

Section 4

The 2004 FSIS Domestic Monitoring Plan Veterinary Drugs

Phase I. Generating and Ranking the List of Candidate Compounds

List of Candidate Compounds

The candidate veterinary drugs of concern selected by members of the Surveillance Advisory Team (SAT) are presented below. Since FSIS wishes to prioritize which *analyses* should be conducted, compounds that are, or are likely to be, detected by the same analytical methodology have been grouped together. Compounds banned from extralabel use under the Animal Medicinal Drug Use Clarification Act (AMDUCA), are shown in bold type.

Antibiotics:

- At present, the following antibiotics are quantitated using the 7-plate bioassay¹ 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, lincomycin, pirlimycin, clindamycin, and oleandomycin.
- **Chloramphenicol**
- Florfenicol (chloramphenicol derivative)
- Thiamphenicol (chloramphenicol derivative)
- **Fluoroquinolones in FSIS MRM (ciprofloxacin, desethyleneciprofloxacin, danofloxacin, difloxacin, enrofloxacin, marbofloxacin, orbifloxacin, and sarafloxacin)**
- **Avoparcin (glycopeptide)**
- **Vancomycin (glycopeptide)**

Other Veterinary Drugs:

- Amprolium (coccidiostat)
- Arsenicals (detected as elemental arsenic)
- Avermectins in FSIS MRM (doramectin, ivermectin, and moxidectin) (antiparasitics)

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

- Eprinomectin (ivermectin)
- Benzimidazoles in FSIS MRM (thiabendazole and its 5-hydroxythiabendazole metabolite, albendazole 2-animosulfone metabolite, benomyl in the active hydrolyzed form carbendazim, oxfendazole, mebendazole, cambendazole, and fenbendazole) (anthelmintics)
- Berenil (antiprotozoal)
- Carbadox (antimicrobial)
- **Clenbuterol and other unapproved beta agonists (growth promotants)²**
- Ractopamine (beta agonist)
- Clorsulon (anthelmintic)
- Dexamethasone (glucocorticoid)
- Methyl prednisone (glucocorticoid)
- Prednisone (glucocorticoid)
- Halofuginone (antiprotozoal, coccidiostat)
- Hormones, naturally-occurring (17- β estradiol, progesterone, testosterone)
- **DES (hormone, synthetic)**
- MGA (hormone, synthetic)
- Trenbolone (hormone, synthetic)
- Zeranol (hormone, synthetic)
- Lasalocid (coccidiostat)
- Levamisole (anthelmintic)
- Morantel and pyrantel (anthelmintic)
- Nicarbazin (coccidiostat)
- **Nitrofurans (incl. furazolidone, nitrofurazone) (antimicrobial)**
- **Nitromidazoles in FSIS MRM (dimetridazole, ipronidazole) (antiprotozoals)**
- **Ronidazole (nitroimidazole) (antimicrobial)**
- Etodolac (nonsteroidal anti-inflammatory drug [NSAID])
- Flunixin (NSAID)
- **Phenylbutazone (NSAID)**
- Dipyrone (NSAID)
- Sulfonamides in FSIS MRM (incl. sulfapyridine, sulfadiazine, sulfathiazole, sulfamerazine, sulfamethazine, sulfachlorpyridazine, sulfadoxine, sulfamethoxypyridazine, sulfaquinoxaline, sulfadimethoxine, sulfisoxazole, sulfacetamide, sulfamethoxazole, sulfamethizole, sulfanilamide, sulfaguanidine, sulfabromomethazine, sulfasalazine, sulfaethoxypyridazine, sulfaphenazole, and sulfatroxazole) (antimicrobials, some are coccidiostats)
- Sulfanitran (antibacterial, coccidiostat)
- Thyreostats (incl. thiouracil)
- Veterinary tranquilizers in FSIS MRM (azaperone and its metabolite azaperol, xylazine, haloperidol, acetopromazine, propionylpromazine, and chlorpromazine)

Ranking of Candidate Compounds

Drugs Banned from Extralabel use under AMDUCA

²The screening test used by FSIS has been officially validated for clenbuterol (bovine and porcine) and has been extended to salbutamol and cimaterol (bovine). The method has also demonstrated the ability to detect other beta agonists, including ractopamine. The follow-up confirmatory method may detect several unapproved beta agonists, including the following: clenbuterol; cimaterol; fenoterol; mabuterol; salbutamol; brombuterol; and terbutaline.

FDA has advised FSIS that drugs banned from extralabel use under AMDUCA, are of high public health concern. Therefore, these 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. All these drugs are listed in Table 4.2a, *Drugs Banned from Extralabel use under AMDUCA*.

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, 2004 Domestic Residue Program*."

The results of the compound scoring process are presented in Table 4.1, *Scoring Table for Veterinary Drugs*.

Compound Ranking

1. Background

As stated above, FSIS chose to employ 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 estimates for each compound or compound class could be generated:

$$\begin{aligned} \text{Risk} &= \text{Exposure} \times \text{Toxicity} && (4.1) \\ &= \text{Consumption} \times \text{Residue Levels} \times \text{Toxicity} \\ &= \text{Consumption} \times \text{"Risk Per Unit of Consumption"} \end{aligned}$$

Given the limited resources available for this priority-setting effort, FSIS did not attempt to associate different degrees of risk with different amounts or percentages by which the tolerance or action level was exceeded. FSIS instead determined that the best available method for the measurement of relative toxicity is associated with the tolerance or action level. *Specifically, the frequency of violation of the tolerance or action level was used as an indicator of the risk per unit of consumption of a product.*

The first criterion evaluated in Table 4.1, *FSIS Historical Testing Information on Violations*, is based on the percent of tested carcasses found to have residues in excess of the tolerance or action level, from FSIS random sampling programs of animals entering the food supply. Specifically, compounds were scored by two methods: (a) the maximum violation rate seen in any production class (averaged over 1993 - 2002); and (b) the maximum, for any class, of the violation rate (again, averaged over 1993 - 2002), 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.³ Therefore, it can be seen from Equation (4.1) that the violation rate scores assigned in Table 4.1 represent a rough overall estimate of *relative* risk per unit of consumption.⁴ 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 it was expected that each of these would be positively correlated with the violation rate. Therefore, they might 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 "Regulatory Concern" category was designed to predict the "likelihood of occurrence of violations, based on regulatory intelligence information about possible misuse."

"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 the withdrawal time is not observed prior to slaughter, the carcass may contain violative levels of residues, since the time necessary for sufficient metabolism and/or elimination of the drug would not have passed. "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 were correlated. In an effort to impute values for the missing data, a linear regression model was applied. The dependent variable in this model was the category "FSIS Historical Testing Information on Violations," while the only significant independent variable was the product of the scores for "Regulatory Concern" and "Relative Number of Animals Treated."

Table 4.1 lists 12 compounds or compound classes for which current, reliable data were available to score the category "FSIS Historical Testing Information on Violations," and 20 compounds or compound classes for which there were not. Of the 12 compounds for which there were violation rate scores, 3 (nitroimidazoles, fluoroquinolones, and phenylbutazone) were eliminated from the regression calculation because, as explained in the definition of "Regulatory Concern" at the end of this section, their scores in this category automatically default to a "4" because they are banned from extralabel use under AMDUCA. A least squares linear regression model, using the value of the independent variable from the remaining 11 scored compounds or compound classes, was then used to predict scores in the category

³ For a more detailed explanation, refer the *Scoring Key for Veterinary Drugs*.

⁴ 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 (4.6); the results are presented in Table 4.5.

"FSIS Historical Testing Information on Violations" for the 20 compounds for which this information is not available. The following equation was derived:

$$V_p = 0.81 + 0.16 * (W * N) \quad (4.2)$$

Where:

- V_p = Predicted score for "FSIS Historical Testing Information on Violations"
- N = score for "Relative Number of Animals Treated"
- W = score for "Withdrawal Time"
- $W * N$ = product of W and N .

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

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

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

The model represented by Equation (4.2) was significant, with an overall model p-value of 0.0316, and an R^2 value of 0.61, accounting for 61 percent of the variability in the data.

Where current, reliable historical testing data were available for a compound or compound class, FSIS used the score assigned in Table 4.1. Where current, reliable historical data were not available, FSIS used the predicted score generated by Equation (4.2).

