# 2007 FSIS National Residue Program Scheduled Sampling Plans

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Dedicated to the memory of William Randall Sutton, PhD (June 22, 1954 -- September 25, 2007) Esteemed co-worker and friend

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 2006 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 Zoonotic Diseases and Residue Surveillance Division, Residue Branch, 344 Aerospace Center, 1400 Independence Avenue, SW, Washington, DC 20250-3700, telephone (202) 690-6566, 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<sup>\*</sup> and FDA<sup>\*\*</sup> 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.

To protect consumers from chemical residues, FSIS collects samples of meat, poultry, and egg products at inspected establishments and analyzes these 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) statistical analyses of compounds of concern; (3) appropriate regulatory follow-up of reports of violative tissue residues; and (4) collection, analyses, 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.

<sup>&</sup>lt;sup>\*</sup> Tolerance levels established by EPA are published in 40 CFR.

<sup>&</sup>lt;sup>\*\*</sup> 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 the 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 endogenous 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. 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 retained and condemned 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 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 the agency 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, serve as a deterrent for violators, and enables FSIS to make better use of resources.

Data gathered in the NRP is 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.

# **Components of the National Residue Program**

The NRP is comprised of sampling plans to address chemical and drug residues in domestic and imported food animal and egg products. All products, whether domestic or imported, must fall within the tolerance levels set by Food and Drug Administration (FDA) and Environmental Protection Agency (EPA).

#### I. Domestic Sampling Plan

- *Scheduled sampling* is a process for the determination of compounds of concern, pairing compounds of concern with production classes, and sample numbers for compound-production class pairs. Compound-production class pairs are determined at Surveillance Advisory Team (SAT) and FSIS Residue Branch determines sample numbers. Residue Branch staff employ statistical analysis techniques to calculate sample numbers. Beginning with the 2006 NRP, FSIS uses sample sizes of either 230 or 300 for each compound-production class pair. Statistically, applying sampling rates of 230 and 300 assures a probability of detecting a residue violation (if the true violation rate among healthy appearing animals is 1 percent) of 90 and 95%, respectively. Residue Branch has adopted a sample size of 300 as a public health standard for determining if HACCP is effective. FSIS Senior Management, FSIS Laboratories, the FDA, and the EPA review and make a final determination of sample numbers. Scheduled sampling<sup>1</sup> is applied to healthy appearing food animals and egg products for the following types of assessments:
  - *Exposure Assessments* are designed to determine the prevalence of residues in the nations food supply. Residue samples collected for exposure assessments are subject to voluntary retention by industry, condemnation by FSIS, and voluntary recall by industry, and by FDA for regulatory action when a sample contains violative levels of residues.
  - *Exploratory Assessments* are designed by Residue Branch to investigate violations identified in exposure assessments, compounds that have no established tolerances, and when suggested by intelligence from the field. Exploratory assessments could be subjected to mandatory retention by FSIS, condemnation by FSIS, and voluntary recalls by FSIS.
- Inspector generated sampling is not scheduled and is not directed by FSIS Headquarters. Inspector generated sampling is conducted by in-plant public health veterinarians, using FSIS Form 10,000-2, when there is reason to believe that an animal may have violative levels of residues. Currently, inspector generated sampling targets *individual suspect animals* and *suspect populations of animals*. In inspector generated sampling, the carcass is retained pending the results of laboratory testing and a carcass that is found to contain violative levels of residues is condemned.
  - Sampling for individual suspect animals is performed in-plant using one of the available residue screening tests: Fast antimicrobial screening test (FAST) and swab test on premises (STOP). FAST and STOP are used only for the detection of antimicrobial and sulfonamide residues. If the result of a screening test is positive, the sample is sent to an FSIS laboratory for confirmation. The in-plant inspector selects a carcass for sampling based on professional judgment, and public health criteria developed by FSIS. These criteria include animal disease signs and symptoms, producer history, and results from random scheduled

sampling. In 2007, STOP will be phased out and FAST will become the only screening test for in-plant use.

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

#### **II. Import Sampling Plan**

Animal and egg products imported to the US have passed inspection in their country; therefore, import sampling is reinspection. The levels of reinspection are:

- *Normal sampling*, which is defined as random sampling from a lot;
- *Increased sampling (random sampling)*, which is defined as above the normal sampling as the result of an Agency management decision; and
- *Intensified sampling (biased sampling)*, which is defined as occurring when a previous sample for a type of inspection 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 retain the lot pending the laboratory results. For intensified sampling, the lot must be held pending laboratory results. The level of reinspection that is applied depends on the country's performance history. The data obtained from laboratory analysis are entered into an FSIS Data Base System, the Automated Import Information System (AIIS). Import sampling is designed to verify that the chemical residue programs in countries exporting meat, poultry, or egg products to the U.S. are equivalent to those in the U.S.

<sup>1</sup>Domestic samples are scheduled by FSIS on FSIS Form 10,201-3. This form directs public health veterinarians to collect tissue samples for laboratory analysis for a determination of residue levels.

# Summary Table I Status of the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) Prohibited Drugs 2007 FSIS NRP – Domestic and Import Sampling

AMDUCA <sup>1</sup> Prohibited Drug	Scheduled Samples		Tatal
AMDUCA Frontolled Drug	Domestic	Import	Total
Avoparcin (glycopeptide)	Not in the 2007 NRP.	Not in the 2007 NRP.	
Chloramphenicol	300 samples each are scheduled for dairy cows, formula- fed veal, young chickens, and young turkeys.	78, 90, 16, and 8 samples are scheduled for fresh beef, veal, turkey, and chicken, respectively.	1,392
<i>beta</i> -Agonists <sup>2</sup>	300 samples each are scheduled for heifers, formula-fed veal, non-formula-fed veal, and market hogs. Confirmation performed by FDA.	90 and 30 samples are scheduled for veal and pork fresh, respectively.	1,320
Diethylstilbestrol <sup>3</sup>	Not in the 2007 NRP.	Not in the 2007 NRP.	
Fluoroquinolones <sup>4</sup>	Not in the 2007 NRP.	Not in the 2007 NRP.	
Nitrofurans <sup>5</sup>	300 samples each are scheduled for market hogs, sows, and roaster pigs.	No samples are scheduled for the 2007 NRP.	900
Nitroimidazoles <sup>6</sup>	300 samples are scheduled for young chickens.	8 samples are scheduled for fresh chicken	308
Phenylbutazone <sup>7</sup>	No samples are scheduled for the 2007 NRP.	No samples are scheduled for the 2007 NRP.	

#### Summary Table I Status of the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) Prohibited Drugs 2007 FSIS NRP – Domestic and Import Sampling

AMDUCA <sup>1</sup> Prohibited Drug	Schedulea	Scheduled Samples	Total
AMDUCA Pronibiled Drug	Domestic	Import	
Ronidazole	Not in the 2007 NRP.	Not in the 2007 NRP.	
Vancomycin	Not in the 2007 NRP.	Not in the 2007 NRP.	

<sup>3</sup> Xenobiotic hormone.

<sup>&</sup>lt;sup>1</sup> 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. <sup>2</sup> 1200 animals will be sampled in the FSIS domestic program. A pound of liver will be collected and sent to WL for screening and confirmation by HPLC/MS/MS.

This method detects beta-agonists, clenbuterol, salbutamol, cimaterol, and ractopamine, in bovine, porcine, ovine, and caprine liver and bovine retina. Note that although the method is validated for retina, eye balls are not being collected for the 2007 NRP. FSIS has completed validation work to extend the method to muscle and plans to add zilpaterol.

<sup>&</sup>lt;sup>4</sup> The fluoroquinolones, enrofloxacin and danofloxacin, are approved for use steers and heifers.

<sup>&</sup>lt;sup>5</sup> Furazolidone and nitrofurazone; antimicrobials.

<sup>&</sup>lt;sup>6</sup> Nitroimidazoles in the FSIS multi residue method (MRM) are dimetridazole and ipronidazole; antiprotozoal

<sup>&</sup>lt;sup>7</sup> Although not in the FSIS Scheduled sampling plan for 2007, testing for phenylbutazone will be conducted for inspector generated samples found FAST positive.

# Summary Table II Rank and Status of Veterinary Drugs 2007 FSIS NRP – Domestic and Import Scheduled Sampling

Dauk	Vatarin am Drug	Score	Scheduled Samples				
Rank	Veterinary Drug	score	Domestic	Import	Total		
1	Antibiotics <sup>1</sup>	15.0	300, 300, 300, 300, 230, 230, 230, 300, 30	657 samples are scheduled for fresh beef, fresh pork, fresh veal, fresh turkey, fresh chicken, and fresh varied combo.	3,769		
2	Carbadox <sup>3</sup>	15.0	300 samples each are scheduled for market hogs and roaster pigs.	No samples are scheduled for the 2007 NRP.	600		
3	Avermectins <sup>4</sup>	14.0	300, 300, 300, 300, 300, 230, 230, 230,	583 samples are scheduled for fresh beef, processed beef, fresh veal, fresh lamb and mutton, and fresh goat.	3,093		
4	Thyreostats <sup>5</sup>	12.3	300 samples are scheduled for formula-fed veal.	90 samples are scheduled for fresh veal.	390		
5	Sulfonamides <sup>6</sup>	12.0	300 samples each are scheduled for market hogs, steers, dairy cows, beef cows, bulls, mature turkeys, bob veal, roaster pigs, non-formula-fed veal, young chickens, young turkeys, sheep, lambs, goats and heavy calves, respectively.	836 samples are scheduled for fresh beef, processed beef, fresh pork, processed pork, fresh veal, fresh turkey, processed turkey, fresh varied combo, and processed varied combo.	5,536		
6	Zeranol <sup>7</sup>	12.0	230 samples are scheduled for formula-fed veal.	90 samples each are scheduled for fresh veal.	320		
7	Berenil <sup>8</sup>	11.4	No samples are scheduled for the 2007 NRP.	No samples are scheduled for the 2007 NRP.			

Rank	Veterinary Drug	Score	Scheduled Samples				
тапк		Score	Domestic	Import	Total		
8	Dipyrone <sup>9</sup>	11.4	Not in the 2007 NRP	Not in the 2007 NRP			
9	Florfenicol <sup>10</sup>	10.5	300, 300, and 230 samples are scheduled for dairy cows, formula-fed veal, and non-formula-fed veal, respectively.	45 samples are scheduled for fresh beef.	875		
10	Thiamphenicol <sup>11</sup>	7.6	Not in the 2007 NRP	Not in the 2007 NRP			
11	Methyl prednisone <sup>12</sup>	7.2	Not in the 2007 NRP	Not in the 2007 NRP			
12	Dexamethasone <sup>13</sup>	7.2	No samples are scheduled for the 2007 NRP.	No samples are scheduled for the 2007 NRP.			
13	Flunixin <sup>14</sup>	7.0	No samples are scheduled for the 2007 NRP	78 samples are scheduled for fresh beef.	78		
14	Trenbolone	6.7	230 samples are scheduled for formula-fed veal.	No samples are scheduled for the 2007 NRP.	230		
15	Amprolium <sup>15</sup>	6.4	Not in the 2007 NRP	Not in the 2007 NRP			

Rank	Veterinary Drug	Score	Scheduled Samples			
капк		score	Domestic	Import	Total	
16	Prednisone <sup>16</sup>	6.4	Not in the 2007 NRP	Not in the 2007 NRP		
17	Etodolac <sup>17</sup>	6.4	Not in the 2007 NRP	Not in the 2007 NRP		
18	Clorsulon <sup>18</sup>	5.1	Not in the 2007 NRP	Not in the 2007 NRP		
19	Arsenicals <sup>19</sup>	4.5	300 samples each are scheduled for market hogs and young chickens. <sup>20</sup>	145 samples each are scheduled for fresh pork, fresh turkey, fresh chicken, processed chicken, and processed turkey.	445	
20	Eprinomectin	4.4	Not in the 2007 NRP	Not in the 2007 NRP		
21	Hormones (naturally- occurring) <sup>21</sup>	4.4	Not in the 2007 NRP	Not in the 2007 NRP		
22	Lasalocid <sup>22</sup>	4.3	Not in the 2007 NRP.	Not in the 2007 NRP		
23	Halofuginone <sup>23</sup>	3.8	Not in the 2007 NRP	Not in the 2007 NRP		

Rank	Veterinary Drug	Score	2007 FSIS INRP – Domestic and Import Samplin Scheduled Sam		Total
Кипк	velerinary Drug	score	Domestic	Import	10101
24	Benzimidazoles <sup>24</sup>	3.6	Not in the 2007 NRP	Not in the 2007 NRP	
25	Levamisole <sup>25</sup>	3.5	Not in the 2007 NRP	Not in the 2007 NRP	
26	Melengesterol acetate <sup>26</sup> (MGA)	3.0	300 samples are scheduled for heifers.	No samples are scheduled for the 2007 NRP.	300
27	Veterinary tranquilizers <sup>27</sup>	2.9	Not in the 2007 NRP	Not in the 2007 NRP	
28	Nicarbazin <sup>28</sup>	2.9	Not in the 2007 NRP	Not in the 2007 NRP	
29	ß-Agonists	2.8	300 samples each are scheduled for heifers, formula-fed veal and non-formula-fed veal, and market hogs.	90 and 30 samples are scheduled for fresh veal and fresh pork, respectively.	1,320
30	Morantel and pyrantel	2.2	Not in the 2007 NRP	Not in the 2007 NRP	

<sup>&</sup>lt;sup>1</sup> At present, the following antibiotics are quantitated using the 7-plate bioassay after a specific identification is made using mass spectroscopy (MS) or using high performance liquid chromatography (HPLC): tetracycline, oxytetracycline, chlortetracycline, gentamicin, streptomycin, dihydrostreptomycin, erythromycin, tylosin, neomycin, beta-lactams (quantitated as penicillins and cephalosporins are not differentiated within this category), and tilmicosin (quantitated by HPLC). The following antimicrobials can be identified by MS; however, no quantitative methods are available: spectinomycin, hygromycin, amikacin, kanamycin, apramycin, tobramycin, lincomycin, pirlimycin, clindamycin, and oleandomycin.

<sup>2</sup> Young chickens and young turkeys have a 0% violation rate for antibiotics for the 3 year period (2001-2003). These production classes were rotated back into the scheduled sampling program for 2007 based on the expert opinion of the Surveillance Advisory Team (SAT).
<sup>3</sup> Antimicrobial.
<sup>4</sup> Doramectin, ivermectin, and moxidectin; Antiparasitic.
<sup>5</sup> Includes thiouracil.
<sup>6</sup> Sulfonamides in the FSIS multi-residue method (MRM): Sulfapyridine, sulfadiazine, sulfathiazole, sulfamethazine, sulfachloropyridazine, sulfadoxine, sulfamethoxypyridazine, sulfadimethoxine, sulfadimethoxine, sulfacetamide, sulfamethoxazole, sulfamethizole, sulfamethizole, sulfanilamide, sulfaguanidine, sulfabromomethazine, sulfasalazine, sulfaethoxypyridazine, sulfaphenazole, and sulfatroxazole; Antimicrobials, some are coccidiostats;

FDA has not set a tolerance for the following sulfonamides: sulfapyridine, sulfadiazine, sulfadoxine, sulfamethoxypyridazine, sulfasalazine, sulfasalazine, sulfatoxine, sulfamethoxypyridazine, sulfasalazine, sulfasalazine, sulfasalazine, sulfatoxine, s

<sup>7</sup> Xenobiotic hormone

<sup>8</sup> Antiprotozoal.

<sup>9</sup> Non-Steroidal Anti-Inflammatory Drug (NSAID).

<sup>10</sup> Chloramphenicol derivative.

<sup>11</sup> Chloramphenicol derivative

<sup>12</sup> Glucocorticoid.

<sup>13</sup> Glucocorticoid.

<sup>14</sup> Non-Steroidal Anti-Inflammatory Drug (NSAID).

<sup>15</sup> Coccidiostat

<sup>16</sup> Glucocorticoid

<sup>17</sup> Non-Steroidal Anti-Inflammatory Drug (NSAID).

<sup>18</sup> Anthelmintic, Trematodes

<sup>19</sup> Detected as As

<sup>20</sup> 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).

<sup>21</sup> 17-Estradiol, testosterone, and progesterone

<sup>22</sup> Coccidiostat

<sup>23</sup> Antiprotozoal, coccidiostat

<sup>24</sup> 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

<sup>25</sup> Anthelmintic

<sup>26</sup> Xenobiotic hormone

<sup>27</sup> Azaperone and its metabolite azaperol, xylazine, haloperidol, acetopromazine, propionylpromazine, and chlorpromazine

<sup>28</sup> Coccidiostat

## Summary Table III Rank and Status for Pesticides 2006 FSIS NRP, Domestic Scheduled Sampling Plan

Daul		G	Status in the 2007 NRP		
Rank	Compound / Compound Class <sup>1</sup>	Score	Domestic	Import	– Total
1	Benzimidazole Pesticides – those compounds in the FSIS multi-residue method (MRM) <sup>2</sup>	11.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
2	Imazalil	16.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
3	Arsanilic acid	13.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
4	1,2,4-Triazole	12.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
5	Propiconazole metabolite 1,2,4-triazole	12.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
6	Triazole analine	12.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
7	Triazole lactic acid	12.0	Not in the 2007 NRP.	Not in the 2007 NRP.	

