	230	45	45	45	45
Antibiotics ¹¹	Roaster pigs	0.785	867	0.81	< 1	300	300	300	300	300	300
Antibiotics ¹¹	Sheep	0.106	1,390	0.00	N/A	300	300	60	60	60	60
Antibiotics ¹¹	Sows	15.221	3,196	0.44	< 1	300	300	300	230	230	230
Antibiotics ¹¹	Steers	207.157	3,133	0.03	N/A	300	300	300	300	300	300
Totals		-				5,700					4,045
Arsenicals	Beef cows	11.920	1,325	0.00	N/A	300	300	300	300	300	300
Arsenicals	Egg products	22.875	1,494	0.00	N/A	300	300	300	300	300	300
Arsenicals	Mature turkeys	0.544	436	0.00	N/A	300	300	300	300	300	300
Totals						900					900
Avermectins	Boars/stags	1.213	967	0.00	N/A	300	300	300	300	300	300
Avermectins	Bulls	6.416	2,884	0.31	< 1	300	300	300	300	300	300
Avermectins	Goats	0.381	2,827	1.8	> 1	300	230	230	230	230	230
Avermectins	Heavy calves	0.155	1,632	0.37	< 1	300	300	135	135	135	135
Avermectins	Lambs	2.256	2,475	0.20	> 1	300	300	300	300	300	300
Avermectins	Mature sheep	0.099	1,117	0.36	> 1	300	230	230	230	230	230
Avermectins	Non-formula-fed veal	0.042	1,081	0.37	> 1	300	230	90	90	90	90
Avermectins	Rabbits	0.014	581	0.00	N/A	300	300	45	45	45	45
Avermectins	Roaster pigs	0.733	433	0.00	N/A	300	300	300	300	300	300
Avermeetins	Sows	14.213	1.747	0.00	N/A	300	300	300	300	300	300
Totals		17.213	1,/ 7/	0.00	11/21	3,000	500	500		500	2,230

Table 5 (continued) Number of Scheduled Samples for Veterinary Drug/Production Class Pairs 2008 NRP, Domestic Scheduled Sampling

				<u>000 NKP, 1</u>	Domestic Sc	chequied San	npung				
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
1		0.1.40		NT / A	NT/A	200	200	230	220	220	220
beta Agonists	Goats	0.149	0	N/A	N/A	300	300		230	230	230
beta Agonists	Market hogs	102.036	1,496	0.00	N/A	300	300	300	300	300	300
beta Agonists	Non-formula-fed veal	0.017	395	0.25	> 1	300	230	90	90	90	90
Totals						900					620
Carbadox	Market hogs	230.045	575	0.00	N/A	300	300	300	300	300	300
Carbadox	Roaster pigs	0.645	498	0.60	N/A	300	300	300	300	300	300
Totals	t C					600					600
				3							
Chloramphenicol	Bob veal	N/A	0	N/A	N/A	300	300	300	300	300	300
Chloramphenicol	Heifers	N/A	0	N/A	N/A	300	300	300	300	300	300
Chloramphenicol	Mature chickens	N/A	488	0.00	N/A	300	300	300	300	300	300
Chloramphenicol	Mature turkeys	N/A	204	0.00	N/A	300	300	300	300	300	300
Chloramphenicol	Steers	N/A	0	N/A	N/A	300	300	300	300	300	300
Totals						1,500					1,500
Florfenicol	Beef cows	21.211	0	N/A	N/A	300	300	300	230	230	230
Florfenicol	Mature chickens	8.397	0	N/A	N/A N/A	300	300	300	230	230	230
Florfenicol	Non-formula-fed veal	0.036	78	4.32	$\rightarrow 1$	300	135	90	90	90	<u> </u>
Totals		0.050	/0	4.52		900	155		, ,0		550
Totais						200					
Flunixin	Bulls	2.412	232	0.43	> 1	300	135	135	90	90	90
Flunixin	Dairy cows	7.356	1,502	0.93	> 1	300	90	90	90	90	90
Totals						600					180
MGA	Heifers	21.297	1,181	0.00	< 1	300	300	300	300	300	300
Totals	nellers	21.297	1,101	0.00		300	300		500	300	300
Totais						300					300
Nitrofurans	Dairy cows	N/A	538	0.37	> 1	300	230	230	230	230	230
Nitrofurans	Market hogs	N/A	0	N/A	N/A	300	300	300	300	300	300
Nitrofurans	Sows	N/A	0	N/A	N/A	300	300	300	300	300	300
Totals			~			900					830
Nitroimidazoles	Young chickens	N/A	0	N/A	N/A	300	300	300	300	300	300
Totals				5		300					300

Table 5 (continued) Number of Scheduled Samples for Veterinary Drug/Production Class Pairs 2008 NRP, Domestic Scheduled Sampling

				$\frac{1}{100}$	Domestic Sc	chequied San	ipning				
Veterinary Drug (or drug class)	Production Class	Priority Score ¹	Number of Samples ²	% Violation	% 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
Sulfonamides	Bob veal	0.180	3,469	0.72	> 1	300	230	230	230	230	230
Sulfonamides	Dairy cows	16.656	2,794	0.36	> 1	300	230	230	230	230	230
Sulfonamides	Egg products	40.368	1,649	0.00	N/A	300	300	300	300	300	300
Sulfonamides	Goats	0.324	1,750	0.06	N/A	300	300	230	230	230	230
Sulfonamides	Heavy calves	0.132	1,983	0.20	> 1	300	230	135	135	135	135
Sulfonamides	Heifers	85.188	2,223	0.04	N/A	300	300	300	300	300	300
Sulfonamides	Market hogs	222.624	4,489	0.49	> 1	300	230	230	230	230	230
Sulfonamides	Mature chickens	8.328	1,460	0.00	N/A	300	300	300	300	300	300
Sulfonamides	Non-formula-fed veal	0.036	1,631	0.55	< 1*	300	300	90	90	90	90
Sulfonamides	Roaster pigs	0.624	1,028	1.65	> 1	300	230	230	230	230	230
Sulfonamides	Sows	12.096	2,503	0.40	N/A	300	300	300	300	300	300
Sulfonamides	Steers	164.628	3,565	0.14	> 1	300	230	230	230	230	230
Sulfonamides	Young chickens	533.940	2,338	0.04	N/A	300	300	300	300	300	300
Totals						3,900					3,105
Thyreostats	Beef cows	10.343	0	N/A	N/A	300	300	300	300	300	300
Totals						300					300
Trenbolone	Formula fed veal	0.551	1,399	0.00	< 1	300	300	90	90	90	90
Trenbolone	Non-formula-fed veal	0.015	174	1.15	> 1	300	230	90	90	90	90
Totals						600					180
Zeranol	Formula fed veal	0.551	1,985	2.27	< 1	300	230	90	90	90	90
Zeranol	Non-formula-fed veal	0.015	0	N/A	N/A	300	300	90	90	90	90
Totals						600					180

¹ For an explanation of this score, see Table 4.

² Number of Samples (1997-2006) 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, 1997-2006.

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 2006 based on the guideline that one violation within 300 samples represent 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.

Table 5 (continued) Number of Scheduled Samples for Veterinary Drug/Production Class Pairs 2008 NRP, Domestic Scheduled Sampling

⁵ The number obtained from the last column of Table 4

⁷ The following minor species have been rotated out of the FSIS scheduled sampling plan: bison; geese; 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 1 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

⁶ If the violation rate for a compound-production class pair was determined to be 0% for the 3 year period (2004-2006), 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.