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

As indicated above, the score for "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 4.3 and the scores for relative public health concern are summarized in Table 4.1.

$$\begin{aligned} \text{Relative Public Health Concern} = & \text{Predicted or Actual score for} & (4.3) \\ & \text{"FSIS Historical Testing Information on Violations"} \text{ (Estimate of Relative Hazard)} \\ & \times \text{modifier for "Acute or Chronic Toxicity Concerns"} \\ & \times \text{modifier for "Impact on New and Existing Human Disease"} \end{aligned}$$

x modifier for "Lack of FSIS Testing Information on Violations"

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.

Finally, the category "Lack of FSIS Testing Information on Violations" has been incorporated because violation data for a compound may be absent, dated or sparse. The lack of test information increases the relative public health need to obtain information on residue violations for a compound or compound class. For example, consider two hypothetical compounds, A and B. Compound A has been tested extensively and has a measured violation rate; however, there are no test data for compound B. Since there are no test data for B, a violation rate is calculated. If the measured violation rate for A and the calculated rate for B are identical and if their scores for the categories "Regulatory Concern," "Withdrawal Time," and "Number of animals treated" are also identical, FSIS believes there is greater need to sample for B than for A, because there is extensive information on A, but not for B.

The use categories for acute and chronic toxicity concerns, impact on new and existing human disease and lack of testing information on violations introduces 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 4.3. 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," and in the magnitude of the calculated value for "Lack of FSIS Testing Information on Violations." FSIS selected the formula shown in the column for "Relative Public Health Concern Score" in Table 4.1. The selection is based on a consensus 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 (4.4). 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 product of the above categories was then multiplied by a modifier for "Lack of FSIS Testing Information on Violations." 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 (4.4) summarizes the way final adjustments were made.

$$\begin{aligned} \text{Relative public health concern rating, veterinary drugs} & \qquad \qquad \qquad (4.4) \\ = V*((D+3*T)/4) * \{1+[(L-1)*0.05]\} \end{aligned}$$

Where: 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"
 L = score for "Lack of FSIS Testing Information on Violations"

In this formula, the category of "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. Further, the final ratings of compounds or compound classes receiving scores of 4, 3, 2, and 1 in "Lack of FSIS Testing Information on Violations" would be increased by 15%, 10%, 5%, and 0% respectively. In other words, the rating of a compound or compound class that had never been tested by FSIS (in the production classes and matrices of concern) would be increased by 15%, while the rating of one that had been recently tested by FSIS (again, in the production classes and matrices of concern) would remain unchanged.

The formulas used here for the veterinary drugs, and in Chapter 6 for the pesticides, have been normalized to give the same maximum value. Because the formula for the pesticides uses different terms (i.e., scoring categories) from that for 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 4.2b, *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 4.2b 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.⁵ Data on relative consumption are applied subsequently, in Phase IV, when relative exposure values for each compound/production class (C/PC) pair are estimated.

Phase II. Selecting Drugs for Inclusion in the 2004 NRP

Following the completion of the ranking of the veterinary drugs, FSIS (1) used the ranking scores for relative public health concern as criteria for selecting compounds and compound classes to include in the 2004 NRP and (2) determined which of these compounds and compound classes could be included in the 2004 NRP, based on the availability of laboratory resources.

The consensus of FSIS and FDA was that those compounds and compound classes ranked 11th or higher (out of a total of 31) represent a potential public health concern sufficient to justify their inclusion in the 2004 NRP. In addition, FDA expressed an interest in having FSIS perform limited testing on two compound that did not fall within this group of 24 (veterinary tranquilizers, ranked 29th, in market hogs); and MGA (ranked 23rd).

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 include the following veterinary drugs in the 2004 Monitoring Plan:

Antibiotics:

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,

⁵ See footnote 4.

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, lincomycin, pirlimycin, clindamycin, and oleandomycin.

- Chloramphenicol

Other Veterinary Drugs:

- Arsenicals (detected as elemental arsenic)
- Avermectins in FSIS MRM (incl. doramectin, ivermectin, moxidectin) (antiparasitics)
- Carbadox (antimicrobial)
- Clenbuterol and other unapproved beta agonists (growth promotants)⁶
- Flunixin (NSAID)
- MGA (hormone, synthetic)
- Phenylbutazone (NSAID)
- Phenylbutazone (ELISA)
- Sulfonamides in FSIS MRM

In the 2004 NRP, FSIS plans to employ 12 methodologies that analyze for veterinary drugs. Six of the 12 are single-compound methodologies, and six are MRM's (phenylbutazone is detected by the FSIS MRM for chlorinated hydrocarbon and chlorinated organophosphate compounds). Together, these methodologies encompass approximately 60 different compounds.

Table 4.2 lists all of the original candidate veterinary drugs in rank order. This table specifies whether each compound or compound class will be sampled under the 2004 Monitoring Plan. For each highly ranked compound or compound class that was not included in the 2004 Monitoring Plan, 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.

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

The SAT participants (principally those from FDA) identified the production classes of concern for each of the drugs and drug classes to be included in the 2004 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 4.3, *Production Classes to be Considered for Each Veterinary Drug/Drug Class*. C/PC pairs included in the 2004 NRP are designated by a "●." Those C/PC pairs that are of regulatory concern, but that could not be included in the 2004 NRP because of laboratory resource constraints, are marked with a "○." Since all production classes will be sampled by the chlorinated hydrocarbon/chlorinated organophosphate (CHC/COP) method (see Section 6), and since this method also detects phenylbutazone, the latter will, by default, likewise be sampled in all production classes. However, phenylbutazone is not of regulatory concern in all production classes. Those production classes in which phenylbutazone will be sampled, but where it is not of regulatory concern, are designated by a "◐" (i.e., these production classes will be sampled for phenylbutazone, but only because it is automatically detected through the CHC/COP methodology). **In addition, FSIS has suspended monitoring testing for certain production classes in 2004, which are marked with a "■."**

⁶See footnote 2.

Nomenclature

Production classes are defined as follows:

- Bulls are mature, sexually 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.
- Bob veal are calves up to three weeks of age or 150 pounds
- Formula-fed veal are confinement-raised calves fed on a liquid milk replacer diet and weighing more than 150 pounds.
- Non-formula-fed veal are calves fed a diet that includes solid feeds such as grass and grains requiring a functional rumen and weighing between 150 and 400 pounds.
- Heavy calves are non-formula-fed calves weighing greater than 400 pounds with the physical characteristics of a calf.
- Market hogs are swine usually marketed near six months of age and 200 to 300 pounds live weight.
- Boars are mature, sexually intact male swine.
- Stags are male swine castrated after they have reached sexual maturity.
- Sows are mature female swine.
- Sheep are mature sheep with no distinction by gender.
- Lambs are young sheep for which there is proof that the ovine was less than 14 months of age, or that exhibit a break joint (epiphysis) of the distal metacarpal bone of either foreleg.
- Goats are of either sex and any age.
- Horses are of either sex and any age.
- Bison are of either sex and any age.
- Young chickens are broilers/fryers that are usually less than 10 weeks of age, roasting chickens that are young chickens of either sex usually less than 12 weeks of age, and capons, which are surgically neutered male chickens usually less than 4 months of age.
- Mature chickens are adult female chickens usually more than 10 months of age.
- Young turkeys are fryer turkeys that are either male or female and usually less than 12 weeks of age, and roaster turkeys that are either male or female usually less than 6 months of age.
- Mature turkeys are of either sex and usually more than 15 months of age.
- Ducks are of either sex and any age.
- Geese are of either sex and any age.
- Other fowl include ratites (typically ostriches, emus, and rheas), guineas, squabs (young, fledgling pigeons), adult pigeons, pheasants, grouse, partridges, quail, etc.
- Rabbits are any of several lagomorph mammals.
- Egg products are dried, frozen, or liquid eggs.

Phase IV. Allocation of Sampling Resources

"Full-Resource" Sampling

Table 4.4 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 2002 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 (4.5), 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 4.3:

$$(\text{Est. rel. \% domestic consumption})_{PC} = \frac{(\text{Annual production, pounds dressed wt.})_{PC}}{\text{Total annual production, all production classes}} \quad (4.5)$$

All calculations and results are presented in Table 4.4, *Estimated Relative Consumption, Domestically Produced Meat, Poultry, and Egg Products*.