Based on Surveillance Advisory Team (SAT) expert opinion, compounds above this point represent more of a potential public health risk than is indicated by their priority scores.

# Summary Table III (continued) Rank and Status for Pesticides 2007 FSIS NRP, Domestic Scheduled Sampling Plan

Dauh	Compound / Compound Class <sup>1</sup>	Score	Status in the 2007 NRP		Total
Rank	Compound / Compound Class		Domestic	Import	
8	Chlorinated hydrocarbons (CHCs) and chlorinated organophosphates (COPs) – those compounds in the FSIS multi-residue method (MRM) <sup>3</sup>	16.0	90, 300, 300, 300, 300, 300, 230, 230, and 230 samples are scheduled for equine, heifers, dairy cows, beef cows, sows, boars and stags, goats, sheep, and lambs, respectively.	908 samples are scheduled for fresh and processed beef, fresh and processed pork, fresh and processed lamb mutton, fresh goat, fresh turkey, fresh and processed chicken, processed turkey, and fresh and processed varied combo	3,188
9	Chlorinated organophosphates (COPs) and organo phosphates (OPs) - those compounds not in FSIS COP and OP multi-residue method (MRM) <sup>4</sup>	16.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
10	Triazines – those compounds not in FSIS triazine multi- residue method (MRM) <sup>5</sup>	15.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
11	Carbamates – those compounds in the FSIS carbamate triazine multi-residue method (MRM) <sup>6</sup>	14.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
12	Synthetic Pyrethrins – those compounds in the FSIS synthetic pyrethrin multi-residue method (MRM) <sup>7</sup>	14.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
13	1-(2,4-Dichlorophenyl)-2-(1H-imidazole-1-yl)-1- ethanol <sup>8</sup>	14.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
14	1,1-(2,2-Dichloroethylidene)bis(4-methoxybenzene) <sup>9</sup>	14.0	Not in the 2007 NRP.	Not in the 2007 NRP.	

# Summary Table III (continued) Rank and Status for Pesticides 2007 FSIS NRP, Domestic Scheduled Sampling Plan

Dauk	Compound / Compound Class <sup>1</sup>	Score	Status in the 2007 NRP		Total
Rank	Compouna / Compouna Class		Domestic	Import	Total
15	1-Methoxy-4-(1,2,2,2-tetrachloroethyl)benzene) <sup>10</sup>	14.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
16	3-(1-(2,4-Dichlorophenyl)-2-(1H-imidazole-1- yl)ethoxy)-1,2-propane diol <sup>11</sup>	14.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
17	Cyhalothrin, lambda	14.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
18	Fipronil <sup>12</sup>	14.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
19	MB45950	14.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
20	MB46513	14.0	Not in the 2007 NRP.	Not in the 2007 NRP.	
21	Methoxychlor olefin	14.0	Not in the 2007 NRP.	Not in the 2007 NRP.	

## Summary Table III (continued) Rank and Status for Pesticides 2007 FSIS NRP, Domestic Scheduled Sampling Plan

<sup>2</sup> 5-Hydroxythiabendazole, benomyl (as carbendazim), and thiabendazole.

<sup>3</sup> HCB, alpha-BHC, lindane, heptachlor, dieldrin, aldrin, endrin, ronnel, linuron, oxychlordane, chlorpyrifos, nonachlor, heptachlor epoxide A, heptachlor epoxide B, endosulfan I, endosulfan I sulfate, endosulfan II, trans-chlordane, cis-chlordane, chlorfenvinphos, p,p'-DDE, p, p'-TDE, o,p'-DDT, p,p'-DDT, carbophenothion, captan, tetrachlorvinphos [stirofos], kepone, mirex, methoxychlor, phosalone, coumaphos-O, coumaphos-S, toxaphene, famphur, PCB 1242, PCB 1248, PCB 1254, PCB 1260, dicofol\*, PBBs\*, polybrominated diphenyl ethers\*, deltamethrin\*) (\*identification only).

<sup>4</sup> 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, ethion monooxon, 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, 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 sulfox sulfone, sulprofos sulfoxide, tribufos (DEF).

<sup>5</sup> 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.

<sup>6</sup> Regulatory method is needed: Aldicarb, aldicarb sulfoxide, aldicarb sulfone, carbaryl, carbofuran, carbofuran, 3-hydroxy.

<sup>7</sup> Cypermethrin, *cis*-permethrin, *trans*-permethrin, fenvalerate, *zeta*-cypermethrin.

<sup>8</sup> Regulatory method is needed.

<sup>9</sup> Regulatory method is needed.

<sup>10</sup> Regulatory method is needed.

<sup>11</sup> Regulatory method is needed.

<sup>12</sup> Regulatory method is needed.

<sup>&</sup>lt;sup>1</sup> 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 2007 NRP, see Table 30.

# Summary Table IV Rank and Status of Veterinary Drugs 2007 FSIS NRP, Domestic and Import Scheduled Sampling

Unavoidable Contaminant <sup>1</sup>	Scheduled Samples				
	Domestic	Import	Total		
Lead and cadmium	300 samples for lead and 300 samples for cadmium are scheduled for mature turkeys.	No samples are scheduled for the 2007 NRP.	600		

<sup>&</sup>lt;sup>1</sup> 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 these sampling plans is detailed in this document, the FSIS National Residue Program Scheduled Sampling Plan (NRP), *Blue Book*.

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 residue 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 bioassay<sup>1</sup> only)

- At present, the following antibiotics are quantitated using the 7-plate bioassay after a specific identification is made using mass spectroscopy (MS) or using high performance liquid chromatography (HPLC): tetracycline, oxytetracycline, chlortetracycline, gentamicin, streptomycin, dihydrostreptomycin, erythromycin, tylosin, neomycin, β-lactams (quantitated as penicillin-G; penicillins and cephalosporins are not differentiated within this category), and tilmicosin (quantitated by HPLC). The following antimicrobials can be identified by MS; however, no quantitative methods are available: spectinomycin, hygromycin, amikacin, kanamycin, apramycin, tobramycin, lincomycin, pirlimycin, clindamycin, and oleandomycin
- Avoparcin (classification: glycopeptide; AMDUCA prohibited)
- Chloramphenicol (classification: antibiotic; AMDUCA prohibited)
- Florfenicol (classification: antibiotic; chloramphenicol derivative)
- Fluoroquinolones in FSIS MRM (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)
- $\beta$ -Agonists (ractopamine, clenbuterol, cimaterol, and salbutamol; growth promotants<sup>2</sup>)

<sup>&</sup>lt;sup>1</sup> 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, HPLC, or mass spectrometry) to establish their identities, where such follow-up methodologies are available. Tetracycline, oxytetracycline, and chlortetracycline share patterns of inhibition and are individually identified by follow-up with the HPLC method for tetracyclines; tilmicosin, tylosin, lincomycin, clindamycin, erythromycin, and pirlimycin, which are individually identified by ion-trap LC/MS/MS. Tissues found to be positive for tilmicosin are quantitated by a NADA method using HPLC. Amikacin, apramycin, dihydrostreptomycin, gentamycin, hygromycin, kanamycin, neomycin, spectinomycin, streptomycin, and tobramycin are individually identified by ion-trap LC/MS/MS. Confirmation for sulfanamides and flunixin are also provided by the residue chemistry section at the FSIS, Midwestern Laboratory.

 $<sup>^{2}</sup>$  This method detects ß-agonists, clenbuterol, salbutamol, cimaterol, and ractopamine, in bovine, porcine, ovine, and caprine liver and bovine retina. Note that although the method is validated for retina, eye balls are not being collected for the 2007 NRP. FSIS has completed validation work to extend the method to muscle and plans to add zilpaterol.

- Clorsulon (classification: anthelmintic)
- Dexamethasone (classification: glucocorticoid)
- Diethylstilbestrol (DES; AMDUCA prohibited synthetic hormone)
- Dipyrone (classification: NSAID<sup>3</sup>)
- Eprinomectin (classification: antiparasitic; avermectin)
- Etodolac (classification: NSAID)
- Flunixin (classification: NSAID)
- Halofuginone (classification: antiprotozoal, coccidiostat)
- Hormones, endogenous production (17-β estradiol, progesterone, testosterone)
- Hormones, xenobiotics (Melengestrol acetate, trenbolone, zeranol)
- Lasalocid (classification: coccidiostat)
- Levamisole (classification: anthelmintic)
- Methyl prednisone (classification: glucocorticoid)
- Morantel and pyrantel (classification: anthelmintic)
- Nicarbazin (classification: coccidiostat)
- Nitrofurans (compounds: furazolidone, nitrofurazone; AMDUCA prohibited antimicrobials)
- Nitromidazoles (classification: antiprotozoals; compounds in FSIS MRM: dimetridazole, ipronidazole)
- Phenylbutazone (classification: NSAID)
- Prednisone (classification: glucocorticoid)
- Ronidazole (classification: antimicrobial; compound: nitroimidazole)
- Sulfonamides (classification: antimicrobials, and some are coccidiostats; compounds in FSIS MRM: sulfapyridine, sulfadiazine, sulfathiazole, sulfamerazine, sulfamethazine, sulfachlorpyridazine, sulfadoxine, sulfamethoxypyridazine, sulfaquinoxaline, sulfadimethoxine, sulfisoxazole, sulfacetamide, sulfamethoxazole, sulfamethizole, sulfanilamide, sulfaguanidine, sulfabromomethazine, sulfasalazine, sulfaethoxypyridazine, sulfaphenazole, and sulfatroxazole)
- Sulfanitran (classification: antibacterial, coccidiostat)<sup>4</sup>
- Thyreostats (compound: thiouracil)
- 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 *Table 2A*, *Drugs Banned from Extralabel use under AMDUCA prohibited*.

<sup>&</sup>lt;sup>3</sup> NSAID = *non*-steroidal anti-inflammatory drug

<sup>&</sup>lt;sup>4</sup> 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, 2007 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 techniques and principles from the field of risk assessment 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 of each of the candidate compounds or compound classes in meat, poultry, and egg products, then that 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

Given the limited resources available for this priority-setting effort, 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, *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 program. Drug compounds were scored by two methods: (a) the maximum violation rate seen in any production class (averaged over 1996-2005); and (b) the maximum, for any class, of the violation rate (again, averaged over 1996-2005),

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.<sup>5</sup> 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.<sup>6</sup> 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 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*, 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, since 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" simply 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 "Regulatory Concern" and "Withdrawal Time." A scatter plot for the dependent and independent variables is shown in Graph III, *Scatter plot for Violation Rate vs. the Product of Regulatory Concern times 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 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:

<sup>&</sup>lt;sup>5</sup> For a more detailed explanation, refer the *Scoring Key for Veterinary Drugs*.

<sup>&</sup>lt;sup>6</sup> 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 = 1.5818 + 0.16 \* (R\*W) Vp = Predicted score for "FSIS Historical Testing Information on Violations"<math>W = score for "Withdrawal Time R = Score for "Regulatory Concern"R\*W = Product of R and W.

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<sup>2</sup>
- W<sup>2</sup>
- N<sup>2</sup>
- The product of R and W
- The product of R and N
- The product of W and N.

No terms involving "Number of Animals Treated" were included in the final equation since none were found to be significant factors in the regression model.

The model represented by Equation 2 was found to be insignificant at the probability value of 0.05. The overall model p-value is 0.1075 and the regression value ( $R^2$ ) is 0.32, which explains a 32% variability in the data. In statistics, regression analysis examines the relation of a dependent variable (response variable) to specified independent variables.

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 purely 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.

Equation 3
Relative Public Health Concern = <i>Predicted</i> or <i>Actual</i> 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. 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:

 $R = V^*((D+3^*T)/4)$  V = Predicted or Actual score for "FSIS Historical Testing Information on Violations" D = score for "Impact on New and Existing Human Disease" T = score for "Acute or Chronic Toxicity Concerns" 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 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 Table 2B, *Rank and Status for Veterinary Drugs*, the drugs are ranked by their rating scores, as generated using the above weighting formula. The scores presented in Table 2B 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.<sup>7</sup> 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 2007 NRP and to determine which compounds and compound classes to include in the 2007 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 1-6, 9, 14, and 19 (out of a total of 30) represent a potential public health concern sufficient to justify their inclusion in the 2007 NRP. In addition, based on intelligence from the field, FDA expressed an interest in having FSIS perform limited testing on three additional compounds: ractopamine (ranked 29<sup>th</sup>) and MGA (ranked 24<sup>th</sup>).

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 2007 NRP for domestic sampling:

- Antibiotics
- Arsenicals
- Avermectins
- *beta*-Agonists<sup>8</sup> (Ractopamine)
- Chloramphenicol
- Florfenicol
- Melengestrol acetate (MGA)
- Nitrofurans

<sup>&</sup>lt;sup>7</sup> See footnote 4.

<sup>&</sup>lt;sup>8</sup>See footnote 2.

- Nitroimidazoles
- *Phenylbutazone (ELISA)* Note that phenylbutazone will not be scheduled in the 2007 NRP. However, FAST positive samples will be tested for phenylbutazone.
- Sulfonamides
- Thyreostats
- Trenbolone
- Zeranol

In the 2007 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.

Table 2B 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 2007 NRP. For each highly ranked compound or compound class that is not included for domestic sampling in the 2007 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

The SAT participants identify the production classes of concern for each of the drugs and drug classes to be included in the 2007 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*. Compound/Production Class pairs included in the 2007 NRP are designated by a "●." Those C/PC pairs that are of regulatory concern, but that could not be included in the 2007 NRP because of laboratory resource constraints, are marked with a "○."

A number of production classes will be sampled by the chlorinated hydrocarbon/chlorinated organophosphate (CHC/COP) method (see Pesticides). The CHC/COP method also detects phenylbutazone. However, phenylbutazone will not be scheduled in the 2007 NRP. Although phenylbutazone will not be scheduled, FAST positive samples will be tested for phenylbutazone.

FSIS suspended scheduled testing for certain production classes in 2005; these are marked with a "..."

Production class nomenclature:

- Bulls are mature, intact male cattle;
- Beef cows are sexually mature female cattle of beef type, ordinarily having given birth to one or more calves;
- Dairy cows are sexually mature female cattle of dairy type, ordinarily having given birth to one or more calves;
- Heifers are young, female cattle that have not yet given birth to a calf;
- Steers are male cattle castrated before sexual maturity;
- Calves/veal definitions are under FSIS review;

- Market hogs are swine usually marketed near six months of age and 200 to 300 pounds live weight;
- Boars are mature swine showing male sexual characteristics;
- Stags are male swine castrated after they have reached sexual maturity;
- Sows are mature female swine ordinarily having given birth to one or more litters;
- Sheep include mature sheep with no distinction by gender;
- Lambs are generally defined as sheep younger than 14 months and having a break joint in at least one leg;
- Goats are of both sex and any age;
- Horses are of either sex or any age;
- Other livestock include bison, deer, elk, etc.;
- Young chickens include: broilers/fryers that are usually less than 10 weeks of age, roasting chickens are young chickens of either sex usually less than 12 weeks of age, and capons that are surgically neutered male chickens usually less than 8 months of age;
- Mature chickens are adult female chickens usually more than 10 months of age;
- Young turkeys include fryer/roaster turkeys that are either male or female and usually less than 12; weeks of age, and turkeys that are either male or female usually less than 6 months of age;
- Mature turkeys are of both sex and usually more than 15 months of age;
- Ducks are of both sex and any age;
- Geese are of both sex and any age;
- 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;
- Roaster Pigs are animals of both sexes and any age that are marketed with the carcass unsplit and with head on;
- Egg products are yolks, whites, or whole eggs after breaking and can be dried, frozen, or liquid.

## **IV. Allocation of Sampling Resources**

## "Full-Resource" Sampling

Table 4 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 2005 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 4:

Equation 5 Percent Estimated Relative Percent of Domestic Consumption (ERC)  $ERC = AP/TP \ge 100$ AP = Annual Production (dressed weight in pounds)TP = Total Annual Production of all Production Classes All calculations and results are presented in Table 4, *Estimated Relative Consumption, Domestically Produced Meat, Poultry, and Egg Products.* 

FSIS has the analytical capability to sample production classes of concern for the following compounds and compound classes: antibiotics (by bioassay); arsenicals; avermectins; sulfonamides; and phenylbutazone (via the CHC/COP methodology). **Note that phenylbutazone will not be scheduled in the 2007 NRP. However, FAST positive samples will be tested for phenylbutazone.** 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 5 and as presented in Table 4). The resulting priority score for compound-production class pairs is shown in tables 5 and 6 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 5, 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, for each production class in which the specified drug might appear (as indicated in Table 6). The compound-production class pairs were sorted by their sampling priority scores and into two classes of sample numbers. Initially (see Table 5), compound-production class pairs in these classes were assigned sampling numbers of 300 and 230 (except equine, which are assigned 90 samples). The cutoff scores for Relative Public Health Concern corresponding to each sampling level were as follows: > 1.0 = 300 samples and < 1.0 = 230 samples. 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, from among four different sampling options: high regulatory concern (300 samples per year) and moderate regulatory concern (230 samples/year) 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. 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).