FSIS has sufficient analytical capability to consider sampling production classes of concern for the following compounds/compound classes: antibiotics (by bioassay); arsenicals; avermectins; sulfonamides; and phenylbutazone (via the CHC/COP methodology). To establish a relative sampling priority for each C/PC pair, the ranking score (as calculated in Table 4.1) was multiplied by the estimated relative percent of domestic consumption for each production class (as calculated in Table 4.5 and as presented in Table 4.4). This is shown in Equation (4.6):

$$(\text{Relative sampling priority})_{C/PC} = (\text{Ranking score})_C \times (\text{Rel. \% domestic consumption})_{PC} \quad (4.6)$$

Equation (4.6) is analogous to the equation used to estimate risk (Equation (4.1)), in which risk per unit of consumption is multiplied by consumption. While the results of Equation (4.6) 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 (4.6) is based upon average consumption across the entire U.S. population, rather than upon maximally exposed individuals.

In Table 4.5, *Veterinary Drug Compound/Production Class Pairs, Sorted by Sampling Priority Score, "Full Resource" Sampling*, the calculation shown in Equation (4.6) 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 4.6). The C/PC pairs were sorted by their sampling priority scores, and roughly divided into quartiles. Initially, C/PC pairs in the first through fourth quartiles were assigned sampling numbers of 460, 300, 230, and 90, respectively. The cutoff scores for Relative Public Health Concern corresponding to each sampling level were as follows: $> 78 = 460$ samples; $3.85 - 46.6 = 300$ samples; $0.31 - 3.02 = 230$ samples; $< 0.31 = 90$ samples. These priority scores were combined with historical violation rate information for each individual C/PC pair, information on laboratory sampling capacity, and the number of slaughter facilities to select, for each pairing, from among four different sampling options: very high regulatory concern (460 analyses/year); high regulatory concern (300 analyses/year); moderate regulatory concern (230 samples/year); low regulatory concern (90 samples/year).⁷ The larger sample sizes, which provide the greater chance of detecting violations, are directed towards those C/PC pairs that have been identified as representing higher levels of relative public health concern. 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 460, 300, 230, and 90 are 99%, 95%, 90%, and 60%, respectively. The higher sampling levels are useful when FSIS wishes to monitor slaughter classes with somewhat lower violation rates (which is typically done for larger slaughter classes, since these represent a larger potential consumer exposure). For example, if the true violation rate is 0.5%, increasing the sampling level from 300 to 460 increases the chance of detecting a violation from 78% to 90%. By contrast, the lower sampling levels enable FSIS to ensure, without expending excessive resources that gross residue violation problems do not exist in minor slaughter classes. For example, while 90 samples offers only a 60% probability of violation detection at a violation rate of 1%, at a violation rate of 3% the detection probability increases to 94%.

Horses, rabbits, ratites, squab, geese, ducks, and bison will not be scheduled for the 2004 domestic monitoring program for the 2004 NRP because the minor species are low production animals. However, horses are of concern for residue violations and enforcement testing will continue. 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 used "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 4.6a, *Adjusted Number of Analyses for Each Veterinary Drug Compound/Production Class Pair, "Full Resource" Sampling*, lists the number of analyses assigned to each C/PC pair in Table 4.5. It also lists, for the period 01/01/1993 - 12/31/2002, the total number of samples analyzed by FSIS under its Monitoring Plan (i.e., random sampling only) for each C/PC pair, 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). Using this data, the following rules were applied to adjust the sampling numbers:

- Less than 300 samples from the C/PC pair tested over the 10-year period: +1 level (i.e., increase by one sampling level, e.g., from 230 samples to 300 samples).
- At least 300 samples tested over the 10-year period, violation rate $\geq 0.50\%$, but $< 0.70\%$: +1 level.
- At least 300 samples tested over the 10-year period, violation rate $\geq 0.70\%$: +2 levels.
- At least 300 samples tested over the 10-year period, violation rate = 0.00%: -1 level.
- The maximum number of samples to be scheduled for testing is 460.

All of the above adjustments were applied, and the sampling numbers obtained following these adjustments are listed in Table 4.6a and 4.6b under the heading "Initial Adjustment" (initial adjusted number of samples).

Adjusting for laboratory capacity

Following this, 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.

For antibiotics and sulfonamides, it was decided to increase the number of analyses in market hogs from 460 to 1000. The increase in sampling numbers for market hogs for antibiotics was offset by reducing the number of samples for young chickens, formula-fed veal, and bob veal.

For sulfonamides, the number of samples for market hogs was increased to 1000. The number of samples for steers and bob veal was reduced from 460 to 300 for both production classes. FSIS is in the process of validating FAST in swine; to complete the validation study, a large number of samples is needed.

Adjustment for the Number of Slaughter Facilities

An adjustment to the total number of monitoring 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 2002) 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 monitoring 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, but greater than 10, the number of monitoring samples was adjusted down by 1 level. If the total number of facilities is less than 10, the number of monitoring samples was adjusted down by 2 levels. Based on these parameters, the number of monitoring samples was adjusted for the following production classes: "Young Turkeys", "Mature Chickens", "Ducks", "Mature Turkeys" and "Horses."

Adjustment for a zero (0%) violation rate for the three year period, 2000 – 2002

FSIS historical violation data were examined for the 2000 - 2002 production years. For compound slaughter class pairs that had a zero percent violation rate for the three year period, the number of scheduled samples was reduced to zero.

Final Adjustment

The sample numbers obtained following adjustments for laboratory capacity, production, and violation rate data are listed in Table 4.6, under the heading "Final Adjustment."

"Limited Resource" Sampling

The 2004 NRP includes a number of compounds for which FSIS does not have extensive sampling data. In monitoring for these compounds, FSIS is concerned with obtaining information on their occurrence in particular 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 2004 NRP, selection of production classes for the limited resource sampling for compounds (Table 4.6b) was made as follows:

- Chloramphenicol is of concern in dairy cows, formula-fed veal, non-formula-fed veal, young chickens, mature chickens, young turkeys, and mature turkeys. The analytical capacity is 910 samples for chloramphenicol for the 2004 NRP.
- Flunixin is of concern in dairy cows. The analytical capacity for domestic scheduled sampling of flunixin is 300 samples; therefore, 300 dairy cows will be scheduled for the 2004 NRP.
- MGA is of concern in heifers, steers, formula-fed veal, and non-formula-fed veal. The analytical capacity for MGA in 2004 is 300 samples, and the top priority production class is heifers. FSIS will conduct 300 analyses for MGA in heifers.
- Ractopamine is not scheduled in the 2004 NRP; however, ractopamine is identified in the clenbuterol MRM. Clenbuterol is scheduled to be tested in steers, formula-fed veal, and market hogs.
- Clenbuterol is of concern in steers, formula-fed veal, and market hogs. The analytical capacity for clenbuterol in 2004 is 830 samples. FSIS will conduct 830 analyses for clenbuterol in steers, formula-fed veal, and market hogs.

The above information is presented in tabular format at the end of Section 10 in Table 10.1, *Detailed Sampling Plan, 2004 FSIS NRP, Domestic Monitoring Plan and Exploratory Projects*, Table 10.2, *Summary, 2004 FSIS NRP, Domestic Monitoring Plan and Exploratory Projects*, and in Table 10.6, *Combined Summary, 2004 FSIS NRP, Domestic Monitoring Plan and Exploratory Projects and Import Monitoring Plan*.

Scoring Key for Veterinary Drugs

FSIS Historical Testing Information on Violations (01/01/1993 - 12/31/2002)

Violation rate scores were calculated by two different methods, A and B, 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 1993 - 2002, divided by the total number of samples analyzed). Score as follows:

4 = > 0.70%

3 = 0.31% - 0.70 %

2 = 0.15% - 0.30%

1 = < 0.15%

NT = Not tested by FSIS

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

Note that the above violation rate criteria are different from those used in planning the 1998 – 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:

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

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.

Lack of FSIS Testing Information on Violations

This represents the extent to which FSIS analytical testing information on a residue is limited, absent or obsolete.

- 4 = FSIS has not included this compound in its sampling program within the past 10 years (1/1/1993 - 12/31/2002); or FSIS has included this compound within its program only between 6 and 10 years ago (1/1/1993 - 12/31/1997), but the sampling does not meet the criteria specified for a "3;" or

FSIS has included this compound in its sampling program, but the information is not at all useful in predicting future violation rates, because of subsequent significant changes in the conditions of use of the compound (e.g., the reduction in withdrawal time for carbadox), or because regulatory intelligence information indicates that the situation has changed significantly since the last time the compound was sampled; or because the compound is of concern in several production classes of interest, but testing has been carried out in only one.

- 3 = FSIS has tested within the past 5 years (1/1/1998 - 12/31/2002), but in fewer than 75% of the production classes of interest; or even if 75% of production classes were tested, there was no production class from which at least 300 samples have been analyzed; or the only testing was between 6 and 10 years ago, where FSIS has analyzed at least 75% of production classes of interest for at least 2 of these 5 years, with a total of at least 500 samples per production class during this 5-year period and, in the case of a multiresidue method (MRM), the method used covers all compounds of interest with the compound class; or, the compound would normally have qualified for a "1" or "2," but the method used was not sufficiently sensitive to permit accurate determination of the true violation rate.
- 2 = FSIS has included this compound in its sampling program within the past 5 years in at least 75%, but less than 100% of the production classes of interest, with at least 300 samples in at least one production class; or 100% of the production classes of interest have been sampled, but the amount and duration of sampling has been insufficient to qualify for a "1."
- 1 = FSIS has included this compound in its sampling program within the past 5 years, and has analyzed 100% of the production classes of interest for at least 2 of these 5 years, with a total of at least 500 samples per production class during this 5-year period, and in the case of an MRM, the method used covers all compounds of interest with the compound class. Or if FSIS has included this compound in its sampling program for at least 4 of the past 5 years, and at least 6,000 samples have been analyzed during this period.

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

- 4 = Withdrawal time greater than 14 days
- 3 = Withdrawal time between 8 and 14 days
- 2 = Withdrawal time between 1 and 7 days
- 1 = Zero-day withdrawal time

Impact on New and Existing Human Disease

This represents the extent to which the use or misuse of this compound may contribute to new and existing human disease, principally from the potential to change patterns of antibiotic resistance in human pathogens.

- 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 4.1
Scoring Table for Veterinary Drugs
2004 FSIS NRP, Domestic Monitoring Plan

Compound / Compound Class	Historical Testing Info. on Violations (FSIS) (V)	Regulatory Concern (CVM) (R)	Withdrawal Time (CVM) (W)	Relative Number Animals Treated (CVM) (N)	Predicted $V = 0.81227 + 0.16319 * W * N$	Predicted V, Except When Actual V is Available	Impact New & Existing Human Disease (CDC) (D)	Acute or Chronic Toxicity Concerns (CVM) (T)	Lack of Testing Info. on Violations (FSIS) (L)	Relative Public Health Concern Score = $V * [(D+3*T)/4] * \{1 + [(L-1) * 0.05]\}$
Antibiotics quantitated by the FSIS Bioassay MRM	4	4	4	4	3.42	4.00	3	4	1	15.0
Carbadox (antimicrobial)	3	4	4	3	2.77	3.00	3	4	3	12.4
Sulfonamides (antimicrobials, some are coccidiostats)	4	4	3	4	2.77	4.00	3	3	1	12.0
Florfenicol (chloramphenicol deriv.)	NT	3	4	4	3.42	3.42	3	3	4	11.8
Avermectins in FSIS MRM (incl. doramectin, ivermectin, moxidectin) (antiparasitics)	3	3	4	4	3.42	3.00	2	4	1	10.5
Sulfanitran (antibacterial, coccidiostat)	NT	4	3	4	2.77	2.77	3	3	4	9.6
Arsenicals (detected as As)	3	4	2	4	2.12	3.00	3	2	1	6.8
Flunixin	3	4	2	3	1.79	3.00	1	2	2	5.5
Ractopamine (beta agonist)	NA-O [NT]	4	2	3	1.79	1.79	2	3	3	5.4
Thyreostats (incl. thiouracil)	NT	4	3	1	1.30	1.30	2	4	4	5.2
Dipyron (NSAID)	NT	4	3	1	1.30	1.30	1	4	4	4.9
Berenil (antiprotozoal, Histomonas)	NA-G, Mx	4	4	1	1.47	1.47	2	3	4	4.6
Trenbolone (hormone, synthetic)	NT	4	1	3	1.30	1.30	3	3	4	4.5
Zeranol (hormone, synthetic)	NT	3	1	3	1.30	1.30	3	3	4	4.5
Methyl prednisone (glucocorticoid)	NT	4	2	2	1.47	1.47	1	3	4	4.2
Eprinomectin (ivermectin)	NT	2	2	3	1.79	1.79	2	2	4	4.1
Clorsulon (anthelmintic, Trematodes)	NT	2	3	2	1.79	1.79	2	2	4	4.1
Dexamethasone (glucocorticoid)	NA-O	4	2	2	1.47	1.47	1	3	3	4.0
Thiamphenicol (chloramphen. deriv.)	NT	3	2	1	1.14	1.14	3	3	4	3.9

Table 4.1 - Continued
Scoring Table for Veterinary Drugs
2004 FSIS NRP, Domestic Monitoring Plan

Compound / Compound Class	Historical Testing Info. on Violations (FSIS) (V)	Regulatory Concern (CVM) (R)	Withdrawal Time (CVM) (W)	Relative Number Animals Treated (CVM) (N)	Predicted $V = 0.81227 + 0.16319 * W * N$	Predicted V, Except When Actual V is Available	Impact New & Existing Human Disease (CDC) (D)	Acute or Chronic Toxicity Concerns (CVM) (T)	Lack of Testing Info. on Violations (FSIS) (L)	Relative Public Health Concern Score = $V * [(D + 3 * T) / 4] * \{1 + [(L - 1) * 0.05]\}$
Amprolium (coccidiostat)	NT	4	2	2	1.47	1.47	3	2	4	3.8
Hormones, naturally-occurring	NT	2	1	4	1.47	1.47	2	2	4	3.4
Lasalocid (coccidiostat)	NT	2	1	3	1.30	1.30	3	2	4	3.4
MGA (hormone, synthetic)	1	3	1	4	1.47	1.00	3	3	3	3.3
Levamisole (anthelmintic, Nematodes)	3	3	3	2	1.79	3.00	1	1	3	3.3
Prednisone (glucocorticoid)	NT	2	2	1	1.14	1.14	1	3	4	3.3
Etodolac (NSAID)	NT	3	2	1	1.14	1.14	1	3	4	3.3
Halofuginone (antiprotozoal, coccidiostat)	1	1	2	2	1.47	1.00	2	2	3	2.2
Benzimidazoles (anthelmintic)	1	1	3	2	1.79	1.00	1	2	4	2.0
Veterinary tranquilizers	NT	4	2	2	1.47	1.47	1	1	4	1.7
Nicarbazin (coccidiostat)	NA-O [1]	2	2	1	1.14	1.14	2	1	4	1.6
Morantel and pyrantel (anthelmintic)	1	1	1	2	1.14	1.00	2	1	3	1.4

Key:
MRM = multiresidue method
NT = not tested by FSIS (01/01/1993 - 12/31/2002)
NA = compound has been tested by FSIS (01/01/1993 - 12/31/2002), but the information is not applicable
NA-G = testing carried out in limited geographical area only, and thus does not necessarily represent overall national violation rate, e.g., sampling for berenil in Puerto Rico
NA-Mx = new information indicates that testing was not carried out in the correct matrix, e.g., berenil testing carried out in plasma rather than serum)
NA-O = data is preliminary, because useable data on this compound (i.e., data not subject to any of the various problems listed immediately above) has been collected for only one year
FSIS = scores in this column supplied by FSIS
CVM = scores in this column supplied by CVM
CDC = scores in this column supplied by CDC.

Table 4.2a
Drugs Banned from Extralabel use under AMDUCA*
2004 FSIS NRP, Domestic Monitoring Plan

Rank	Drug	Status in the 2004 NRP
1	Chloramphenicol	Domestic: 230, 90, 90, 230, 90, 90, 90, 90 samples for dairy cows, formula-fed veal, non-formula-fed veal, young chickens, mature chickens, young turkeys and mature turkeys, respectively. Import: 90 samples for fresh beef and 24 samples for fresh veal
2	Nitrofurans, including furazolidone and nitrofurazone (antimicrobials)	NIP; no method
3	Clenbuterol**	Domestic: 300, 230, and 300 samples are scheduled for steers, formula-fed veal, and market hogs, respectively. Confirmation done by FDA-NCTR. Import: No samples scheduled
4	Ronidazole (nitroimidazole; antimicrobial use)	NIP
5	Nitroimidazoles (FSIS MRW: dimetridazole and ipronidazole; antiprotozoal use)	NIP
6	Avoparcin (glycopeptide)	NIP
7	Vancomycin (glycopeptide)	NIP
8	Diethylstilbestrol (DES; synthetic hormone)	Domestic: special project for 2004
9	Phenylbutazone (NSAID)	Monitoring Plan: Immunoassay (ELISA) and as part of the CHC/COP MRM Domestic: all production classes except horses, bob-veal, ducks, bison, ratites, geese, rabbits, and squab Import: all production classes except processed veal

*Drugs banned from extralabel use under AMDUCA were not evaluated using the ranking formula for inclusion in Table 4.2a. Instead, these drugs were automatically assigned a high sampling priority and will be included in the NRP if methodologies and resources are available.