Minor species, rabbits, ratites, squab, geese, ducks, and bison, have not be scheduled for the domestic sampling program beginning in the 2006 NRP. The reason is that minor species are low production animals. Not scheduling the minor species will allow FSIS to focus those resources on the development of methodologies in areas that are of high public health concern.

### **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 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 6, *Number of Scheduled Samples for Veterinary Drug/Production Class Pairs, 2007 NRP Domestic Scheduled Sampling*, lists the number of analyses assigned to each C/PC pair in Table 5. The table also reports the total number of samples analyzed in the FSIS scheduled sampling plan for the period 01/01/1996-12/31/2005, 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 01/01/1996-12/31/2005, increase the sampling level by +1 (if 230 were assigned initially, increase to 300 samples).
- If the number of samples tested in the FSIS scheduled sampling plan for a compound-production class pair for the period 01/01/1996-12/31/2005 was 230 samples, and a violation rate of equal to or greater than 50%, and less than 70% (≥ 0.50%, and < 0.70%) was found, increase the sampling level by +1 (if 230 were assigned initially, increase to 300 samples).
- If 230 samples were tested in the FSIS scheduled sampling plan for a compound-production class pair for the period 01/01/1996-12/31/2005, and a violation rate of greater than or equal to 70% (≥ 0.70%) was found, increase the sampling level by +1 (if 230 were assigned initially, increase to 300 samples).
- If at least 300 samples tested in the FSIS scheduled sampling plan for a compound-production class pair (for the period 01/01/2003-12/31/2005), and a violation rate of 0.00% was found, rotate the C/PC pair out of the NRP.<sup>9</sup>
- 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 6 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.

<sup>9</sup> Compound-production class pairs removed from scheduled sampling will be reintroduced at a later date.

No adjustments for laboratory capacity were made for the 2007 NRP.

#### 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 2003) 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). The total number of samples will not be reduced below 230. Based on these parameters, no adjustments were made for the 2007 NRP. No adjustment will be made for the minor species (bison, ducks, rabbits, geese, squab, and ratites) since these minor species were suspended from testing beginning in the 2006 NRP.

#### Adjustment for a zero (0%) violation rate for the three year period, 2003 - 2005

FSIS historical violation data were examined for the 2003-2005 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 6, under the heading "Final Adjustment."

### "Limited Resource" Sampling

The 2007 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, a minimum of 300 analyses are scheduled in each production class to be sampled. This yields a 95% chance of detecting a violation, if the true violation rate is 1%. However, because of laboratory resource limitations, it is not always possible to sample at this level.

For the 2007 NRP, selection of production classes for the limited resource sampling for compounds (Table 6) was made as follows:

• *beta*-Agonists (ractopamine, clenbuterol, cimaterol, and salbutamol) are of concern in heifers, formula-fed veal, non-formula-fed veal, and market hogs for the 2007 NRP; the analytical capacity for the *beta*-agonists in the 2007 NRP is 1,200 samples. FSIS will schedule 1,200

analyses for *beta*-agonists in heifers, formula-fed veal, non-formula-fed veal, and market hogs for domestic sampling and 120 import samples for a total of 1,320 samples.

- Chloramphenicol is of concern in dairy cows, formula-fed veal, young chickens, and young turkeys for the 2007 NRP; the analytical capacity is 1,200 samples for chloramphenicol in the 2007 domestic NRP. FSIS will schedule 1,200 analyses for chloramphenicol for dairy cows, formula-fed veal, young chickens, and young turkeys for domestic scheduled sampling and 192 samples for the import program for a total of 1,392 samples.
- Florfenicol is of concern in dairy cows, formula-fed veal, and non-formula-fed veal. The analytical capacity is 830 samples for florfenicol in the domestic 2007 NRP. FSIS will schedule 830 analyses for florfenicol in dairy cows, formula-fed veal, and non-formula-fed veal for domestic sampling and 45 samples for the import program for a total of 875 samples.
- No flunixin samples are scheduled for the 2007 domestic NRP. However, 78 import samples for flunixin are scheduled in the 2007 NRP import program.
- Melengestrol Acetate (MGA) is of concern in heifers, steers, formula, and non-formula-fed veal. The analytical capacity for MGA in 2007 is 300 samples, and the top priority production class is heifers. Therefore, FSIS will schedule 300 analyses for MGA in heifers for domestic sampling for the 2007 NRP. No import samples are scheduled for MGA.
- Nitrofurans (furazolidone and furaltadone) are of concern in market hogs, sows, and roaster pigs. The analytical capacity for nitrofurans in the 2007 NRP is 900 samples. FSIS will schedule 900 analyses for nitrofurans in market hogs, sows, and roaster pigs for domestic sampling in the 2006 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 2007 domestic NRP is 300 samples. FSIS will schedule 300 analyses for nitroimidazoles for young chickens in the 2007 NRP and will also schedule 8 import samples for a total of 308 nitroimidazole samples.
- No phenylbutazone samples are scheduled for the domestic 2007 NRP or for the import program. However, testing for phenylbutazone will be conducted for FAST positive samples.
- The *beta*-agonist, ractopamine, is of concern in heifers, market hogs, formula-fed veal and nonformula-fed veal in the 2007 domestic NRP; the analytical capacity for ractopamine for the 2007 NRP is 1,200 samples. FSIS will schedule 1,200 analyses for ractopamine in heifers, market hogs, formula-fed veal and non-formula-fed veal for domestic and 120 import samples for a total of 1,320 samples.
- Thyreostats are of concern formula-fed veal the 2007 domestic NRP; the analytical capacity for thyreostats is 300 samples. FSIS will schedule 300 analyses in formula-fed veal for domestic sampling and 90 samples for import sampling for a total of 390 samples.
- Trenbolone is of concern in formula-fed veal for the 2007 NRP; the analytical capacity for trenbolone is 230 samples in 2007 domestic NRP. FSIS will schedule 230 samples in formula-fed veal for domestic sampling. No samples will be scheduled for the import program.

• Zeranol is of concern in formula-fed veal for the 2007 NRP; the analytical capacity for zeranol is 230 samples in the domestic 2007 NRP. FSIS will also schedule 90 import samples for a total of 320 samples.

The above information is presented in tabular format at the end of the section, "Summary of Domestic and Import Sampling," in Table 56, *Combined Summary, 2005 FSIS NRP, Domestic and Import Scheduled Sampling, and Exploratory Assessments.* 

### V. Scoring Key

### FSIS Historical Testing Information on Violations (01/01/1996 - 12/31/2005)

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 1996 - 2005, 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%. These 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:

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

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 indicate 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 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 contained within 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 Drugs2007 FSIS NRP, Domestic Scheduled Sampling

Compound / Compound Class	Historical Testing for Violations <sup>1</sup> (V)	Regulatory Concern <sup>2</sup> (R)	Withdrawal Time <sup>3</sup> (W)	Relative Number Treated <sup>4</sup> (N)	Predicted V (V = 1.5818 + 0.16 (R*W)) <sup>5</sup>	Impact New & Existing Human Disease <sup>6</sup> (D)	Acute or Chronic Toxicity Concerns <sup>7</sup> (T)	Relative Public Health Concern Score (P = V*[(D+3*T)/4])
Antibiotics <sup>8</sup>	4	4	4	4	4.00	3	4	15.00
Carbadox <sup>9</sup>	4	4	4	3	4.00	3	4	15.00
Sulfonamides <sup>10</sup>	4	4	3	4	4.00	3	3	12.00
Florfenicol	NA-3 <sup>11</sup>	3	4	4	3.50	3	3	10.51
Avermectins <sup>12</sup>	4	3	4	4	4.00	2	4	14.00
Arsenicals <sup>13</sup>	2	4	2	4	2.00	3	2	4.50
Flunixin	4	4	2	3	4.00	1	2	7.00
ß-agonist (Ractopamine)	1	4	2	3	1.00	2	3	2.75
Thyreostats <sup>14</sup>	NA-0 <sup>15</sup>	4	3	1	3.50	2	4	12.26
Dipyrone <sup>16</sup>	Not Tested	4	3	1	3.50	1	4	11.38
Berenil <sup>17</sup>	NA-2 <sup>18</sup>	4	4	1	4.14	2	3	11.39
Trenbolone <sup>19</sup>	NA-2 <sup>20</sup>	4	1	3	2.22	3	3	6.67
Zeranol <sup>21</sup>	4 <sup>22</sup>	4	1	3	4.00	3	3	12.00
Methyl prednisone	Not Tested	4	2	2	2.86	1	3	7.15
Eprinomectin	Not Tested	2	2	3	2.22	2	2	4.44
Clorsulon <sup>23</sup>	Not Tested	2	3	2	2.54	2	2	5.08
Dexamethasone	NA-O <sup>24</sup>	4	2	2	2.86	1	3	7.15
Thiamphenicol	Not Tested	3	2	1	2.54	3	3	7.63
Amprolium <sup>25</sup>	Not Tested	4	2	2	2.86	3	2	6.44
Hormones, endogenous <sup>26</sup>	Not Tested	4	1	4	2.22	2	2	4.44

### Table 1 - continuedScoring Table for Veterinary Drugs2007 FSIS NRP, Domestic Scheduled Sampling

Compound / Compound Class	Historical Testing for Violations <sup>1</sup> (V)	Regulatory Concern <sup>2</sup> (R)	Withdrawal Time <sup>3</sup> (W)	Relative Number Treated <sup>4</sup> (N)	Predicted V (V = 1.5818 + 0.16 (R*W)) <sup>5</sup>	Impact New & Existing Human Disease <sup>6</sup> (D)	Acute or Chronic Toxicity Concerns <sup>7</sup> (T)	Relative Public Health Concern Score (P = V*[(D+3*T)/4])
Lasalocid <sup>27</sup>	Not Tested	2	1	3	1.90	3	2	4.28
Melengesterol acetate (MGA) <sup>28</sup>	1	2	1	4	1.00	3	3	3.00
Levamisole <sup>29</sup>	NA-1 <sup>30</sup>	3	3	2	3.02	1	1	2.02
Prednisone <sup>31</sup>	Not Tested	3	2	1	2.54	1	3	6.35
Etodolac <sup>32</sup>	Not Tested	3	2	1	2.54	1	3	6.35
Halofuginone <sup>33</sup>	NA-1 <sup>34</sup>	1	2	2	1.90	2	2	3.80
Benzimidazoles <sup>35</sup>	Not Tested	1	3	2	2.06	1	2	3.61
Veterinary tranquilizers	Not Tested	4	2	2	2.86	1	1	2.86
Nicarbazin <sup>36</sup>	Not Tested	2	2	1	2.22	2	1	2.78
Morantel and pyrantel <sup>37</sup>	Not Tested	1	1	2	1.74	2	1	2.18

<sup>&</sup>lt;sup>1</sup> Scores for historical testing information for residue violations, *V*, are provided by USDA's Food Safety and Inspection Service (FSIS).

<sup>&</sup>lt;sup>2</sup> Scores for regulatory concern, R, are provided by FDA's Center for Veterinary Medicine (CVM).

<sup>&</sup>lt;sup>3</sup> Scores for withdrawal time *W*, are provided by FDA's Center for Veterinary Medicine (CVM).

<sup>&</sup>lt;sup>4</sup> Scores for relative number of animals treated, *N*, are provided by FDA's Center for Veterinary Medicine (CVM).

<sup>&</sup>lt;sup>5</sup> 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.

<sup>&</sup>lt;sup>6</sup> Scores impact on new and existing human disease, *D*, are provided by FDA's Centers for Disease Control (CDC).

<sup>&</sup>lt;sup>7</sup> Scores for acute or chronic toxicity concerns, *T*, are provided by FDA's Center for Veterinary Medicine (CVM).

<sup>&</sup>lt;sup>8</sup> Antibiotics quantitated by the FSIS Bioassay Multi-Residue Method (MRM). At present, the following antibiotics are quantitated using the 7-plate bioassay after a specific identification is made using mass spectroscopy (MS) or using high performance liquid chromatography (HPLC): tetracycline, oxytetracycline, chlortetracycline, gentamicin, streptomycin, dihydrostreptomycin, erythromycin, tylosin, neomycin, *beta*-lactams (quantitated as penicillin-G; penicillins and cephalosporins are not differentiated within this category), and tilmicosin (quantitated by HPLC). The following antimicrobials can be identified by MS; however, no quantitative methods are available: spectinomycin, hygromycin, amikacin, kanamycin, apramycin, tobramycin, pirlimycin, clindamycin, and oleandomycin.

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

### Table 1 - continuedScoring Table for Veterinary Drugs2007 FSIS NRP, Domestic Scheduled Sampling

performance liquid chromatography (HPLC), or mass spectrometry, MS) to establish their identities, where such follow-up methodologies are available. Tetracycline, oxytetracycline, and chlortetracycline share patterns of inhibition and are individually identified by follow-up with the HPLC method for tetracyclines; tilmicosin, tylosin, lincomycin, clindamycin, erythromycin, and pirlimycin, which are individually identified by ion-trap LC/MS/MS. Tissues found to be positive for tilmicosin are quantitated by a NADA method using HPLC. Amikacin, apramycin, dihydrostreptomycin, gentamycin, hygromycin, kanamycin, neomycin, spectinomycin, streptomycin, and tobramycin are individually identified by ion-trap LC/MS/MS. Confirmation for sulfa drugs and flunixin are also provided by the residue chemistry section at the FSIS, Midwestern Laboratory. <sup>9</sup> Antimicrobial. <sup>10</sup> Antimicrobials and some are coccidiostats. <sup>11</sup> NA-3 = The data are preliminary. Data have been collected for only 1-2 years for 2 or more production classes. <sup>12</sup> Avermectins in the FSIS MRM are doramectin, ivermectin, moxidectin. <sup>13</sup> Detected as As. <sup>14</sup> Includes thiouracil.  $^{15}$  NA-O = The data are preliminary. Data have been collected for only one year for 2 or more production classes. <sup>16</sup> NSAID. <sup>17</sup> Antiprotozoal, histomonas.  $^{18}$  NA-2 = Scheduled sampling data have been collected for a single production class and for a limited time period. <sup>19</sup> Xenobiotic hormone.  $^{20}$  NA-2 = Scheduled sampling data have been collected for a single production class and for a limited time period. <sup>21</sup> Xenobiotic hormone; FDA increased the score for regulatory concern for zeranol from 3 (2005 NRP) to 4 for the 2006 NRP.  $^{22}$  NA-2 = Scheduled sampling data have been collected for a single production class and for a limited time period. <sup>23</sup> Anthelmintic, Trematodes.  $^{24}$  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. <sup>25</sup> Coccidiostat. <sup>26</sup> FDA increased the score for regulatory concern for naturally occurring hormones from 2 (2005 NRP) to 4 for the 2006 NRP. <sup>27</sup> Coccidiostat. <sup>28</sup> Xenobiotic hormone; FDA decreased the score for regulatory concern for melengestrol acetate (MGA) from 3 (2005 NRP) to 2 for the 2006 NRP. <sup>29</sup> Anthelmintic, Nematodes.  $^{30}$  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. <sup>31</sup> FDA increased the score for regulatory concern for prednisone from 2 (2005 NRP) to 3 for the 2006 NRP. <sup>32</sup> NSAID. <sup>33</sup> Antiprotozoal, coccidiostat.  $^{34}$  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. <sup>35</sup> Anthelmintics. <sup>36</sup> Coccidiostat. <sup>37</sup> Anthelmintics.

## Table 2ADrugs Banned from Extra Label Use Under AMDUCA2007 FSIS NRP – Domestic Scheduled Sampling

AMDUCA <sup>1</sup> Prohibited Drug	Status in the 2007 NRP
Avoparcin	Not in the 2007 NRP.
Chloramphenicol	<i>Domestic Scheduled Sampling</i> : 300 samples each are scheduled for dairy cows, formula-fed veal, young chickens, and young turkeys.
	<i>Import Scheduled Sampling</i> : 78, 90, 16, and 8 samples are scheduled for fresh beef, veal, turkey, and chicken, respectively.
$\beta$ -Agonists <sup>2</sup>	<i>Domestic Scheduled Sampling</i> : 300 samples each are scheduled for heifers, formula-fed veal, non-formula-fed veal, and market hogs. Confirmation done by FDA-NCTR. <sup>3</sup>
	<i>Import Scheduled Sampling</i> : 90 and 30 samples are scheduled for veal and pork fresh, respectively.
Diethylstilbestrol <sup>4</sup>	Not in the 2007 NRP.
Fluoroquinolones <sup>5</sup>	Not in the 2007 NRP.
Nitrofurans <sup>6</sup>	<i>Domestic Scheduled Sampling</i> : 300 samples each are scheduled for market hogs, sows, and roaster pigs.
	Import Scheduled Sampling: No samples are scheduled for the 2007 NRP.
Nitroimidazoles <sup>7</sup>	Domestic Scheduled Sampling: 300 samples are scheduled for young chickens.
Nitronnituazoies	Import Scheduled Sampling: 8 samples are scheduled for fresh chicken.