**The clenbuterol methodology employs a screen that has been officially validated for clenbuterol (bovine and porcine) and has been extended to salbutamol and cimaterol (bovine). The method has also demonstrated the ability to detect other beta agonists, including ractopamine. The follow-up confirmatory method may detect several unapproved beta agonists, including the following: clenbuterol; cimaterol; fenoterol; mabuterol; salbutamol; brombuterol; and terbutaline.

Table 4.2b
Rank and Status of Veterinary Drugs
2004 FSIS NRP, Domestic Monitoring Plan

Rank	Drug	Score	Status in the 2004 NRP
1	Antibiotics 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, lincomycin, pirlimycin, clindamycin, and oleandomycin.	15.0	Monitoring Plan: MRM Domestic: all production classes except sheep, rabbits, ratites, geese, squab, horses, goats, ducks, steers, young turkeys, bulls, mature turkeys, and egg products Imported: all fresh product classes
2	Carbadox (antimicrobial)	12.4	Monitoring Plan: Not scheduled
3	Sulfonamides in FSIS MRM (sulfapyridine, sulfadiazine, sulfathiazole, sulfamerazine, sulfamethazine, sulfachloropyridazine, sulfadoxine, sulfamethoxyipyridazine, sulfaquinoxaline, sulfadimethoxine, sulfisoxazole, sulfacetamide, sulfamethoxazole, sulfamethizole, sulfanilamide, sulfaguanidine, sulfabromomethazine, sulfasalazine, sulfaethoxyipyridazine, sulfaphenazole, and sulfatroxazole) (antimicrobials, some are coccidiostats)*	12.0	Monitoring Plan: MRM. Domestic: all production classes except young chickens, young turkeys, heifers, egg products, sows, mature chickens, ducks, goats, horses, bison, squab, sheep, ratites, geese, and rabbits Imported: all production classes
4	Florfenicol (chloramphenicol derivative)	11.8	NIP
5	Avermectins in FSIS MRM (doramectin, ivermectin, and moxidectin) (antiparasitic)	10.5	Monitoring Plan, MRM Domestic: scheduled for beef cows, bulls, goats, non-formula fed veal, and sheep production classes Imported: all non-avian fresh product classes, except goats
6	Sulfanitran (antibacterial, coccidiostat)	9.6	NIP; no method; need to add to sulfonamide MRM, or find a new method
7	Arsenicals (detected as As)	6.8	Domestic: scheduled for young chickens, young turkeys, and goats Imported: All avian production classes. Fresh goat and pork. Processed pork and beef/pork
8	Flunixin (NSAID)	5.5	Domestic: 300 dairy cows
9	Ractopamine (beta agonist)	5.4	Monitoring Plan: Not scheduled for 2004
10	Thyreostats (incl. thiouracil)	5.2	NIP
11	Dipyron (NSAID)	4.9	NIP
Based on consultation with FDA, CDC, and other agencies, compounds below this point (with the exception of MGA and veterinary tranquilizers) were not considered to represent a potential public health risk. However, samples may be collected for testing for these compounds on an as-needed basis. Based on these considerations, the following compounds were not selected for inclusion in the 2004 FSIS National Residue Program (NRP).			
12	Berenil (antiprotozoal)	4.6	NIP
13	Trenbolone (hormone, synthetic)	4.5	NIP
14	Zeranol (hormone, synthetic)	4.5	Monitoring Plan: Domestic: Not scheduled for 2004

Table 4.2b - Continued
Rank and Status for Veterinary Drugs
2004 FSIS NRP, Domestic Monitoring Plan

Rank	Drug	Score	Status in the 2004 NRP
15	Methyl prednisone (glucocorticoid)	4.2	NIP
16	Eprinomectin (ivermectin)	4.1	NIP
17	Clorsulon (anthelmintic)	4.1	NIP
18	Dexamethasone (glucocorticoid)	4.0	NIP
19	Thiamphenicol (chloramphenicol derivative)	3.9	NIP
20	Amprolium (coccidiostat)	3.8	NIP
21	Hormones, naturally-occurring (17-estradiol, testosterone, and progesterone)	3.4	NIP
22	Lasalocid (coccidiostat)	3.4	NIP
23	MGA (hormone, synthetic)	3.3	Monitoring Plan: Domestic: 300 heifers
24	Levamisole (anthelmintic)	3.3	NIP
25	Prednisone (glucocorticoid)	3.3	NIP
26	Etodolac (NSAID)	3.3	NIP
27	Halofuginone (antiprotozoal, coccidiostat)	2.2	NIP
28	Benzimidazoles in FSIS MRM (thiabendazole and its 5-hydroxythiabendazole metabolite, albendazole 2-animosulfone metabolite, benomyl in the active hydrolyzed form carbendazim, oxfendazole, mebendazole, cambendazole, and fenbendazole) (anthelmintics)	2.0	NIP
29	Veterinary tranquilizers (azaperone and its metabolite azaperol, xylazine, haloperidol, acetopromazine, propionylpromazine, and chlorpromazine)	1.7	NIP
30	Nicarbazin (coccidiostat)	1.6	NIP
31	Morantel and pyrantel (anthelmintic)	1.4	NIP

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

Key:

MRM = Multiresidue method

CHC/COP = Chlorinated hydrocarbon/chlorinated organophosphate

NIP = Not included in 2004 FSIS National Residue Program (NRP)

NSAID = Non-steroidal anti-inflammatory drug

FDA-NCTR = Food and Drug Administration, National Center for Toxicological Research, Jefferson, AR.

In the second column, where multiple compounds have been grouped together for analysis or potential analysis by a single MRM, the title of that group has been bolded (e.g., “Antibiotics in FSIS Bioassay MRM”).

Table 4.3
Production Classes to be Considered for Each Veterinary Drug/Drug Class
2004 FSIS NRP, Domestic Monitoring Plan

ERC	Production Class	Drug and Priority Rating						AMDUCA Drugs			
		Antibiotics 15.0	Avermectins 10.5	Arsenic 6.8	Flunixin 5.5	MGA ^a 3.3	Sulfonamides 12	CAM ^b	Clenbuterol	Phen ^c (CHC)	Phen ^d (ELISA)
0.021	Horses	■	■				■			■	●
0.547	Bulls	■	●				●			●	
1.806	Beef cows	●	●	■			●			●	●
1.543	Dairy cows	●	■		●		●	●		●	●
8.57	Heifers	●	■			●	■			●	●
14.471	Steers		■			○	●		●	●	●
0.026	Bob veal	●	■				●	○		■	
0.154	Formula-fed veal	●	■			○	●	●	●	●	
0.009	Non-formula-fed veal	●	●			○	●	●		●	
0.014	Heavy calves	●	■				●			●	●
0.016	Bison	■	■				■			■	
0.009	Sheep	■	●				■			●	
0.201	Lambs	●	■				●			●	
0.03	Goats	■	●	●			■			●	
18.487	Market hogs	●	■	■			●		●	●	
0.011	Roaster pigs	●	■	■			●			●	
0.064	Boars/Stags	●	■	■			●			●	
1.013	Sows	●	■	■			■			●	
42.943	Young chickens	●		●			■	●		●	
0.566	Mature chickens	●		■			■	●		●	
6.851	Young turkeys	■		●			■	●		●	
0.086	Mature turkeys	■		■			●	●		●	
0.16	Ducks	■		■			■			■	
0.003	Geese	■		■			■			■	
>>0.01	Squab	■					■			■	
0.007	Ratites	■	■				■			■	
0.002	Rabbits	■	○				■			■	
2.388	Egg products	○		■			■			●	

a. MGA = Melengestrol acetate

b. CAM = Chloramphenicol

c. Phen (CHC) = Phenulbutazone by the CHC method

d. Phen (ELISA) = Phenylbutazone by ELISA method

Table 4.3
Production Classes to be Considered for Each Veterinary Drug/Drug Class
2004 FSIS NRP, Domestic Monitoring Plan

Key:

ERC = Estimated relative percent of domestic consumption, calendar year 2002. 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 4.4). See explanation in text, Section 4, for values used for ratites and squab.

● = Scheduled for sampling under the 2004 FSIS NRP

○ = Of potential regulatory concern, but could not be sampled under the 2004 FSIS NRP because of laboratory resource constraints or methodological limitations

◐ = Not of regulatory concern, but sampled anyway because comes through during CHC/COP method

■ = FSIS has suspended monitoring testing for this drug/production class pair in 2004.

Table 4.4
Estimated Relative Consumption, Domestically Produced Meat, Poultry, and Egg Products
2004 FSIS NRP, Domestic Monitoring Plan

PRODUCTION CLASS	NUMBER HEAD SLAUGHTERED	LBS./ ANIMAL, DRESSED WT.	TOTAL LBS., DRESSED WT.	EST. RELATIVE CONSUMPTION
Bulls	598,000	912	545,376,000	0.547
Beef cows	3,051,000	590	1,800,090,000	1.806
Dairy cows	2,607,000	590	1,538,130,000	1.543
Heifers	11,342,000	753	8,540,526,000	8.570
Steers	17,523,000	823	14,421,429,000	14.471
Bob veal	347,145	75	26,035,875	0.026
Formula-fed veal	626,868	245	153,582,660	0.154
Non-formula-fed veal	24,254	350	8,488,900	0.009
Heavy calves	35,280	400	14,112,000	0.014
SUBTOTAL, CATTLE	36,154,547		27,047,770,435	27.141
Market hogs	95,459,000	193	18,423,587,000	18.487
Roaster pigs	[160,000]	70	11,200,000	0.011
Boars/Stags	271,000	235	63,685,000	0.064
Sows	3,185,000	317	1,009,645,000	1.013
SUBTOTAL, SWINE	99,075,000		19,508,117,000	19.576
Sheep	148,000	63	9,324,000	0.009
Lambs	2,944,000	68	200,192,000	0.201
SUBTOTAL, OVINE	3,092,000		209,516,000	0.21
Goats	595,501	50	29,775,050	0.030
Horses	42,312	500	21,156,000	0.021
Bison	25,340	610	15,457,400	0.016
TOTAL, ALL LIVESTOCK	138,321,547		46,765,403,435	46.994
Young chickens			42,794,468,277	42.943
Mature chickens			563,586,672	0.566
Young turkeys			6,827,679,975	6.851
Mature turkeys			85,602,119	0.086
Ducks			159,260,242	0.160
Geese			3,301,258	0.003
Other fowl (includes ratites)			7,363,383	0.007
SUBTOTAL, POULTRY			50,441,261,926	50.616
Rabbits			2,556,797	0.003
Egg products			2,379,668,000	2.388
GRAND TOTAL, ALL PRODUCTION CLASSES			99,655,278,608	100%

Notes on Table --- Sources of data: The numbers in this table were derived from National Agricultural Statistical Service (NASS) data on animals (and egg products) presented for slaughter (or processing) in federally inspected establishments, for calendar year 2002 (CY '02), with the exception of the numbers for veal and calves, which were obtained from the FSIS Automated Data Reporting System. **Livestock:** For livestock, NASS does not provide figures for total pounds dressed weight. Therefore, CY '02 NASS figures for number of head slaughtered were multiplied by CY '02 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. **Poultry, rabbits, and egg products:** For these production classes, figures for total pounds dressed weight, CY '02, were available from NASS, and it was therefore not necessary to calculate them from the number of head slaughtered. **Purpose:** 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 domestically produced product consumed domestically, vs. that which is exported).*

Table 4.5
Veterinary Drug Compound/Production Class Pairs,
Sorted by Sampling Priority Score, “Full-Resource” Sampling
2004 FSIS NRP, Domestic Monitoring Plan

Rank	Compound Class	Compound Priority Rating (P)	Production Class	Relative Percent Consumption in 2002 (C)	Priority Score (P * C)	Unadjusted Number of Samples
1	Antibiotic	15.00	Young chickens	42.943	644.145	460
2	Sulfonamides	12.00	Young chickens	42.943	515.316	460
3	Arsenicals	6.80	Young chickens	42.943	292.012	460
4	Antibiotic	15.00	Market hogs	18.487	277.305	460
5	Sulfonamides	12.00	Market hogs	18.487	221.844	460
6	Antibiotic	15.00	Steers	14.471	217.065	460
7	Avermectins	10.50	Market hogs	18.487	194.114	460
8	Sulfonamides	12.00	Steers	14.471	173.652	460
9	Avermectins	10.50	Steers	14.471	151.946	460
10	Antibiotic	15.00	Heifers	8.570	128.550	460
11	Arsenicals	6.80	Market hogs	18.487	125.712	460
12	Sulfonamides	12.00	Heifers	8.570	102.840	460
13	Antibiotic	15.00	Young turkeys	6.851	102.765	460
14	Avermectins	10.50	Heifers	8.570	89.985	460
15	Sulfonamides	12.00	Young turkeys	6.851	82.212	460
16	Arsenicals	6.8	Young turkeys	6.851	46.587	300
17	Sulfonamides	12.00	Egg products	2.388	28.656	300
18	MGA	3.3	Heifers	8.570	28.281	300
19	Antibiotic	15.00	Beef cows	1.806	27.090	300
20	Antibiotic	15.00	Dairy cows	1.543	23.145	300
21	Sulfonamides	12.00	Beef cows	1.806	21.672	300
22	Avermectins	10.50	Beef cows	1.806	18.963	300
23	Sulfonamides	12.00	Dairy cows	1.543	18.516	300
24	Arsenicals	6.80	Egg products	2.388	16.238	300
25	Avermectins	10.50	Dairy cows	1.543	16.202	300
26	Antibiotic	15.00	Sows	1.013	15.195	300
27	Arsenicals	6.80	Beef cows	1.806	12.281	300
28	Sulfonamides	12.00	Sows	1.013	12.156	300
29	Avermectins	10.50	Sows	1.013	10.637	300
30	Antibiotic	15.00	Mature chickens	0.566	8.490	300
31	Antibiotic	15.00	Bulls	0.547	8.205	300
32	Arsenicals	6.80	Sows	1.013	6.888	300
33	Sulfonamides	12.00	Sows	1.013	12.156	300
34	Sulfonamides	12.00	Mature chickens	0.566	6.792	300
35	Sulfonamides	12.00	Bulls	0.547	6.564	300
36	Avermectins	10.50	Bulls	0.547	5.744	300
37	Arsenicals	6.80	Mature chickens	0.566	3.849	300
38	Antibiotic	15.00	Lambs	0.201	3.015	230
39	Sulfonamides	12.00	Lambs	0.201	2.412	230
40	Antibiotic	15.00	Ducks	0.160	2.400	230
41	Antibiotic	15.00	Formula-fed veal	0.154	2.310	230

Table 4.5 - continued
Veterinary Drug Compound/Production Class Pairs,
Sorted by Sampling Priority Score, “Full-Resource” Sampling
2004 FSIS NRP, Domestic Monitoring Plan