### Table 2A - continuedDrugs Banned from Extra Label Use Under AMDUCA2007 FSIS NRP – Domestic Scheduled Sampling

AMDUCA <sup>1</sup> Prohibited Drug	Status in the 2007 NRP
Phenylbutazone <sup>8</sup>	Domestic Scheduled Sampling: No samples are scheduled for the 2007 NRP
	Domestic Scheduled Sampling: No samples are scheduled for the 2007 NRP
Ronidazole <sup>9</sup>	Not in the 2007 NRP.
Vancomycin <sup>10</sup>	Not in the 2007 NRP.

<sup>&</sup>lt;sup>1</sup> Drugs banned from extralabel use under AMDUCA were not evaluated using the ranking formula for inclusion in Table 2A. Instead, these drugs were automatically assigned a high sampling priority and will be included in the NRP if methodologies and resources are available.

<sup>&</sup>lt;sup>2</sup> 1200 animals will be sampled in the FSIS domestic program. A pound of liver will be collected and sent to WL for screening and confirmation by HPLC/MS/MS. This method detects  $\beta$  -agonists, clenbuterol, salbutamol, cimaterol, and ractopamine, in bovine, porcine, ovine, and caprine liver and bovine retina. Note that although the method is validated for retina, eye balls are not being collected for the 2007 NRP. FSIS has completed validation work to extend the method to muscle and plans to add zilpaterol.

<sup>&</sup>lt;sup>3</sup> Food and Drug Administration, National Center for Toxicological Research, Jefferson, AR.

<sup>&</sup>lt;sup>4</sup> Xenobiotic hormone.

<sup>&</sup>lt;sup>5</sup> The fluoroquinolones, enrofloxacin and danofloxacin, are approved for use steers and heifers.

<sup>&</sup>lt;sup>6</sup> Furazolidone and nitrofurazone; antimicrobials.

<sup>&</sup>lt;sup>7</sup> Nitroimidazoles in the FSIS multi residue method (MRM) are dimetridazole and ipronidazole; antiprotozoal

<sup>&</sup>lt;sup>8</sup> The Surveillance Advisory Team (SAT) decided that all cattle classes will be sampled for phenylbutazone (ELISA method) for the 2007 NRP; non-Steroidal Antiinflammatory Drug (NSAID).

<sup>&</sup>lt;sup>9</sup> Antimicrobial.

<sup>&</sup>lt;sup>10</sup> Glycopeptide.

Rank	Drug	Score	Status in the 2007 NRP
1	Antibiotics <sup>1</sup>	15.0	<i>Domestic Scheduled Sampling</i> : 300, 300, 300, 300, 230, 230, 230, 300, 30
			<i>Import Scheduled Sampling</i> : 657 samples are scheduled for fresh beef, fresh pork, fresh veal, fresh turkey, fresh chicken, and fresh varied combo.
2	2 Carbadox <sup>3</sup> 15.0	15.0	Domestic Scheduled Sampling: 300 samples each are scheduled for market hogs and roaster pigs.
2		13.0	Import Scheduled Sampling: No samples are scheduled for the 2007 NRP.
3	Avermectins <sup>4</sup> 14.0	14.0	<i>Domestic Scheduled Sampling</i> : 300, 300, 300, 300, 300, 230, 230, 230,
		14.0	<i>Import Scheduled Sampling</i> : 583 samples are scheduled for fresh beef, processed beef, fresh veal, fresh lamb and mutton, and fresh goat.
4	4 Thyreostats <sup>5</sup>	12.3	Domestic Scheduled Sampling: 300 samples are scheduled for formula-fed veal.
			Import Scheduled Sampling: 90 samples are scheduled for fresh veal.

Rank	Drug	Score	Status in the 2007 NRP
5	5 Sulfonamides <sup>6</sup>		<i>Domestic Scheduled Sampling</i> : 300 samples each are scheduled for market hogs, steers, dairy cows, beef cows, bulls, mature turkeys, bob veal, roaster pigs, non-formula-fed veal, young chickens, young turkeys, sheep, lambs, goats and heavy calves, respectively.
		12.0	<i>Import Scheduled Sampling</i> : 836 samples are scheduled for fresh beef, processed beef, fresh pork, processed pork, fresh veal, fresh turkey, processed turkey, fresh varied combo, and processed varied combo.
6	Zeranol <sup>7</sup>	12.0	Domestic Scheduled Sampling: 230 samples are scheduled for formula-fed veal.
			Import Scheduled Sampling: 90 samples each are scheduled for fresh veal.
7	Bereni1 <sup>8</sup>	11.4	Domestic Scheduled Sampling: No samples are scheduled for the 2007 NRP.
			Import Scheduled Sampling: No samples are scheduled for the 2007 NRP.
8	8 Dipyrone <sup>9</sup>	11.4	Domestic Scheduled Sampling: Not in the 2007 NRP.
		11.4	Import Scheduled Sampling: Not in the 2007 NRP.

Rank	Drug	Score	Status in the 2007 NRP
9	9 Florfenicol <sup>10</sup>	10.5	<i>Domestic Scheduled Sampling</i> : 300, 300, and 230 samples are scheduled for dairy cows, formula-fed veal, and non-formula-fed veal, respectively.
			Import Scheduled Sampling: 45 samples are scheduled for fresh beef.
10	10 Thiamphenicol <sup>11</sup>	7.6	Domestic Scheduled Sampling: Not in the 2007 NRP.
10			Import Scheduled Sampling: Not in the 2007 NRP.
	11 Methyl prednisone <sup>12</sup>	7.2	Domestic Scheduled Sampling: Not in the 2007 NRP.
			Import Scheduled Sampling: Not in the 2007 NRP.
12	Dexamethasone <sup>13</sup>	7.2	Domestic Scheduled Sampling: No samples are scheduled for the 2007 NRP.
			Import Scheduled Sampling: No samples are scheduled for the 2007 NRP.

Rank	Drug	Score	Status in the 2007 NRP
13			Domestic Scheduled Sampling: No samples are scheduled for the 2007 NRP.
15	Flunixin <sup>14</sup>	7.0	Import Scheduled Sampling: 78 samples are scheduled for fresh beef.
14		6.7	Domestic Scheduled Sampling: 230 samples are scheduled for formula-fed veal.
14	Trenbolone		Import Scheduled Sampling: No samples are scheduled for the 2007 NRP.
1.5	A 11 15	<i>с</i> <b>л</b>	Domestic Scheduled Sampling: Not in the 2007 NRP.
15	Amprolium <sup>15</sup>	6.4	Import Scheduled Sampling: Not in the 2007 NRP.
	16 Prednisone <sup>16</sup> 6.4		Domestic Scheduled Sampling: Not in the 2007 NRP.
16		6.4	Import Scheduled Sampling: Not in the 2007 NRP.

Rank	Drug	Score	Status in the 2007 NRP
17			Domestic Scheduled Sampling: Not in the 2007 NRP.
17	Etodolac <sup>17</sup>	6.4	Import Scheduled Sampling: Not in the 2007 NRP.
18	10 77 18		Domestic Scheduled Sampling: Not in the 2007 NRP.
18	Clorsulon <sup>18</sup>	5.1	Import Scheduled Sampling: Not in the 2007 NRP.
10	Arsenicals <sup>19</sup>		<i>Domestic Scheduled Sampling</i> : 300 samples each are scheduled for market hogs and young chickens. <sup>20</sup>
19	Arsenicais	4.5	<i>Import Scheduled Sampling</i> : 145 samples each are scheduled for fresh pork, fresh turkey, fresh chicken, processed chicken, and processed turkey
20			Domestic Scheduled Sampling: Not in the 2007 NRP.
20	Eprinomectin	4.4	Import Scheduled Sampling: Not in the 2007 NRP.

Rank	Drug	Score	Status in the 2007 NRP
21			Domestic Scheduled Sampling: Not in the 2007 NRP.
	Hormones, naturally-occurring <sup>21</sup>	4.4	Import Scheduled Sampling: Not in the 2007 NRP.
22	Lasalocid <sup>22</sup>	4.3	Domestic Scheduled Sampling: Not in the 2007 NRP.
	Lasalocid	4.3	Import Scheduled Sampling: Not in the 2007 NRP.
23	Halofuginone <sup>23</sup>	3.8	Domestic Scheduled Sampling: Not in the 2007 NRP.
		5.0	Import Scheduled Sampling: Not in the 2007 NRP.
24	24 Benzimidazoles in the FSIS MRM <sup>24</sup>	3.6	Domestic Scheduled Sampling: Not in the 2007 NRP.
24			Import Scheduled Sampling: Not in the 2007 NRP.

Rank	Drug	Score	Status in the 2007 NRP
25	25 Levamisole <sup>25</sup>	3.5	Domestic Scheduled Sampling: Not in the 2007 NRP.
			Import Scheduled Sampling: Not in the 2007 NRP.
26	Melengesterol acetate <sup>26</sup> (MGA)	3.0	<i>Domestic Scheduled Sampling</i> : 300 samples are scheduled for heifers.
		5.0	Import Scheduled Sampling: No samples are scheduled for the 2007 NRP.
27	Veterinary tranquilizers <sup>27</sup>	2.9	Domestic Scheduled Sampling: Not in the 2007 NRP.
			Import Scheduled Sampling: Not in the 2007 NRP.
28	28 Nicarbazin <sup>28</sup> 2.	2.9	Domestic Scheduled Sampling: Not in the 2007 NRP.
20		<i>,</i>	Import Scheduled Sampling: Not in the 2007 NRP.

Rank	Drug	Score	Status in the 2007 NRP
20	29 $\beta$ -agonists <sup>29</sup>	2.8	<i>Domestic Scheduled Sampling</i> : 300 samples each are scheduled for heifers, formula-fed veal and non-formula-fed veal, and market hogs.
29			<i>Import Scheduled Sampling</i> : 90 and 30 samples are scheduled for fresh veal and fresh pork, respectively.
20	Morontol and associate to to to the	2.2	Domestic Scheduled Sampling: Not in the 2007 NRP.
30	30 Morantel and pyrantel tartarate	2.2	Import Scheduled Sampling: Not in the 2007 NRP.

<sup>&</sup>lt;sup>1</sup> At present, the following antibiotics are quantitated using the 7-plate bioassay after a specific identification is made using mass spectroscopy (MS) or using high performance liquid chromatography (HPLC): tetracycline, oxytetracycline, chlortetracycline, gentamicin, streptomycin, dihydrostreptomycin, erythromycin, tylosin, neomycin, beta-lactams (quantitated as penicillins and cephalosporins are not differentiated within this category), and tilmicosin (quantitated by HPLC). The following antimicrobials can be identified by MS; however, no quantitative methods are available: spectinomycin, hygromycin, amikacin, kanamycin, apramycin, tobramycin, lincomycin, pirlimycin, clindamycin, and oleandomycin.

<sup>5</sup> Includes thiouracil.

<sup>7</sup> Xenobiotic hormone.

<sup>8</sup> Antiprotozoal.

<sup>&</sup>lt;sup>2</sup> Young chickens and young turkeys have a 0% violation rate for antibiotics for the 3 year period (2001-2003). These production classes were rotated back into the scheduled sampling program in the 2006 NRP based on the expert opinion of the Surveillance Advisory Team (SAT).

<sup>&</sup>lt;sup>3</sup> Antimicrobial.

<sup>&</sup>lt;sup>4</sup> Doramectin, ivermectin, and moxidectin; Antiparasitic.

<sup>&</sup>lt;sup>6</sup> Sulfonamides in the FSIS multi-residue method (MRM): Sulfapyridine, sulfadiazine, sulfathiazole, sulfamerazine, sulfamethazine, sulfachloropyridazine, sulfadoxine, sulfamethoxypyridazine, sulfaquinoxaline, sulfadimethoxine, sulfasotazole, sulfacetamide, sulfamethoxazole, sulfamethizole, sulfanilamide, sulfaguanidine, sulfabromomethazine, sulfasalazine, sulfaethoxypyridazine, sulfadiazine, sulfadoxine, sulfatoxazole; Antimicrobials, some are coccidiostats; FDA has not set a tolerance for the following sulfonamides: sulfapyridine, sulfadiazine, sulfadoxine, sulfamethoxypyridazine, sulfacetamide, sulfamethoxazole, sulfamethizole, sulfacetamide, sulfaguanidine, sulfadiazine, sulfadoxine, sulfadoxine, sulfamethoxypyridazine, sulfacetamide, sulfamethoxazole, sulfamethizole, sulfacetamide, sulfaguanidine, sulfasalazine, sulfabromomethizole, and sulfatroxazole.

<sup>&</sup>lt;sup>9</sup> Non-Steroidal Anti-Inflammatory Drug (NSAID).

<sup>10</sup> Chloramphenicol derivative.

- <sup>11</sup> Chloramphenicol derivative.
- <sup>12</sup> Glucocorticoid.
- <sup>13</sup> Glucocorticoid.
- <sup>14</sup> NSAID.
- <sup>15</sup> Coccidiostat
- <sup>16</sup> Glucocorticoid
- <sup>17</sup> NSAID, Inspector Generated FAST positive samples will be screened.
- <sup>18</sup> Anthelmintic, Trematodes.
- <sup>19</sup> Detected as As.

<sup>20</sup> 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).

<sup>21</sup> 17-Estradiol, testosterone, and progesterone.

<sup>22</sup> Coccidiostat.

<sup>23</sup> Antiprotozoal, coccidiostat.

<sup>24</sup> 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); Anthelmintic.

<sup>25</sup> Anthelmintic.

<sup>26</sup> Xenobiotic hormone.

<sup>27</sup> Azaperone and its metabolite azaperol, xylazine, haloperidol, acetopromazine, propionylpromazine, and chlorpromazine.

<sup>28</sup> Coccidiostat.

<sup>29</sup> $\beta$ -Agonist.

### Table 3A Production Classes Considered for each Veterinary Drug and Drug Class (AMDUCA Drugs) 2007 FSIS NRP, Domestic Scheduled Sampling

			Animal Medicinal Dr	ug Use Clarification A	ct of 1994 (AMDU	UCA) Prohibited Drugs	jii
ERC <sup>i</sup>	Production Class	$\beta$ -Agonists <sup>iii</sup>	Chloramphenicol	Fluoroquinolones	Nitrofurans	Nitroimidazoles	Phenylbutazone <sup>iv</sup> (ELISA method)
0.05	Equine						
0.428	Bulls						
1.474	Beef cows						
1.346	Dairy cows			0			
7.045	Heifers			0			
13.206	Steers			0			
0.014	Bob veal		0				
0.116	Formula-fed veal						
0.002	non-Formula-fed veal						
0.018	Heavy calves						
0.01	Sheep						
0.166	Lambs						
0.012	Goats						
18.79	Market hogs	•			•		
0.039	Roaster pigs				•		
0.07	Boars/Stags						
0.93	Sows				•		
46.04	Young chickens		$\bullet$				
0.81	Mature chickens						
6.62	Young turkeys						
0.06	Mature turkeys						
2.55	Egg products						

 $\bullet$  = Compound/Production Class Pairs included in the 2007 NRP.

O = Compound/Production Class Pairs that are of regulatory concern, but are not included in the 2007 NRP because of laboratory resource constraints.

 $\Box$  = FSIS suspended scheduled sampling for this drug-production class pair for the 2007 NRP.

<sup>&</sup>lt;sup>i</sup> ERC = Estimated relative percent of domestic consumption, calendar year 2005. 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).

<sup>&</sup>lt;sup>ii</sup> 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. <sup>iii</sup> This method applicable to identification of B-agonists in bovine retinal tissue (except for zilpaterol); bovine, porcine, ovine and caprine liver; and bovine and porcine muscle at  $\geq 3$  ppb for clenbuterol, salbutamol, and cimaterol;  $\geq 6$  ppb for zilpaterol; and  $\geq 21$  ppb for ractopamine. Although method is validated for retina and eye balls are not being collected for the 2007 NRP.

<sup>&</sup>lt;sup>iv</sup> Phenylbutazone will not be scheduled in the 2007 NRP; however, FAST positive samples will be tested for phenylbutazone (ELISA method).