Rank	Compound Class	Compound Priority Rating (P)	Production Class	Relative Percent Consumption in 2002 (C)	Priority Score (P * C)	Unadjusted Number of Samples
42	Avermectins	10.50	Lambs	0.201	2.111	230
43	Sulfonamides	12.00	Ducks	0.160	1.920	230
44	Sulfonamides	12.00	Formula-fed veal	0.154	1.848	230
45	Avermectins	10.50	Formula-fed veal	0.154	1.617	230
46	Antibiotic	15.00	Mature turkeys	0.086	1.290	230
47	Arsenicals	6.80	Ducks	0.160	1.088	230
48	Sulfonamides	12.00	Mature turkeys	0.086	1.032	230
49	Antibiotic	15.00	Boars/Stags	0.064	0.960	230
50	Sulfonamides	12.00	Boars/Stags	0.064	0.768	230
51	Avermectins	10.50	Boars/Stags	0.064	0.672	230
52	Arsenicals	6.80	Mature turkeys	0.086	0.585	230
53	Antibiotic	15.00	Goats	0.030	0.450	230
54	Arsenicals	6.80	Boars/Stags	0.064	0.435	230
55	Antibiotic	15.00	Bob veal	0.026	0.390	230
56	Sulfonamides	12.00	Goats	0.030	0.360	230
57	Antibiotic	15.00	Horses	0.021	0.315	230
58	Avermectins	10.50	Goats	0.030	0.315	230
59	Sulfonamides	12.00	Bob veal	0.026	0.312	230
60	Avermectins	10.50	Bob veal	0.026	0.273	90
61	Sulfonamides	12.00	Horses	0.021	0.252	90
62	Antibiotic	15.00	Bison	0.016	0.240	90
63	Avermectins	10.50	Horses	0.021	0.221	90
64	Antibiotic	15.00	Heavy calves	0.014	0.210	90
65	Arsenicals	6.80	Goats	0.030	0.204	90
66	Sulfonamides	12.00	Bison	0.016	0.192	90
67	Sulfonamides	12.00	Heavy calves	0.014	0.168	90
68	Avermectins	10.50	Bison	0.016	0.168	90
69	Antibiotic	15.00	Roaster pigs	0.011	0.165	90
70	Antibiotic	15.00	Squab	0.010	0.150	90
71	Avermectins	10.50	Heavy calves	0.014	0.147	90
72	Antibiotic	15.00	Non-formula-fed veal	0.009	0.135	90
73	Antibiotic	15.00	Sheep	0.009	0.135	90
74	Sulfonamides	12.00	Roaster pigs	0.011	0.132	90
75	Sulfonamides	12.00	Squab	0.010	0.120	90
76	Avermectins	10.50	Roaster pigs	0.011	0.116	90
77	Sulfonamides	12.00	Non-formula-fed veal	0.009	0.108	90
78	Sulfonamides	12.00	Sheep	0.009	0.108	90
79	Antibiotic	15.00	Ratites	0.007	0.105	90
80	Avermectins	10.50	Non-formula-fed veal	0.009	0.095	90

Table 4.5 - continued
Veterinary Drug Compound/Production Class Pairs,
Sorted by Sampling Priority Score, “Full-Resource” Sampling
2004 FSIS NRP, Domestic Monitoring Plan

Rank	Compound Class	Compound Priority Rating (P)	Production Class	Relative Percent Consumption in 2002 (C)	Priority Score (P * C)	Unadjusted Number of Samples
81	Avermectins	10.50	Sheep	0.009	0.095	90
82	Sulfonamides	12.00	Ratites	0.007	0.084	90
83	Arsenicals	6.80	Roaster pigs	0.011	0.075	90
84	Avermectins	10.50	Ratites	0.007	0.074	90
85	Antibiotic	15.00	Geese	0.003	0.045	90
86	Sulfonamides	12.00	Geese	0.003	0.036	90
87	Antibiotic	15.00	Rabbits	0.002	0.030	90
88	Sulfonamides	12.00	Rabbits	0.002	0.024	90
89	Arsenicals	6.80	Geese	0.003	0.020	90

Table 4.6a
Adjusted Number of Analyses for Each Veterinary Drug Compound/Production Class Pair, "Full Resource" Sampling
2004 FSIS NRP, Domestic Monitoring Plan

CC.	PC.	PS.	NS. ^a	VR. (%) (10 Year) ^b	VR. (%) (3 Year) ^b	UNS. ^c	Adj. ^d	IA. ^e	ALC.	APV.	FA. ^f
Antibiotics	Young Chickens	644.145	3,153	0.02	0.07	460		460	300		300
Antibiotics	Market Hogs	277.305	4,760	0.32	0.29	460		460	1,000		1,000
Antibiotics	Steers	217.065	3,911	0.03	0.00	460		460			0
Antibiotics	Heifers	128.550	3,650	0.05	0.07	460		460			460
Antibiotics	Young Turkeys	102.765	4,489	0.13	0.00	460		460		300	0
Antibiotics	Beef Cows	27.090	4,370	0.14	0.34	300		300			300
Antibiotics	Dairy Cows	23.145	5,027	0.52	0.86	300	1	460			460
Antibiotics	Sows	15.195	4,224	0.43	1.16	300		300			300
Antibiotics	Mature Chickens	8.490	3,153	0.03	0.14	300		300		230	230
Antibiotics	Bulls	8.205	2,705	0.00	0.00	300	-1	230			0
Antibiotics	Lambs	3.015	3,904	0.15	0.10	230		230			230
Antibiotics	Ducks	2.400	3,674	0.11	0.00	230		230		90	0
Antibiotics	Formula-fed Veal	2.310	5,603	0.39	0.23	230		230	90		90
Antibiotics	Mature Turkeys	1.290	1,855	0.11	0.00	230		230		90	0
Antibiotics	Boars/Stags	0.960	3,088	0.23	0.57	230		230			230
Antibiotics	Goats	0.450	2,940	0.07	0.00	230		230			0
Antibiotics	Bob Veal	0.390	4,339	0.31	2.26	230	2	460	300		300
Antibiotics	Horses	0.315	2,827	6.15	6.10	230		230		90	0
Antibiotics	Bison	0.240	51	0.00	0.00	90	1	230			0
Antibiotics	Heavy Calves	0.210	3,052	0.39	0.44	90		90			90
Antibiotics	Roaster Pigs	0.165	608	1.15	1.13	90	2	300			300
Antibiotics	Squab	0.150	56	0.00	0.00	45		45			0
Antibiotics	Non-formula-fed Veal	0.135	2,525	0.55	0.33	90	1	230			230
Antibiotics	Sheep	0.135	2,556	0.04	0.00	90		90			0
Antibiotics	Ratites	0.105	168	0.00	0.00	90	-1	45			0
Antibiotics	Geese	0.045	442	0.00	0.00	90		90		45	0
Antibiotics	Rabbits	0.030	1,390	3.02	2.80	90		90			0
Total Samples						6,405		7,170			4,520

Table 4.6a - Continued
Adjusted Number of Analyses for Each Veterinary Drug Compound/Production Class Pair, "Full Resource" Sampling
2004 FSIS NRP, Domestic Monitoring Plan

CC.	PC.	PS.	NS. ^a	VR. (%) (10 Year) ^b	VR. (%) (3 Year) ^b	UNS. ^c	Adj. ^d	IA. ^e	ALC.	APV.	FA. ^f
Avermectins	Market Hogs	194.114	2,819	0.00	0.00	460	-1	300			0
Avermectins	Steers	151.946	3,986	0.03	0.00	460		460			0
Avermectins	Heifers	89.985	2,946	0.00	0.00	460	-1	300			0
Avermectins	Beef cows	18.963	3,214	0.12	0.11	300		300			300
Avermectins	Dairy Cows	16.202	2,822	0.11	300.00			300			0
Avermectins	Sows	10.637	2,237	0.00	0.00	300	-1	230			0
Avermectins	Bulls	5.744	2,362	0.34	0.36	300		300			300
Avermectins	Lambs	2.110	2,624	0.08	0.00	230		230			0
Avermectins	Formula-fed Veal	1.617	2,672	0.00	0.00	230	-1	90			0
Avermectins	Boars/Stags	0.672	1,454	0.00	0.00	230	-1	90			0
Avermectins	Goats	0.315	2,949	1.05	1.78	230	2	300			300
Avermectins	Bob Veal	0.273	555	0.00	0.00	90	-1	45			0
Avermectins	Horses	0.221	1,898	0.79	0.89	90	2	300			0
Avermectins	Bison	0.168	40	0.00	0.00	90	-1	45			0
Avermectins	Heavy Calves	0.147	2,498	0.28	0.00	90		90			0
Avermectins	Roaster Pigs	0.116	415	0.00	0.00	90	-1	45			0
Avermectins	Non-formula-fed veal	0.095	1,614	0.43	0.41	90		90			90
Avermectins	Sheep	0.095	1,721	0.29	1.32	90		90			90
Avermectins	Ratites	0.074	141	0.00	0.00	90	1	230			0
Total Samples						2,450		2,545			1,080

Table 4.6a - Continued
Adjusted Number of Analyses for Each Veterinary Drug Compound/Production Class Pair, "Full Resource" Sampling
2004 FSIS NRP, Domestic Monitoring Plan