## Table 3B Production Classes Considered for each Veterinary Drug and Drug Class 2007 FSIS NRP, Domestic Scheduled Sampling

		Veterinary Drug and Priority Rating						
$ERC^{i}$	Production Class	Antibiotics	Arsenicals	Avermectins	Berenil	Carbadox	Dipyrone	Florfenicol
		15	4.5	14.0	11.4	15.0	11.4	10.5
0.05	Equine	•		•				
0.428	Bulls			•	•			
1.474	Beef cows	•						
1.346	Dairy cows	•		•			0	
7.045	Heifers	•		•				
13.206	Steers							
0.014	Bob veal							
0.116	Formula-fed veal	•						
0.002	non-Formula-fed veal	•		•				
0.018	Heavy calves	•		●				
0.02	Bison							
0.01	Sheep							
0.166	Lambs							
0.012	Goats			●				
18.79	Market hogs					•		
0.039	Roaster pigs	•				•	8	
0.07	Boars/Stags	•				0	8	
0.93	Sows	•				0		
46.04	Young chickens	•				G		
0.81	Mature chickens							
6.62	Young turkeys	•				9		
0.06	Mature turkeys					ē	ē	
0.18	Ducks					ē	ē	3
0.003	Geese					9		
>0.01	Squab				•	0		
< 0.01	Ratites					0 		
< 0.01	Rabbits				3			-
2.55	Egg products	0			-			

## Table 3B - continued Production Classes Considered for each Veterinary Drug and Drug Class 2007 FSIS NRP, Domestic Scheduled Sampling

		Veterinary Drug and Priority Rating						
ERC	Production Class	Flunixin	Melengestrol Acetate (MGA)	β-Agonists	Sulfonamides	Thyreostats	Trenbolone	Zeranol
		7.0	3.0	2.8	12.0	12.3	6.7	12.0
0.05	Equine							
0.428	Bulls	0			•			
1.474	Beef cows	0			•			
1.346	Dairy cows	0						
7.045	Heifers		•	•		0		
13.206	Steers		0	0	•	0		
0.014	Bob veal				•			
0.116	Formula-fed veal		0	•			•	•
0.002	non-Formula-fed veal		0	•	•		0	0
0.018	Heavy calves	0					0	0
0.02	Bison							
0.01	Sheep							
0.166	Lambs							
0.012	Goats							
18.79	Market hogs			•				
0.039	Roaster pigs			0				
0.07	Boars/Stags							
0.93	Sows							
46.04	Young chickens							
0.81	Mature chickens							
6.62	Young turkeys			0				
0.06	Mature turkeys				•			
0.18	Ducks							
0.003	Geese							
>0.01	Squab							
< 0.01	Ratites							
< 0.01	Rabbits							
2.55	Egg products						[ ]	

### Table 3B - continued Production Classes Considered for each Veterinary Drug and Drug Class 2007 FSIS NRP, Domestic Scheduled Sampling

- $\bullet$  = Compound/Production Class Pairs included in the 2007 NRP.
- $\Box$  = FSIS suspended scheduled sampling for this drug-production class pair for the 2007 NRP.
- O = Compound/Production Class Pairs that are of regulatory concern, but are not included in the 2007 NRP because of laboratory resource constraints.
- = Compound/Production Class Pairs that have been suspended from testing by FSIS in the 2006 NRP.
- $\blacklozenge$  = Was an exploratory project in the 2006 NRP.

<sup>&</sup>lt;sup>i</sup> ERC = Estimated relative percent of domestic consumption, calendar year 2005. 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).

		2005 Animal and	Egg Production Data <sup>1</sup>				
Cattle							
Production Class	Number of Head Slaughtered <sup>2</sup>	Pounds per Animal (dressed weight)	Total Pounds (dressed weight)	Percent Estimated Relative Consumption (all animal production classes and egg products combined)	Percent Estimated Relative Consumption (cattle)		
Bulls	518,294	859	445,214,546	0.428	1.81		
Beef cows	2,523,000	607	1,531,461,000	1.474	6.23		
Dairy cows	2,252,000	621	1,398,492,000	1.346	5.69		
Heifers	9,761,000	750	7,320,750,000	7.045	29.79		
Steers	16,797,000	817	13,723,149,000	13.206	55.84		
Bob veal	196,868	75	14,765,100	0.014	0.06		
Formula-fed veal	492,645	245	120,698,025	0.116	0.49		
non-Formula-fed veal	7,245	350	2,535,750	0.002	0.01		
Heavy calves	46,721	400	18,688,400	0.018	0.08		
Total Cattle	32,594,773		24,575,753,821	23.649	100.00		

	2005 Animal and Egg Production Data <sup>1</sup>						
		S	lwine				
Production Class	Number of Head Slaughtered <sup>2</sup>	Pounds per Animal (dressed weight)	Total Pounds (dressed weight)	Percent Estimated Relative Consumption (all animal production classes and egg products combined)	Percent Estimated Relative Consumption (swine)		
Market hogs	99,123,000	197	19,527,231,000	18.791	94.76		
Roaster pigs	691,901	58	40,130,258	0.039	0.19		
Boars/Stags	343,849	213	73,239,837	0.070	0.36		
Sows	3,116,000	310	965,960,000	0.930	4.69		
Total Swine	103,274,750		20,606,561,095	19.829	100.00		

	2005 Animal and Egg Production Data <sup>1</sup>						
		(	Ovine				
Production Class	Number of Head Slaughtered <sup>2</sup>	Pounds per Animal (dressed weight)	Total Pounds (dressed weight)	Percent Estimated Relative Consumption (all animal production classes and egg products combined)	Percent Estimated Relative Consumption (ovine)		
Sheep	129,000	69	8,901,000	0.009	4.59		
Goats	541,109	24	12,986,616	0.012	6.69		
Lambs	2,425,000	71	172,175,000	0.166	88.72		
Total Ovine	3,095,109		194,062,616	0.187	100.00		

	2005 Animal and Egg Production Data <sup>1</sup> Equine						
Production Class	Number of Head Slaughtered <sup>2</sup>	Pounds per Animal (dressed weight)	Total Pounds (dressed weight)	Percent Estimated Relative Consumption (all animal production classes and egg products combined)	Percent Estimated Relative Consumption (equine)		
Equine	93,768	500	46,884,000	0.045			
Total Equine	93,768		46,884,000	0.045	100.00		

	2005 Animal and Egg Production Data <sup>1</sup> Bison						
Production Class	Number of Head Slaughtered <sup>2</sup>	Pounds per Animal (dressed weight)	Total Pounds (dressed weight)	Percent Estimated Relative Consumption (all animal production classes and egg products combined)	Percent Estimated Relative Consumption (bison)		
Bison	35,763	610	21,815,430	0.021			
Total Bison	35,763		21,815,430	0.021	100.00		

	2005 Animal and Egg Production Data <sup>1</sup>							
		Pe	oultry					
Production Class	Number of Head Slaughtered <sup>2</sup>	Pounds per Animal (dressed weight)	Total Pounds (dressed weight)	Percent Estimated Relative Consumption (all animal production classes and egg products combined)	Percent Estimated Relative Consumption (poultry)			
Young chickens	8,993,871,716		47,847,682,669	46.043	85.71			
Mature chickens	147,672,000		836,851,300	0.805	1.50			
Young turkeys	2,480,864		6,881,876,000	6.622	12.33			
Mature turkeys	2,469,651		63,895,888	0.061	0.11			
Ducks	27,974,170		188,873,897	0.182	0.34			
Geese	252,462		3,408,189	0.003	0.01			
Other fowl (includes ratites)	1,299,089		2,436,419	0.002	0.00			
Total Poultry	9,176,019,952		55,825,024,362	53.7198	100.00			

	2005 Animal and Egg Production Data <sup>1</sup>						
		R	abbits				
Production Class	Number of Head Slaughtered <sup>2</sup>	Pounds per Animal (dressed weight)	Total Pounds (dressed weight)	Percent Estimated Relative Consumption (all animal production classes and egg products combined)	Percent Estimated Relative Consumption (rabbits)		
Rabbits	384,863		1,972,516	0.002			
Total Rabbits	384,863		1,972,516	0.002	100.00		

	2005 Animal and Egg Production Data <sup>1</sup>						
		Egg	Products				
Production Class	Number of Head Slaughtered <sup>2</sup>	Pounds per Animal (dressed weight)	Total Pounds (dressed weight)	Percent Estimated Relative Consumption (all animal production classes and egg products combined)	Percent Estimated Relative Consumption (eggs)		
Egg Products			2,646,764,000	2.547			
Total Egg Products	Fotal Egg Products         2,646,764,000         2.547         100.00						

	2005 Animal and Egg Production Data <sup>1</sup>							
	Totals for all animal production classes and egg products							
Production Class	Number of Head Slaughtered <sup>2</sup>	Total Pounds (dressed weight)	Percent Estimated Relative Consumption (all animal production classes and egg products combined)	Percent Estimated Relative Consumption (each production class)				
Cattle	32,594,773	24,575,753,821	23.649	100.00				
Swine	103,274,750	20,606,561,095	19.829	100.00				
Ovine	3,095,109	194,062,616	0.187	100.00				
Equine	93,768	46,884,000	0.045	100.00				
Bison	35,763	21,815,430	0.021	100.00				
Poultry	9,176,019,952	55,825,024,362	53.7198	100.00				
Rabbits	384,863	1,972,516	0.002	100.00				
Egg Products		2,646,764,000	2.547					
Totals		103,918,837,840	100.00					

<sup>&</sup>lt;sup>1</sup> The numbers in this table were derived from FSIS electronic Animal Disposition Reporting System (eADRS) and National Agricultural Statistical Service (NASS) data on animals (and egg products) presented for slaughter (or processing) in federally inspected establishments, for calendar year 2005 (CY '05), with the exception of the numbers for veal and calves, which were obtained from the FSIS Automated Data Reporting System (ADRS).

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 produced product that is consumed, regardless of who consumes it (i.e., no distinction is made between domestic products consumed domestically and products that are exported).* 

<sup>&</sup>lt;sup>2</sup> For livestock, NASS does not provide figures for total pounds dressed weight. Therefore, CY '05 NASS figures for number of head slaughtered were multiplied by CY '05 NASS values for average pounds dressed weight per animal (where indicated by square brackets, the latter was unavailable and estimates were used instead), to calculate total pounds dressed weight.

For poultry, rabbits, and egg products the figures for total pounds dressed weight, CY '05, were available from NASS, and it was therefore not necessary to calculate them from the number of head slaughtered.

# Table 5Veterinary Drug Compound/Production Class Pairs,<br/>Sorted by Sampling Priority Score2007 FSIS NRP, Domestic Scheduled Sampling Plan

Veterinary Drug or Drug Class	Compound Priority Rating (P)	Production Class	Relative Percent Consumption in 2005 (C)	Sampling Priority Score (P * C)	Unadjusted Number of Samples
Antibiotic	15.00	Young chickens	46.04	690.600	300
Sulfonamides	12.00	Young chickens	46.04	552.480	300
Carbadox	15.00	Market hogs	18.79	281.850	300
Sulfonamides	12.00	Market hogs	18.79	225.480	300
Arsenicals	4.50	Young chickens	46.04	207.180	300
Avermectins	14.00	Steers	13.21	184.884	300
Sulfonamides	12.00	Steers	13.21	158.472	300
Antibiotic	15.00	Heifers	7.05	105.675	300
Antibiotic	15.00	Young turkeys	6.62	99.300	300
Avermectins	14.00	Heifers	7.05	98.630	300
Arsenicals	4.50	Market hogs	18.79	84.560	300
Sulfonamides	12.00	Young turkeys	6.62	79.440	300
β-agonists	2.80	Market hogs	18.79	52.612	300

# Table 5 - continuedVeterinary Drug Compound/Production Class Pairs,<br/>Sorted by Sampling Priority Score2007 FSIS NRP, Domestic Scheduled Sampling Plan

Veterinary Drug or Drug Class	Compound Priority Rating (P)	Production Class	Relative Percent Consumption in 2005 (C)	Sampling Priority Score (P * C)	Unadjusted Number of Samples
Antibiotic	15.00	Beef cows	1.474	22.110	300
MGA	3.00	Heifers	7.05	21.135	300
Antibiotic	15.00	Dairy cows	1.346	20.190	300
B-agonists	2.80	Heifers	7.05	19.726	300
Avermectins	14.00	Dairy cows	1.35	18.844	300
Sulfonamides	12.00	Beef cows	1.474	17.688	300
Sulfonamides	12.00	Dairy cows	1.346	16.152	300
Florfenicol	10.50	Dairy cows	1.35	14.133	300
Antibiotic	15.00	Sows	0.93	13.950	300
Avermectins	14.00	Bulls	0.43	5.992	300
Sulfonamides	12.00	Bulls	0.428	5.136	300
Avermectins	14.00	Lambs	0.17	2.324	300
Sulfonamides	12.00	Lambs	0.166	1.992	300

# Table 5 - continuedVeterinary Drug Compound/Production Class Pairs,<br/>Sorted by Sampling Priority Score2007 FSIS NRP, Domestic Scheduled Sampling Plan

Veterinary Drug or Drug Class	Compound Priority Rating (P)	Production Class	Relative Percent Consumption in 2005 (C)	Sampling Priority Score (P * C)	Unadjusted Number of Samples
Antibiotic	15.00	Formula-fed veal	0.116	1.740	300
Thyreostats	12.30	Formula-fed veal	0.116	1.427	300
Zeranol	12.00	Formula-fed veal	0.116	1.392	300
Florfenicol	10.50	Formula-fed veal	0.12	1.218	300
Antibiotic	15.00	Boars/Stags	0.07	1.050	300
Antibiotic	15.00	Equine	0.05	0.750	90
Trenbolone	6.37	Formula-fed veal	0.116	0.739	230
Sulfonamides	12.00	Mature turkeys	0.060	0.720	230
Avermectins	14.00	Equine	0.05	0.700	90
Antibiotic	15.00	Roaster pigs	0.039	0.585	230
Carbadox	15.00	Roaster pigs	0.04	0.585	230
Sulfonamides	12.00	Roaster pigs	0.039	0.468	230
β-agonists	2.80	Formula-fed veal	0.12	0.325	230

# Table 5 - continuedVeterinary Drug Compound/Production Class Pairs,<br/>Sorted by Sampling Priority Score2007 FSIS NRP, Domestic Scheduled Sampling Plan

Veterinary Drug or Drug Class	Compound Priority Rating (P)	Production Class	Relative Percent Consumption in 2005 (C)	Sampling Priority Score (P * C)	Unadjusted Number of Samples
Antibiotic	15.00	Heavy calves	0.018	0.270	230
Avermectins	14.00	Heavy calves	0.02	0.252	230
Sulfonamides	12.00	Heavy calves	0.018	0.216	230
Avermectins	14.00	Goats	0.01	0.168	230
Sulfonamides	12.00	Bob veal	0.014	0.168	230
Sulfonamides	12.00	Goats	0.012	0.144	230
Avermectins	14.00	Sheep	0.01	0.140	230
Sulfonamides	12.00	Sheep	0.01	0.12	230
Antibiotic	15.00	Non-Formula-fed veal	0.002	0.030	230
Avermectins	14.00	Non-Formula-fed veal	0.00	0.028	230
Sulfonamides	12.00	Non-Formula-fed veal	0.002	0.024	230
Florfenicol	10.50	Non-Formula-fed veal	0.00	0.021	230
β-agonists	2.80	Non-Formula-fed veal	0.00	0.006	230

### Table 6Number of Scheduled Samples for Veterinary Drug/Production Class Pairs2007 NRP, Domestic Scheduled Sampling

Veterinary Drug (or drug class)	Production Class	Priority Score <sup>1</sup>	Number of Samples <sup>2</sup>	% Violation 3	% Violation <sup>4</sup>	Unadjusted Number of Samples <sup>5</sup>	Adjustment for Violations <sup>6</sup>	Adjustment for minor species <sup>7</sup>	Adjustment for Lab Capacity <sup>8</sup>	Adjustment for Production Facilities <sup>9</sup>	Final <sup>10</sup>
Antibiotics	Equine	0.75	2,786	5.81	0.00	90	0	0	0	0	90
Antibiotics	Beef cows	22.11	3,623	0.11	0.13	300	300	300	300	300	300
Antibiotics	Dairy cows	20.19	4,776	0.54	0.68	300	300	300	300	300	300
Antibiotics	Heifers	105.68	3,906	0.08	0.09	300	300	300	300	300	300
Antibiotics	Formula-fed veal	1.74	4,527	0.66	0.72	300	300	300	300	300	300
Antibiotics	Non-Formula-fed veal	0.03	1,796	1.45	3.24	300	300	300	300	300	230
Antibiotics	Heavy calves	0.27	2,401	0.62	0.66	300	300	300	300	300	230
Antibiotics	Roaster pigs	0.59	626	1.12	0.29	300	300	300	300	300	230
Antibiotics	Boars/Stags	1.05	2,315	0.26	0.12	300	300	300	300	300	300
Antibiotics	Sows	13.95	3,410	0.44	0.51	300	300	300	300	300	300
Antibiotics	Young chickens	690.60	3,623	0.06	0.06	300	300	300	300	300	300
Antibiotics	Young turkeys	99.30	3,255	0.03	0.00	300	0	0	0	0	300
Totals			37,044			3,390	3,000	3,000	3,000	3,000	3,180
Arsenic	Market hogs	84.56	2049	0	0	300	300	300	300	300	300
Arsenic	Young chickens	207.18	6874	0.15	0.08	300	300	300	300	300	300
Totals			8,923			600	600	600	600	600	600
	·	0.70	0.100	0.71	0.00					00	
Avermectins	Equine	0.70	2,123	0.71	0.00	90	90	90	90	90	90
Avermectins	Bulls	5.99	2,898	0.35	0.33	300	300	300	300	300	300
Avermectins	Dairy cows	18.84	2,266	0.09	0.00	300	300	300	300	300	300
Avermectins	Heifers	98.63	2,242	0.00	0.00	300	300	300	300	300	300
Avermectins	Steers	184.88	4,169	0.02	0.07	300	300	300	300	300	300
Avermectins	Non-Formula-fed veal	0.03	1,064	0.28	0.66	230	230	230	230	230	230
Avermectins	Heavy calves	0.25	1,880	0.37	0.93	300	300	300	300	300	300
Avermectins	Sheep	0.14	1,198	0.25	0.45	230	230	230	230	230	230
Avermectins	Lambs	2.32	2,150	0.14	0.53	230	230	230	230	230	230
Avermectins	Goats	0.17	2,885	1.49	2.38	230	230	230	230	230	230
Totals			22,875			2,510	2,510	2,510	2,510	2,510	2,510

### Table 6 - continued Number of Scheduled Samples for Veterinary Drug/Production Class Pairs 2007 NRP, Domestic Scheduled Sampling

			2	<b>1111</b> , 1	Domestic Se	neuuleu San	ipning				
Veterinary Drug (or drug class)	Production Class	Priority Score <sup>1</sup>	Number of Samples <sup>2</sup>	% Violation	% Violation <sup>4</sup>	Unadjusted Number of Samples <sup>5</sup>	Adjustment for Violations <sup>6</sup>	Adjustment for minor species <sup>7</sup>	Adjustment for Lab Capacity <sup>8</sup>	Adjustment for Production Facilities <sup>9</sup>	Final <sup>10</sup>
Sulfonamides	Bulls	5.136	2,803	0.11	0.11	300	300	300	300	300	300
Sulfonamides	Beef cows	17.688	3,179	0.09	0.11	300	300	300	300	300	300
Sulfonamides	Dairy cows	16.152	3,016	0.23	0.28	300	300	300	300	300	300
Sulfonamides	Steers	158.472	3,377	0.12	0.09	300	300	300	300	300	300
Sulfonamides	Bob veal	0.168	3,694	0.70	0.48	300	300	300	300	300	300
Sulfonamides	Non-Formula-fed veal	0.024	1,821	0.55	0.47	300	300	300	300	300	300
Sulfonamides	Heavy calves	0.216	2,226	0.13	0.14	300	300	300	300	300	300
Sulfonamides	Lambs	1.992	2,514	0.16	0.00	300	300	300	300	300	300
Sulfonamides	Goats	0.144	2,048	0.10	0.00	300	300	300	300	300	300
Sulfonamides	Market hogs	225.48	4,542	0.51	0.52	300	300	300	300	300	300
Sulfonamides	Roaster pigs	0.468	716	1.26	2.21	300	300	300	300	300	300
Sulfonamides	Sheep	0.12	521	0.00	NT	300	300	300	300	300	300
Sulfonamides	Young chickens	552.48	2,806	0.04	0.00	300	300	300	300	300	300
Sulfonamides	Young turkeys	79.44	2,597	0.12	0.00	300	300	300	300	300	300
Sulfonamides	Mature turkeys	0.72	1,684	0.24	0.26	300	300	300	300	300	300
Totals			37,544			4,500	4,500	4,500	4,500	4,500	4,500
β-Agonists	Formula-fed veal	N/A	532	0.00	0.00	300	300	300	300	300	300
$\beta$ -Agonists	Non-Formula-fed veal	N/A	NT	NT	NT	300	300	300	300	300	300
$\beta$ -Agonists	Heifers	N/A	NT	NT	NT	300	300	300	300	300	300
$\beta$ -Agonists	Market hogs	N/A	655	0.00	0.00	300	300	300	300	300	300
Totals			1,187			1,200	1,200	1,200	1,200	1,200	1,200
	3.6.1.41	201.05		0.00	0.00	200	200	200	200	200	200
Carbadox	Market hogs	281.85	575	0.00	0.00	300	300	300	300	300	300
Carbadox	Roaster pigs	0.585	498	0.60	1.06	300	300	300	300	300	300
Totals			1,073			600	600	600	600	600	600

### Table 6 - continued Number of Scheduled Samples for Veterinary Drug/Production Class Pairs 2007 NRP, Domestic Scheduled Sampling

2007 NRF, Domestic Scheduleu Sampling											
Veterinary Drug (or drug class)	Production Class	Priority Score <sup>1</sup>	Number of Samples <sup>2</sup>	% Violation	% Violation <sup>4</sup>	Unadjusted Number of Samples <sup>5</sup>	Adjustment for Violations <sup>6</sup>	Adjustment for minor species <sup>7</sup>	Adjustment for Lab Capacity <sup>8</sup>	Adjustment for Production Facilities <sup>9</sup>	Final <sup>10</sup>
Chloramphenicol	Dairy cows	N/A	1,058	0.00	0.00	300	300	300	300	300	300
Chloramphenicol	Formula-fed veal	N/A	1,151	0.00	0.00	300	300	300	300	300	300
Chloramphenicol	Young chickens	N/A	493	0.00	0.00	300	300	300	300	300	300
Chloramphenicol	Young turkeys	N/A	228	0.00	0.00	300	300	300	300	300	300
Totals			2,930			1,200	1,200	1,200	1,200	1,200	1,200
						-					
Florfenicol	Dairy cows	14.13	207	0.48	0.48	300	300	300	300	300	300
Florfenicol	Formula-fed veal	1.22	177	0.00	0.00	300	300	300	300	300	300
Florfenicol	Non-Formula-fed veal	0.02	84	5.95	5.95	230	230	230	230	230	230
Totals			468			830	830	830	830	830	830
	TT 'C	01.105	1.020	0.00	0.00	200	200	200	200	200	200
MGA	Heifers	21.135	1,039	0.00	0.00	300	300	300	300	300	300
Totals			1,039			300	300	300	300	300	300
Nitrofurans	Market hogs	NA	NT	NT	NT	300	300	300	300	300	300
Nitrofurans	Sows	NA	NT	NT	NT	300	300	300	300	300	300
Nitrofurans	Roaster pigs	NA	NT	NT	NT	300	300	300	300	300	300
Totals			NT			900	900	900	900	900	900
Nitroimidazoles	Young chickens	NA	NT	NT	NT	300	300	300	300	300	300
Totals		INA		111	111	<u>300</u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<b>300</b>
							000				
Thyreostats	Formula-fed veal	1.43	NT	NT	NT	300	300	300	300	300	300
Totals			NT			300	300	300	300	300	300
Trenbolone	Formula-fed veal	0.74	NT	NT	NT	230	230	230	230	230	230
Totals			NT			230	230	230	230	230	230
Zeranol	Formula-fed veal	1.39	1,565	2.88	7.85	230	230	230	230	230	230
Totals	- stillulu lou toul	1.07	1,565	2.00	1.00	230	230	230	230	230	230

#### Table 6 - continued Number of Scheduled Samples for Veterinary Drug/Production Class Pairs 2007 NRP, Domestic Scheduled Sampling

<sup>1</sup> For an explanation of this score, see Table 5.

<sup>2</sup> Number of Samples (1996-2005) analyzed by the FSIS Scheduled Sampling Plan.

<sup>3</sup> 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, 1996-2005.

<sup>4</sup> 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 3 year period, 2003-2005.

<sup>5</sup> The number obtained from the last column of Table 5

<sup>6</sup> If the violation rate for a compound-production class pair was determined to be 0% for the 3 year period (2003-2005), 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.

<sup>7</sup> The following minor species have been rotated out of the FSIS scheduled sampling plan: Bison; ducks; geese; squab; ratites; and rabbits.

<sup>8</sup> Change is based on the analytical capabilities of the FSIS Laboratories. No changes were made for the 2007 NRP due to laboratory analytical capacity.

<sup>9</sup> For this adjustment, FSIS considered the total number of production facilities (USDA Inspected Establishments for 2003) 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). The total number of samples will not be reduced below 230. Based on these parameters, the number of scheduled samples was adjusted for the following production classes: "Formula-fed veal", "Bob Veal", "Young Turkeys", "Mature Chickens", and "Mature Turkeys." No adjustment will be made for the minor species (bison, ducks, rabbits, geese, squab, and ratites) since these minor species are suspended from testing for the 2007 NRP.

<sup>10</sup> Final numbers were obtained following an assessment of laboratory capacity, production volume, and 3-year violation rate data. FSIS has suspended scheduled sampling for all drugs in horses and minor species (bison, ducks, ratites, geese, rabbits, and squab).

#### Design of the Import Scheduled Sampling Plan for Veterinary Drugs

#### I. Selecting and Ranking Candidate Drugs

The candidate veterinary drugs of concern selected by members of the Surveillance Advisory Team (SAT) for the import scheduled sampling plan are the same as those listed in the section, *Design of the Domestic Scheduled Sampling Plan for Veterinary Drugs*. Furthermore, in ranking drugs for inclusion in the import scheduled sampling plan, FSIS also employs the ranking scores generated for the domestic scheduled sampling plan. This is because FSIS does not have sufficient historical data on drugs in imported products to predict their violation rates and this is only reinspection because the product was already inspected at the country of origination. However, if FSIS has reason to believe that a compound is being misused in a foreign country then it would add that compound/country pair to the import scheduled sampling plan.

#### **II. Prioritizing Candidate Drugs**

FSIS selects compounds and compound classes from the list of ranked veterinary drugs. The selection is based purely on their relative public health concern. FSIS and SAT decided that those compounds and compound classes that are a potential public health concern justify their inclusion in the 2007 NRP.

Once the high-priority compounds and compound classes had been identified, FSIS applied other practical considerations to determine the compounds FSIS should sample. The principal consideration is the availability of laboratory resources, especially the availability of appropriate analytical methods within the FSIS laboratories. Where the laboratory resources were limited, FSIS decided that more resources should be allocated to test domestic products since imported products have been inspected previously by the importing country. Based on these considerations, the following compounds are included in the 2007 FSIS scheduled sampling plan.

#### Antibiotics:

At present, the following antibiotics are quantitated using the 7-plate bioassay<sup>1</sup> after a specific identification is made using mass spectroscopy (MS) or using high performance liquid chromatography (HPLC): tetracycline, oxytetracycline, chlortetracycline, gentamicin, streptomycin, dihydrostreptomycin, erythromycin, tylosin, neomycin, beta-lactams (quantitated as penicillin-G; penicillins and cephalosporins are not differentiated within this category), and tilmicosin (quantitated by HPLC). The following antimicrobials can be identified by MS; however, no quantitative methods are available for: Spectinomycin; hygromycin; amikacin; kanamycin; apramycin; tobramycin; lincomycin; pirlimycin; clindamycin; and oleandomycin

<sup>&</sup>lt;sup>1</sup> 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, HPLC, or mass spectrometry) to establish their identities, where such follow-up methodologies are available. Tetracycline, oxytetracycline, and chlortetracycline share patterns of inhibition and are individually identified by follow-up with the HPLC method for tetracyclines; tilmicosin, tylosin, lincomycin, clindamycin, erythromycin, and pirlimycin, which are individually identified by ion-trap LC/MS/MS. Tissues found to be positive for tilmicosin are quantitated by a NADA method using HPLC. Amikacin, apramycin, dihydrostreptomycin, gentamycin, hygromycin, kanamycin, neomycin, spectinomycin, streptomycin, and tobramycin are individually identified by ion-trap LC/MS/MS. Confirmation for sulfa drugs and flunixin are also provided by the residue chemistry section at the FSIS, Midwestern Laboratory.

#### Other Veterinary Drugs:

- Avermectins in FSIS MRM (doramectin, ivermectin and moxidectin)..
- Sulfonamides (sulfapyridine, sulfadiazine, sulfathiazole, sulfamerazine, sulfamethazine, sulfachloropyridazine, sulfadoxine, sulfamethoxypyridazine, sulfaquinoxaline, sulfadimethoxine, sulfasoxazole, sulfacetamide, sulfamethoxazole, sulfamethizole, sulfanilamide, sulfaguanidine, sulfabromomethazine, sulfasalazine, sulfaethoxypyridazine, sulfaphenazole, and sulfatroxazole)

#### Banned Drugs

• Chloramphenicol (Single compound method)

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

SAT participants from the FDA identified, for each of the drugs and drug classes to be included in the 2007 NRP, production classes in which they had a concern. The results are presented in Table 7, *Product Classes Considered for Each Drug/Drug Class*. Compound/product class pairs included in the 2007 NRP are designated by a "●". Those compound/product class pairs that are of potential public health concern, but that are not included in the 2007 NRP because of laboratory resource constraints, are marked with a "○".

#### **IV. Allocation of Sampling Resources**

#### Egg Products

The samples for residue analysis for imported egg products are selected in a different manner than the other product classes. In order to establish a history of compliance with the U.S. requirements for each category of egg product, the first ten shipments from individual foreign establishments are subjected to 100 % reinspection. If the egg product is in compliance, the rate of inspection is reduced to a random selection of one reinspection out of eight product lots from each foreign establishment. This reinspection rate will continue as long as the product is in compliance.

#### Animal Product Classes

Table 8, *Estimated Annual Amount (in lbs.) of Product Imported*, lists the estimated amount of all the product classes imported into U.S. and includes the percentage of each of the product classes. The data for the product classes is obtained from Automated Import Information System. The percent of each product class imported annually is calculated as shown in equation 7:

% Product Class Imported ( $P_C$ ) =	Amount Product Class Imported X 100	Equation 7
_	Total Product Imported	_

The relative sampling priority is obtained by multiplying the percent product class ( $P_c$ ) by the drug scores obtained in Phase I, using equation 8.

Relative Sampling Priority =  $(P_C)$  X Drug Score

Based on the scores, one of the following sampling options is chosen: (1) high regulatory concern (300 samples/year) and (2) moderate regulatory concern (230 samples/year), low regulatory concern (90 samples/year). These data are presented in Table 11, *Number of Drug Samples/Product Class*, in the column labeled "Number of Samples."

FSIS, in its import scheduled sampling plan, will not test (1) processed products from eligible foreign countries that also ship fresh products to the United States; and (2) processed products from countries that source all their raw materials from other foreign countries that are eligible to ship fresh product and are actively exporting to the United States. Processed pork from Canada, Denmark, Ireland, Mexico, Netherlands, and varied combination products and chicken processed from Canada, processed beef from Australia, Canada, Mexico, New Zealand and Uruguay will not be sampled since the raw materials used are from countries that are eligible to ship raw products to the U.S.

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

The adjusted number of samples is listed in Table 12, in the column labeled "Adj No of Samples." The final number of samples for a compound/product class is obtained after the allocation of samples among different countries is completed. The final number of samples is listed in Table 12 in the column labeled "Final Number of Samples." The numbers in the column labeled "Adjusted Number of Samples" and "Final Number of Samples" may vary slightly because of the rounding upwards or downwards of the samples.

#### Allocation of Samples among Different Countries

The total number of samples chosen for each compound/product class pair is subdivided among the different countries. The number of samples for each country is based on the relative amount of total product class imported: less than one percent and greater than one percent.

#### Allocation of Samples in Product Classes Whose Total Volume Imported is less than 1%

As stated above, if the amount of an import product class is less than 1%, eight samples per compound/compound class are taken from each country. The relative amounts of lamb/mutton processed, goat fresh, turkey fresh and processed, varied combination fresh and processed are less than 1%. In addition, as stated above if a country is exporting either fresh and processed products or sources all their raw materials from eligible sources then no residue samples are scheduled for processed products from that country. The unadjusted numbers of samples are listed in the columns labeled, "Unadjusted Number of Samples" in Tables 12-21. The adjusted numbers of samples per country/per product class is listed in the column labeled, "Final Number of Samples" in Tables 12-21.

#### Allocation of Samples in Product Classes Where the Total Volume Imported is Greater Than 1%

For major product classes, the number of samples is allocated to each country depending upon the relative amount of product imported from that country. Table 8, *Estimated Annual Amount (in lbs.) of Product Imported/Country*, lists the amount of product imported from each country. The percent of a product class imported from a country is calculated as follows and is in Table 9, *Relative Annual Amount of Product Imported/Country*.

Percent Product Class Imported per Country ( $P_{C/C}$ ) = <u>Amount of Product Class from Country</u> X 100 Total Amount of Product Class

**Equation 9** 

Based upon the relative amount of product class imported per country, the number of samples that should be taken at the port-of-entry was calculated using the following formula:

Unadjusted Number of Samples per Country ( $U_{C/S}$ ) = Total Number of Samples X ( $P_{C/C}$ )/100 ... Equation 10

This is indicated in the column labeled "Unadjusted Number of Samples (U<sub>C/S</sub>)," in Tables 22-29.

After determining the number of samples required from each country, each country with less than eight samples is assigned a minimum of eight samples. This is indicated in the column labeled "Adjustment #1" in Tables 22-29. The results of this adjustment are in the column labeled "Initial Adj #." If the total number of samples for a compound/product class resulted in more than the total number of samples allocated to that compound/product class pair, then a second adjustment had to be made, so that the total number of samples would be within an allocated number. This adjustment is made only to those countries from which greater than eight samples are to be taken. This adjustment is accomplished using the following equations:

Number of Samples after Adjustment #2 =  $(U_{C/S}) - (N \times P_{C/C})$  Equation 11 (P<sub>T/C</sub>)

Where

 $N = (N_1) - (N_T)$   $N_1 =$  Total Number of Samples after Adjustment #1  $N_T =$  Total Number of Samples Allocated  $P_{T/C} =$  Total Percent of Product Class from the Countries That Had Greater Than Eight Samples  $P_{C/C} =$  Percent Product Class Imported Per Country  $U_{C/S} =$  Unadjusted Number of Samples

As mentioned above, if a country is exporting both fresh and processed products or sources all their raw materials from eligible sources then no residue samples will be processed from that country. The final numbers of products sampled are indicated in Tables 22-29 in the column labeled "Final Adj.#."

#### Notes:

The candidate veterinary drugs of concern selected by members of the SAT for the import scheduled sampling Plan are the same as those listed in the section, *Design of the Domestic Scheduled Sampling Plan for Veterinary Drugs*. The number of samples/product class/country is discussed in the section, *Design of the Import Scheduled Sampling Plan for Pesticides*.

Table 7Product Classes Considered for Each Drug/Drug Class2007 FSIS NRP, Import Monitoring Plan

DRUG→	AB	AVM	AS	в-А	СНМР	FLNX	FLF	NTM	SLF	THY	ZRL
Beef, fresh		•			•	•	•				
Beef, processed	0	•			0				•		
Chicken, fresh	•		ullet		•			•			
Chicken, processed	0		●		0						
Goat, fresh											
Lamb/Mutton fresh		•									
Lamb/Mutton processed		•									
Other fowl fresh	ullet				•						
Pork, fresh	•			•					•		
Pork, processed	0		•						•		
Turkey, fresh	•		•						•		
Turkey, processed			•		0						
Veal, fresh		•				•				•	•
Veal, processed	0	•		0	0				•		0
Varied combination fresh									•		
Varied combination, processed	0								•		

Key

 $\bullet$  = Compound/product class sampled in the 2007 FSIS Import Monitoring Plan

 $\bigcirc$  = Compound/product class pair of regulatory concern but not included in the plan because of lab resources

AB=Antibiotics;AVM=Avermectins, AS=Arsenicals; ß-A= beta agonist; CHMP=Chloramphenicol; RCT=Ractopamine; THY=Thyreostats; NTF= Nitrofurans; NTM=Nitroimidazoles; SLF=Sulfonamides; ZRL=Zeralenol

	PRODUCT IMPORTED	% PRODUCT
PRODUCT	IN POUNDS	IMPORTED
Beef, fresh	2524913744.39	59.20%
Beef, processed	214728602.81	5.03%
Pork, fresh	880096436.67	20.63%
Pork, processed	195078933.85	4.57%
Veal, fresh	67737816.30	1.59%
Veal, processed	7054.00	0.0002%
Lamb/Mutton, fresh	186155041.06	4.4%
Lamb/Mutton, processed	522954.00	0.0123%
Goat, fresh	21718247.15	0.5%
Turkey , fresh	8542427.00	0.2003%
Ratite, fresh	212621.00	0.005%
Chicken, fresh	47997850.00	1.1%
Chicken, processed	76057765.00	1.8%
Turkey, processed	13942828.50	0.32688%
Other Fowl, fresh	4719387.00	0.111%
Other Fowl, processed	118621.38	0.003%
Varied combination, fresh	267853.00	0.006%
Varied combination, processed	22562677.38	0.5%
Guineas/squabs	39.00	0.0000009%
Eggs, processed	0.00	0.000
Total/country	4265380899.49	100.00%

### Table 8Estimated Annual Amount (in lbs.) of Product Imported2007 FSIS NRP, Import Monitoring Plan

PRODUCTION					
CLASS	Argentina	Australia	Belgium	Brazil	Canada
Beef, fresh		718192319			839745699
Beef, processed	62566579	2736981		114387747	12373256
Pork, fresh		156046			776492386
Pork, processed	12565		1936224	71958	130272542
Veal, fresh		9842403			28893767
Veal, processed		15.00			6304
Lamb/Mutton, fresh		142078208			413138
Lamb/Mutton, processed		258549			151507
Goat, fresh		20795247			
Turkey, fresh					8541105
Ratite, fresh		186284			
Chicken, fresh					47997850
Chicken, processed					66787811
Turkey, processed					7788455
Other Fowl, fresh					4586916
Other Fowl, processed					72900
Varied combination, fresh					267853
Varied combination, processed		25537			19224539
Guineas/squabs					39
Eggs, processed					
Total/country	62579144	125158288	1936224	114459706	1943616069

PRODUCTION					
CLASS	Costa Rica	Croatia	Denmark	Finland	France
Beef, fresh	19280517				
Beef, processed					
Pork, fresh			80904115	3547519	
Pork, processed		526015	19443146		18091
Veal, fresh					
Veal, processed					
Lamb/Mutton, fresh Lamb/Mutton, processed					
Goat, fresh					
Turkey , fresh					
Ratite, fresh					
Chicken, fresh					
Chicken, processed					
Turkey, processed					
Other Fowl, fresh					132471
Other Fowl, processed					45721
Varied combination, fresh					
Varied combination, processed					
Guineas/squabs					
Eggs, processed					
Total/country	19280517	526015	100347261	3547519	196283

PRODUCTION CLASS	Germany	Honduras	Hungary	Iceland	Ireland	Israel
Beef, fresh		2455019				
Beef, processed						
Pork, fresh					5186678	
Pork, processed	1344272		1841880		1747	
Veal, fresh						
Veal, processed						
Lamb/Mutton, fresh Lamb/Mutton, processed				211922		
Goat, fresh						
Turkey , fresh						
Ratite, fresh						
Chicken, fresh						
Chicken, processed						1352951
Turkey, processed						1334938
Other Fowl, fresh Other Fowl, processed Varied combination, fresh						
Varied combination, processed						
Guineas/squabs						
Eggs, processed						
Total/country	1344272	2455019	1841880	211922	5188425	2687889

PRODUCTION CLASS	Italy	Japan	Mexico	Netherlands	New Zealand	Nicaragua
Beef, fresh		114	18641633		413021868	48278630
Beef, processed			6424093		5908222	
Pork, fresh			2385774	4810780	138421	
Pork, processed	7745881		6994604	5457021		
Veal, fresh					29001646	
Veal, processed			735			
Lamb/Mutton, fresh			24952		43426821	
Lamb/Mutton, processed			36960		75938	
Goat, fresh			10298		912701	
Turkey , fresh			1322			
Ratite, fresh					26337	
Chicken, fresh						
Chicken, processed			7917003			
Turkey, processed			4819435			
Other Fowl, fresh Other Fowl, processed Varied combination, fresh						
Varied combination, processed			3303769		8832	
Guineas/squabs						
Total/country	7745881	114	50560578	10267801	492520786	48278630

PRODUCTION CLASS	Poland	Spain	Sweden	UK	Uruguay
Beef, fresh					465297945
Beef, processed					10331724
Pork, fresh			1223085	2238492	
Pork, processed	18030623	1382365			
Veal, fresh					
Veal, processed					
Lamb/Mutton, fresh Lamb/Mutton, processed					
Goat, fresh					
Turkey , fresh					
Ratite, fresh					
Chicken, fresh					
Chicken, processed					
Turkey, processed					
Other Fowl, fresh Other Fowl, processed Varied combination, fresh Varied combination,					
processed					
Guineas/squabs Total/country	18030623	1382365	1223085	2238492	475629669

Table 10Relative Annual Amount of Product Imported/Country2007 FSIS NRP, Import Monitoring Plan

Production Class	Argentina	Australia	Belgium	Brazil	Canada
Beef, fresh		28.4			33.3
Beef, processed	29.1	1.3		53.3	5.8
Pork, fresh		0.0			88.2
Pork, processed		0.0	1.0		66.8
Veal, fresh		14.5			42.7
Veal, processed		0.2			89.4
Lamb/Mutton, fresh		76.3			0.2
Lamb/Mutton, processed		49.4			29.0
Goat, fresh		95.8			
Turkey , fresh		0.0			100.0
Ratite, fresh		87.6			0.0
Chicken, fresh					100.0
Chicken, processed					87.8
Turkey, processed					55.9
Other Fowl, fresh					97.2
Other Fowl, processed					61.5
Varied combination, fresh					100.0
Varied combination, processed		0.1			85.2

Production						
Class	Costa Rica	Croatia	Denmark	Finland	France	Germany
Beef, fresh	0.763					
Beef, processed						
Pork, fresh			9.193	0.403		
Pork, processed		0.269	9.966		0.009	0.689
Veal, fresh						
Veal, processed Lamb/Mutton,						
fresh Lamb/Mutton, processed						
Goat, fresh						
Turkey , fresh						
Ratite, fresh						
Chicken, fresh Chicken, processed						
Turkey, processed						
Other Fowl, fresh					2.806	
Other Fowl, processed					38.543	
Varied combination, fresh						
Varied combination, processed						

Production							
Class	Honduras	Hungary	Iceland	Ireland	Israel	Italy	Japan
Beef, fresh	0.097						2.878E+09
Beef,							
processed							
Pork, fresh				0.589			
Pork, nesn				0.389			
processed		0.944		0.001		3.971	
processed		0.944		0.001		5.971	
Veal, fresh							
Veal,							
processed							
Lamb/Mutton,							
fresh			0.114				
Lamb/Mutton,							
processed							
Goat, fresh							
Turkey , fresh							
Ratite, fresh							
Chicken, fresh							
Chicken,							
processed					1.778		
Turkey,							
processed					9.574		
Other Fowl,							
fresh							
Other Fowl,							
processed							
Varied							
combination,							
fresh							
Varied							
combination,							
processed							

Production Class	Mexico	Netherlands	New Zealand	Nicaragua	Poland
Beef, fresh	0.738		16.357	1.912	
Beef, processed	2.991		2.751		
Pork, fresh	0.271	0.547	0.0157		
Pork, processed	3.586	2.797	0		9.243
Veal, fresh			42.814		
Veal, processed	10.419		0		
Lamb/Mutton, fresh	0.013		23.328		
Lamb/Mutton, processed	7.068		14521		
Goat, fresh	0.047		4.202		
Turkey , fresh	0.016		0		
Ratite, fresh	0		12387		
Chicken, fresh	0				
Chicken, processed	10.409				
Turkey, processed	34.565				
Other Fowl, fresh					
Other Fowl, processed					
Varied combination, fresh					
Varied combination, processed	14.643		0.039		

Production Class	Spain	Sweden	UK	Uruguay
Beef, fresh				18.428
Beef, processed				4.812
Pork, fresh		0.139	0.254	
Pork, processed	0.709			
Veal, fresh				
Veal, processed Lamb/Mutton, fresh Lamb/Mutton, processed				
Goat, fresh				
Turkey , fresh Ratite, fresh				
Chicken, fresh Chicken, processed				
Turkey, processed Other Fowl,				
fresh Other Fowl, processed				
Varied combination, fresh				
Varied combination, processed				

# Table 11Number of Drug Samples/Product Class2007 FSIS NRP, Import Monitoring Plan

No of Countries	Production Class	Drug	% Product Imported	Score	RSP	No. of Samples	Unadjusted No. of Samples	Final No of Samples
9	Beef, fresh	Antibiotics	58.32%	15	875	300	304	304
1	Chicken, fresh	Antibiotics	1.130%	15	17	90	90	8
10	Pork, fresh	Antibiotics	20.65%	15	310	230	231	231
15	Pork, processed	Antibiotics	4.57%	15	69	90	80	0
2	Turkey , fresh	Antibiotics	0.2012%	15	3	90	16	16
1	Varied combination, fresh	Antibiotics	0.006%	15	0	8	8	8
3	Veal, fresh	Antibiotics	1.60%	15	24	90	90	90
3	Veal, processed	Antibiotics	0.0002%	15	0	90	24	0
1	Chicken, fresh	Arsenic	1.130%	4.5	5	90	90	8
3	Chicken, processed	Arsenic	1.791%	4.5	8	90	90	16
10	Pork, fresh	Arsenic	20.65%	4.5	93	90	90	97
2	Turkey , fresh	Arsenic	0.2012%	4.5	1	16	16	16
3	Turkey, processed	Arsenic	0.32834%	4.5	1	24	24	8
9	Beef, fresh	Avermectins	58.32%	14	816	300	304	304
7	Beef, processed	Avermectins	6.19%	14	87	90	75	75
3	Goat, fresh	Avermectins	0.1%	14	1	90	24	24
5	Lamb/Mutton, fresh	Avermectins	4.384%	14	61	90	90	90
4	Lamb/Mutton, processed	Avermectins	0.0123%	14	0	90	32	0
3	Veal, fresh	Avermectins	1.60%	14	22	90	90	90
9	Beef, fresh	Florfenicol	58.32%	0	0	45	45	45
9	Beef, fresh	Flunixin	58.32%	7	408	90	78	78
1	chicken, fresh	Nitroimidazole	1.130%	4.5	5	90	90	8

# Table 11 - ContinuedNumber of Drug Samples/Product Class2007 FSIS NRP, Import Monitoring Plan

No of Countries	Production Class	Drug	% Product Imported	Score	RSP	No. of Samples	Unadjusted No. of Samples	Final No of Samples
10	Pork, fresh	ß-Agonists	1.60%	12	19	90	90	30
3	Veal, fresh	β-Agonists	1.60%	2.75	4	90	90	90
9	Beef, fresh	Sulfonamides	58.32%	12	700	300	304	304
7	Beef, processed	Sulfonamides	6.19%	12	74	90	75	75
10	Pork, fresh	Sulfonamides	20.65%	12	248	230	230	231
15	Pork, processed	Sulfonamides	4.57%	12	55	90	90	80
2	Turkey , fresh	Sulfonamides	0.2012%	12	2	90	16	16
3	Turkey, processed	Sulfonamides	0.32834%	12	4	24	24	8
1	Varied combination, fresh	Sulfonamides	0.006%	12	0	8	8	8
4	Varied combination, processed	Sulfonamides	0.531%	12	6	90	32	24
3	Veal, fresh	Sulfonamides	1.60%	12	19	90	90	90
3	Veal, processed	Sulfonamides	0.0002%	12	0	90	24	0
3	Veal, fresh	Thyreostats	1.60%	7	11	90	90	90
3	Veal, fresh	Zeranol	1.60%	12	19	90	90	90
	Total					4021	3508	2844

Pork Processed/				
Sulfonamides	% product (Pc/c)	Uc/s=90*(Pc/c)/100	Adjust #1	Final No of Samples
Argentina	0.01	0	8	8
Belgium	0.99	1	8	8
Brazil	0.04	0	8	8
Canada	66.77	60	0	$0^{1}$
Croatia	0.27	0	8	8
Denmark	10.00	9	0	$0^1$
France	0.01	0	8	8
Germany	0.69	1	8	8
Hungary	0.94	1	8	8
Ireland	0.001	0	8	$0^1$
Italy	3.97	4	8	8
Mexico	3.59	3	0	$0^1$
Netherlands	3.00	3	0	$0^1$
Poland	9.24	8	8	8
Spain	0.70	1	8	8
Total	100.22	90	88	80

Table 12Number of Samples/Product Class – Pork, Processed2007 FSIS NRP, Import Monitoring Plan

Table 13Number of Samples/Product Class - Goat, Fresh2007 FSIS NRP, Import Monitoring Plan

Goat Fresh/Avermectins	%product(Pc/c)	Uc/s=90*(Pc/c)/100	Final No of Samples
Australia	95.75	8	8
Mexico	0.05	8	8
New Zealand	4.2	8	8
Total	100	24	24

Table 14Number of Samples/Product Class – Turkey, Fresh2007 FSIS NRP, Import Monitoring Plan

Turkey Fresh/Antibiotics	%product (Pc/c)	Uc/s=90*(Pc/c)/100	Final No of Samples
Canada	99.98	8	8
Mexico	0.02	8	8
Total	100	16	16
Turkey Fresh/Sulfonamides	%product (Pc/c)	Uc/s=90*(Pc/c)/100	<b>Final No of Samples</b>
Canada	99.98	8	8
Mexico	0.02	8	8
Total	100	16	16
Turkey Fresh/Chloramphenicol	%product (Pc/c)	Uc/s=90*(Pc/c)/100	<b>Final No of Samples</b>
Canada	99.98	8	8
Canada Mexico	99.98 0.02	8	8 8
			~
Mexico	0.02 100	8	8
Mexico Total	0.02 100	8 16	8 16
Mexico Total Turkey Fresh/Arsenicals	0.02 100 %product (Pc/c)	8 16 Uc/s=90*(Pc/c)/100	8 16 Final No of Samples

### Table 15Number of Samples/Product Class - Turkey, Processed2007 FSIS Import Monitoring Plan

Turkey Processed/Arsenicals	%product (Pc/c)	Uc/s=90*(Pc/c)/100	<b>Final No of Samples</b>
Canada	55.86	8	$0^1$
Israel	9.57	8	8
Mexico	34.57	8	0 <sup>1</sup>
Total	100	24	8
Turkey Processed/Sulfonamides	%product (Pc/c)	Uc/s=90*(Pc/c)/100	Final No of Samples
Canada	55.86	8	$0^{1}$
Israel	9.57	8	8
Mexico	34.57	8	$0^1$
Total	100	24	8

### Table 16Number of Samples/Product Class - Chicken, Fresh2007 FSIS NRP, Import Monitoring Plan

	i olo i ili , impo	i i mionitoring i mi	
Chicken Fresh/Antibiotics	%product (Pc/c)	Uc/s=90*(Pc/c)/100	Final No of Samples
Canada	100	8	8
Chicken Fresh/Arsenicals	%product (Pc/c)	Uc/s=90*(Pc/c)/100	8
Canada	100	8	
Chicken Fresh/Chloramphenicol	%product (Pc/c)	Uc/s=90*(Pc/c)/100	8
Canada	100	8	8
Chicken Fresh/Nitroimidazole	%product (Pc/c)	Uc/s=90*(Pc/c)/100	
Canada	100	8	8
Chicken Fresh/Antibiotics	%product (Pc/c)	Uc/s=90*(Pc/c)/100	
Canada	100	8	8

### Table 17Number of Samples/Product Class – Varied Combination, Fresh2007 FSIS NRP, Import Monitoring Plan

Varied Combination Fresh/Antibiotics	%product (Pc/c)	Uc/s=90*(Pc/c)/100	Final No of Samples
Canada	100	8	8
Total		8	8
Varied Combination Fresh/Sulfonamides	%product (Pc/c)	Uc/s=90*(Pc/c)/100	Final No of Samples
Canada	100	8	8
Total		8	8

Table 18
Number of Samples/Product Class – Varied Combination, Processed
2007 FSIS Import Monitoring Plan

Varied Combination Processed	%product	Uc/s=90*(Pc/c)/100	Final No of Samples				
/Sulfonamides	( <b>Pc/c</b> )						
Australia	0.15	8	8				
Canada	85.21	8	$0^{1}$				
Mexico	14.64	8	8				
New Zealand	0.04	8	8				
Total	100.04	32	24				

Table 19Number of Samples/Product Class - Beef, Fresh2007 FSIS NRP, Import Monitoring Plan

Beef Fresh/	200	7 FSIS NKP, Impor				Final No of
Antibiotics	%product (Pc/c)	Uc/s=300*(Pc/c)/100	Adjust #1	Initial Adj	A diust # 2	Samples
Australia	- · · /	85.32	Aujust #1	78	, v	78
Canada	28.44 33.25	99.75	0	91	78 91	91
Canada Costa Rica			8	91 8	8	8
Honduras	0.78	2.34 0.3	8	8	8	8
	0.1	0.5	8	8	8	8
Japan Mexico	0.74	2.22	8	8	8	8
New Zealand	16.36	49.08	<u>8</u> 0	45	45	45
Nicaragua	1.91	5.73	8	4 <u>3</u> 8	<u>43</u> 8	43
	1.91	55.26	0	51	50	50
Uruguay <b>Total</b>	10.42	<u> </u>	40	<b>304</b>	<b>304</b>	<b>304</b>
		300	40	304	304	
Beef Fresh/	%product					Final No of
Sulfonamides		Uc/s=300*(Pc/c)/100	Adjust #1	Initial Adj	Adjust # 2	Samples
Australia	28.44	85.32	0	78	78	78
Canada	33.25	99.75	0	91	91	91
Costa Rica	0.78	2.34	8	8	8	8
Honduras	0.1	0.3	8	8	8	8
Japan	0	0	8	8	8	8
Mexico	0.74	2.22	8	8	8	8
New Zealand	16.36	49.08	0	45	45	45
Nicaragua	1.91	5.73	8	8	8	8
Uruguay	18.42	55.26	0	51	50	50
Total	100	300	40	304	304	304
Beef Fresh/						Final No of
Avermectins	%product (Pc/c)	Uc/s=300*(Pc/c)/100	Adiust #1	Initial Adi	Adjust # 2	Samples
Australia	28.44	85.32	0	78	78	78
Canada	33.25	99.75	0	91	91	91
Costa Rica	0.78	2.34	8	8	8	8
Honduras	0.1	0.3	8	8	8	8
Japan	0	0	8	8	8	8
Mexico	0.74	2.22	8	8	8	8
New Zealand	16.36	49.08	0	45	45	45
Nicaragua	1.91	5.73	8	8	8	8
Uruguay	18.42	55.26	0	51	50	50
Total	100	300	40	304	304	304

# Table 19 - continuedNumber of Samples/Product Class - Beef, Fresh2007 FSIS NRP, Import Monitoring Plan

Beef Fresh/				Initial		Final No of
Chloramphenicol	%Product (Pc/c)	Uc/s=90*(Pc/c)/100	Adjust #1	Adj	Adjust # 2	Samples
Australia	28.44	25.596	0	10	10	10
Canada	33.25	29.925	0	12	12	12
Costa Rica	0.78	0.702	8	8	8	8
Honduras	0.1	0.09	8	8	8	8
Japan	0	0	8	8	8	8
Mexico	0.74	0.666	8	8	8	8
New Zealand	16.36	14.724	8	6	6	8
Nicaragua	1.91	1.719	8	8	8	8
Uruguay	18.42	16.578	0	7	7	8
Total	100	90	48	75	75	78
Beef Fresh/				Initial		Final No of
Florofenicol	%Product (Pc/c)	Uc/s=90*(Pc/c)/100	Adjust #1	Adj	Adjust # 2	Samples
Australia	28.44	25.596	0	10	10	5
Canada	33.25	29.925	0	12	12	5
Costa Rica	0.78	0.702	8	8	8	5
Honduras	0.1	0.09	8	8	8	5
Japan	0	0	8	8	8	5
Mexico	0.74	0.666	8	8	8	5
New Zealand	16.36	14.724	8	6	6	5
Nicaragua	1.91	1.719	8	8	8	5
Uruguay	18.42	16.578	0	7	7	5
Total	100	90	48	75	75	45
Beef Fresh/ Flunixin	%Product (Pc/c)	Uc/s=90*(Pc/c)/100	Adjust #1	Initial Adj	Adjust # 2	Final No of Samples
Australia	28.44	25.596	0	10	10	10
Canada	33.25	29.925	0	12	12	12
Costa Rica	0.78	0.702	8	8	8	8
Honduras	0.1	0.09	8	8	8	8
Japan	0	0	8	8	8	8
Mexico	0.74	0.666	8	8	8	8
New Zealand	16.36	14.724	8	6	6	8
Nicaragua	1.91	1.719	8	8	8	8
Uruguay	18.42	16.578	0	7	7	8
Total	100	90	48	75	75	78

		SIS NKP, Import		ig i iali		
Beef Processed/	%Product					Final No of
Sulfonamides	( <b>Pc/c</b> )	Uc/s=90*(Pc/c)/100	Adjust #1	Initial Adj	Adjust # 2	Samples
Argentina	29.14	27	0	27	26	26
Australia	1.27	1.143	0	0	0	$0^1$
Brazil	53.27	47.943	0	50	46	49
Canada	5.76	5.184	0	0	1	$0^1$
Mexico	2.99	2.691	0	0	0	$0^1$
New Zealand	2.75	2.475	0	0	0	$0^1$
Uruguay	4.82	4.338	0	0	0	$0^1$
Total	100	63.774	0	77	74	75
Beef Processed/						Final No of
Avermectins	%Product (Pc/c)	Uc/s=90*(Pc/c)/100	Adjust #1	Initial Adj	Adjust # 2	Samples
Argentina	29.14	27	0	27	26	26
Australia	1.27	1.143	0	0	0	$0^{1}$
Brazil	53.27	47.943	0	50	46	49
Canada	5.76	5.184	0	0	1	$0^1$
Mexico	2.99	2.691	0	0	0	$0^{1}$
New Zealand	2.75	2.475	0	0	0	01
Uruguay	4.82	4.338	0	0	0	$0^1$
Total	100	63.774	0	77	74	75

Table 20Number of Samples/Product Class - Beef, Processed2007 FSIS NRP, Import Monitoring Plan

Table 21Number of Samples/Product Class - Pork, Fresh2007 FSIS NRP, Import Monitoring Plan

Pork		$(U_{C/S})=230*$	A 1. 4 H1	T ·/· 1 A 1·		Final No of
Fresh/Antibiotics	%Product (Pc/c)	(P <sub>C/C</sub> )/100)	Adjust #1	Initial Adj	Adjust # 2	Samples
Australia	0.02	0.046	1	8	8	8
Canada	88	202.4	202	202	152	152
Denmark	9.19	21.137	21	21	15	15
Finland	0.4	0.92	1	8	8	8
Ireland	0.59	1.357	1	8	8	8
Mexico	0.27	0.621	1	8	8	8
Netherlands	0.55	1.265	1	8	8	8
New Zealand	0.02	0.046	1	8	8	8
Sweden	0.14	0.322	1	8	8	8
United Kingdom	0.25	0.575	1	8	8	8
Total	99.43	230	231	287	231	231

Table 21 - continued
Number of Samples/Product Class - Pork, Fresh
2007 FSIS NRP, Import Monitoring Plan

	2007 1	<b>515 WKI</b> , <b>I</b> IIIp				1
Pork	%Product	(U <sub>C/S</sub> )=90 *	A	T	A J	Final No of
Fresh/Arsenicals	(Pc/c)	$(P_{C/C})/100)$	Adjust #1		Adjust # 2	Samples
Australia	0.02	0.046	1	8	8	8
Canada	88	79.2	79	79	25	25
Denmark	9.19	8.271	8	8	8	8
Finland	0.4	0.92	1	8	8	8
Ireland	0.59	1.357	1	8	8	8
Mexico	0.27	0.621	1	8	8	8
Netherlands	0.55	1.265	1	8	8	8
New Zealand	0.02	0.046	1	8	8	8
Sweden	0.14	0.322	1	8	8	8
United Kingdom	0.25	0.575	1	8	8	8
Total	99.43	92.623	95	151	97	97
Pork Fresh/B-	%Product	(U <sub>C/S</sub> )=90 *				Final No of
Agonist	( <b>Pc/c</b> )	(P <sub>C/C</sub> )/100)	Adjust #1	Initial Adi	Adjust # 2	Samples
Australia	0.02	0.046	1 1	8	8	8
Canada	88	79.2	79	79	25	25
Denmark	9.19	8.271	8	8	8	8
			-			8
Finland	0.4	0.92	1	8	8	
Ireland	0.59	1.357	1	8	8	8
Mexico	0.27	0.621	1	8	8	8
Netherlands	0.55	1.265	1	8	8	8
New Zealand	0.02	0.046	1	8	8	8
Sweden	0.14	0.322	1	8	8	8
United Kingdom	0.25	0.575	1	8	8	8
Total	99.43	92.623	95	151	97	97
Pork Fresh/	%Product	(U <sub>C/S</sub> )=230 *				Final No of
Sulfonamides	( <b>Pc/c</b> )	(P <sub>C/C</sub> )/100)	Adjust #1	Initial Adj	Adjust # 2	Samples
Australia	0.02	0.046	1	8	8	8
Canada	88	202.4	202	202	152	152
Denmark	9.19	21.137	21	21	15	15
Finland	0.4	0.92	1	8	8	8
Ireland	0.59	1.357	1	8	8	8
Mexico	0.27	0.621	1	8	8	8
Netherlands	0.55	1.265	1	8	8	8
New Zealand	0.02	0.046	1	8	8	8
Sweden	0.14	0.322	1	8	8	8
United Kingdom	0.25	0.575	1	8	8	8
Total	99.43	230	231	287	231	231

### Table 22Number of Samples/Product Class - Chicken, Processed2007 FSIS NRP, Import Monitoring Plan

Chicken Processed/ Arsenicals	%product (Pc/c)	(U <sub>C/S</sub> )=90 * (P <sub>C/C</sub> )/100)	Adjust #1	Initial Adj		Final No of Samples
Canada	87.81	79.029	8	0	0	$0^1$
Israel	1.78	1.602	8	8	8	8
Mexico	10.41	9.369	8	8	8	8
	100	90	24	16	16	16

Table 23Number of Samples/Product Class - Veal, Fresh2007 FSIS NRP, Import Monitoring Plan

						Final No
Veal Fresh/	%Product	(U <sub>c/s</sub> )		Initial		of
Antibiotics	( <b>P</b> <sub>C/C</sub> )	$=90*[(P_{C/C})/100]$	Adjust #1	Adj	Adjust # 2	Samples
Australia	14.53	13.077	13			13
Canada	42.66	38.394	38			38
New Zealand	42.81	38.529	39			39
Total	100	90	90			90
						Final No
Veal Fresh/	%Product	(U <sub>c/s</sub> )		Initial		of
Avermectins	( <b>P</b> <sub>C/C</sub> )	$=90*[(P_{C/C})/100]$	Adjust #1	Adj	Adjust # 2	Samples
Australia	14.53	13.077	13			13
Canada	42.66	38.394	38			38
New Zealand	42.81	38.529	39			39
Total	100	90	90			90
						Final No
Veal Fresh/	%Product	(U <sub>c/s</sub> )		Initial		of
Flunixins	( <b>P</b> <sub>C/C</sub> )	=90*[(P <sub>C/C</sub> )/100]	Adjust #1	Adj	Adjust # 2	Samples
Australia	14.53	13.077	13			13
Canada	42.66	38.394	38			38
New Zealand	42.81	38.529	39			39
Total	100	90	90			90
						Final No
Veal Fresh/ B-	%Product	(U <sub>c/s</sub> )		Initial		of
agonist	( <b>P</b> <sub>C/C</sub> )	=90*[(P <sub>C/C</sub> )/100]	Adjust #1	Adj	Adjust # 2	Samples
Australia	14.53	13.077	13			13
Canada	42.66	38.394	38			38
New Zealand	42.81	38.529	39			38
Total	100	90	90			90

### Table 23 - continuedNumber of Samples/Product Class - Veal, Fresh2007 FSIS NRP, Import Monitoring Plan

	200715					
Veal Fresh/	%Product	(U <sub>c/s</sub> )		Initial		Final No of
Sulfonamides	( <b>P</b> <sub>C/C</sub> )	=90*[(P <sub>C/C</sub> )/100]	Adjust #1	Adj	Adjust # 2	Samples
Australia	14.53	13.077	13			13
Canada	42.66	38.394	38			38
New Zealand	42.81	38.529	39			39
Total	100	90	90			90
Veal Fresh/ Chloramphenicol	%Product (P <sub>C/C</sub> )	(U <sub>c/s</sub> ) =90*[(P <sub>C/C</sub> )/100]	Adiust #1	Initial Adj	Adjust # 2	Final No of Samples
Australia	14.53	13.077	13			13
Canada	42.66	38.394	38			38
New Zealand	42.81	38.529	39			39
Total	100	90	90			90
Veal Fresh/	%Product	(U <sub>c/s</sub> )		Initial		Final No of
Zeranol	( <b>P</b> <sub>C/C</sub> )	$=90*[(P_{C/C})/100]$	Adjust #1	Adj	Adjust # 2	Samples
Australia	14.53	13.077	13			13
Canada	42.66	38.394	38			38
New Zealand	42.81	38.529	39			39
Total	100	90	90			90
Veal Fresh/ Threostats	%Product (P <sub>C/C</sub> )	(U <sub>c/s</sub> ) =90*[(P <sub>C/C</sub> )/100]	Adjust #1	Initial Adj	Adjust # 2	Final No of Samples
Australia	14.53	13.077	13			13
Canada	42.66	38.394	38			38
New Zealand	42.81	38.529	39			39
Total	100	90	90			90

### Table 24Number of Samples/Product Class - Mutton/Lamb, Fresh2007 FSIS NRP, Import Monitoring Plan

Mutton/Lamb Fresh/Avermectins	% Product (P <sub>C/C</sub> )	(U <sub>C/S</sub> ) = 90*((P <sub>C/C</sub> )/100)	Adjust. #1	Initial Adj		Final No of Samples
Australia	76.32	68.688	69	69	51	51
Canada	0.22	0.198	0	8	8	8
Iceland	0.11	0.099	0	8	8	8
Mexico	0.01	0.009	0	8	8	8
New Zealand	23.32	20.988	21	21	15	15
Total	99.98	89.982	90	114	90	90

<sup>1</sup> There will be no sampling of processed products from countries that also ship fresh products to the United States or source their raw material from other foreign countries that are eligible to ship fresh product and are actually exporting to United States.