CC.	PC.	PS.	NS. ^a	VR. (%) (10 Year) ^b	VR. (%) (3 Year) ^b	UNS. ^c	Adj. ^d	IA. ^e	ALC.	APV.	FA. ^f
Sulfonamides	Young Chickens	515.316	3896	0.1	0	460			300		0
Sulfonamides	Market hogs	221.844	3952	0.46	0.65	460		460	300		1,000
Sulfonamides	Steers	173.652	3254	0.15	0.18	460		460	300		300
Sulfonamides	Heifers	102.840	3095	0.03	0.00	460		460			0
Sulfonamides	Young Turkeys	82.212	3938	0.20	0.00	460		460		300	0
Sulfonamides	Egg Products	28.656	818	0.00	0.00	300	-1	230			0
Sulfonamides	Beef cows	21.672	4006	0.15	0.23	300		300			300
Sulfonamides	Dairy cows	18.516	3434	0.29	0.25	300		300			300
Sulfonamides	Sows	12.156	4319	0.63	0.00	300	1	460	300		0
Sulfonamides	Mature Chickens	6.792	3015	0.00	0.00	300	-1	230		90	0
Sulfonamides	Bulls	6.564	2945	0.10	0.11	300		300			300
Sulfonamides	Lambs	2.412	2964	0.13	0.10	230		230			230
Sulfonamides	Ducks	1.920	2939	0.03	0.00	230		230		45	0
Sulfonamides	Formula-fed veal	1.848	3955	0.20	0.46	230		230		90	90
Sulfonamides	Mature turkeys	1.032	2038	0.39	0.45	230		230		45	45
Sulfonamides	Boars/Stags	0.768	3333	0.63	0.15	230	1	300			300
Sulfonamides	Bob veal	0.312	4196	0.81	0.79	230	2	460	300		300
Sulfonamides	Horses	0.520	1676	0.24	0.16	90		90		45	0
Sulfonamides	Goats	0.360	2666	0.23	0.00	230		230			0
Sulfonamides	Bison	0.192	43	0.00	0.00	90	1	230		90	0
Sulfonamides	Heavy calves	0.168	2765	0.22	0.44	90		230			230
Sulfonamides	Roaster pigs	0.132	490	0.82	0.75	90	2	300			300
Sulfonamides	Squab	0.120	62	0.00	0.00	90	1	230		45	0
Sulfonamides	Non-formula-fed veal	0.108	2507	0.64	0.63	90	1	230			230
Sulfonamides	Sheep	0.108	1386	0.00	0.00	90	-1	45			0
Sulfonamides	Ratites	0.084	133	0.00	0.00	90	1	230		90	0
Sulfonamides	Geese	0.036	120	0.83	NT	90	2	300		90	0
Sulfonamides	Rabbits	0.024	462	0.00	NT	90	-1	45			0
Total Samples						5,880		7,500			3,925

Table 4.6a - Continued
Adjusted Number of Analyses for Each Veterinary Drug Compound/Production Class Pair, "Full Resource" Sampling
2004 FSIS NRP, Domestic Monitoring Plan

CC.	PC.	PS.	NS. ^a	VR. (%) (10 Year) ^b	VR. (%) (3 Year) ^b	UNS. ^c	Adj. ^d	IA. ^e	ALC.	APV.	FA. ^f
Arsenicals	Young Chickens	292.01	6338	0.25	0.11	460		460			460
Arsenicals	Market Hogs	125.71	2501	0.00	0.00	460	-1	300			0
Arsenicals	Young Turkeys	46.59	3380	0.27	0.07	300		300			300
Arsenicals	Egg Products	16.24	825	0.00	0.00	300	-1	230			0
Arsenicals	Beef Cows	12.28	989	0.00	0.00	300	-1	230			0
Arsenicals	Sows	6.89	1832	0.00	0.00	300	-1	230			0
Arsenicals	Mature Chickens	3.85	2052	0.00	0.00	300	-1	230		90	0
Arsenicals	Ducks	1.09	1095	0.18	0.54	230		230		45	0
Arsenicals	Mature Turkeys	0.58	695	0.00	0.00	230	-1	90		45	0
Arsenicals	Boars/Stags	0.44	1012	0.00	0.00	230	-1	90			0
Arsenicals	Goats	0.20	3975	0.30	0.12	90		90			90
Arsenicals	Roaster Pigs	0.08	438	0.00	0.00	90	-1	90			0
Arsenicals	Geese	0.02	NT	NT	NT	90		90		45	0
Total Samples						3,380		2,660			850

Table 4.6b
Adjusted Number of Analyses for Each Veterinary Drug Compound/Production Class Pair, "Limited Resource" Sampling
2004 FSIS NRP, Domestic Monitoring Plan

CC.	PC.	PS.	NS. ^a	VR. (%) (10 Year) ^b	VR. (%) (3 Year) ^b	UNS. ^c	Adj. ^d	IA. ^e	ALC.	APV.	FA. ^f
MGA	Heifers	28.28	264	0.00	0.00	300		300			300
Total Samples						300		300			300

CC.	PC.	PS.	NS. ^a	VR. (%) (10 Year) ^b	VR. (%) (3 Year) ^b	UNS. ^c	Adj. ^d	IA. ^e	ALC.	APV.	FA. ^f
Flunixin	Dairy Cows	8.502	880	0.57	0	300	1	460	300		300
Total Samples						300		460			300

CC.	PC.	PS.	NS. ^a	VR. (%) (10 Year) ^b	VR. (%) (3 Year) ^b	UNS. ^c	Adj. ^d	IA. ^e	ALC.	APV.	FA. ^f
Chloramphenicol	Dairy cows	NA	474	0.00	0.00	45		45	230		230
Chloramphenicol	Formula-fed veal	NA	632	0.00	0.00	90	-1	45	90		90
Chloramphenicol	Non-formula-fed veal	NA	187	0.00	0.00	90	-1	45	90		90
Chloramphenicol	Young chickens	NA	NT	NT	NT	90		230			230
Chloramphenicol	Mature chickens	NA	NT	NT	NT	230		90			90
Chloramphenicol	Young turkeys	NA	NT	NT	NT	90		90			90
Chloramphenicol	Mature turkeys	NA	NT	NT	NT	230		90			90
Total Samples						865		635			910

Table 4.6b - Continued
Adjusted Number of Analyses for Each Veterinary Drug Compound/Production Class Pair, "Limited Resource" Sampling
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CC.	PC.	PS.	NS. ^a	VR. (%) (10 Year) ^b	VR. (%) (3 Year) ^b	UNS. ^c	Adj. ^d	IA. ^e	ALC.	APV.	FA. ^f
Clenbuterol	Steers	NA	NT	NT	NA	300		300			300
Clenbuterol	Formula-fed veal	NA	NT	NT	0.00	90		90	230		230
Clenbuterol	Market hogs	NA	NT	NT	0.00	300		300			300
Total Samples						690		690			830

CC.	PC.	PS.	NS. ^a	VR. (%) (10 Year) ^b	VR. (%) (3 Year) ^b	UNS. ^c	Adj. ^d	IA. ^e	ALC.	APV.	FA. ^f
Phenylbutazone (by ELISA)	Dairy cows		NA	NT	NT	300		300			300
Phenylbutazone (by ELISA)	Beef cows		NA	NT	NT	230		230			230
Phenylbutazone (by ELISA)	Heifers		NA	NT	NT	90		90			90
Phenylbutazone (by ELISA)	Steers		NA	NT	NT	90		90			90
Phenylbutazone (by ELISA)	Heavy calves		NA	NT	NT	90		90			90
Total Samples						800		800			800

a. The total number of samples analyzed in the FSIS Monitoring Plan (01/01/1993 to 12/31/2002)

b. 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)

c. The number obtained from the last column of Table 4.5

d. For a discussion of adjustments to sampling levels (+1, +2, and -1), see the text discussion in Section 4

e. Number of samples proposed following adjustment for historical violation rate information or lack of testing information

f. Final adjustment numbers were obtained following an assessment of laboratory capacity, production volume, and 3-year violation rate data. FSIS has suspended sampling for all drugs in horses and minor species (ducks, ratites, geese, rabbits, and squab). FSIS has also suspended sampling for slaughter classes that have a violation rate of zero for the years 2000-2002.

Key:

CC. = Compound Class

PC. = Production Class

PS. = Priority Score

NS. = Number of Samples (1993-2002 analyzed by the FSIS Monitoring Plan (i.e., random sampling only)

VR. (10 Year) = Violation Rate (1993-2002) is 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).

VR. (3 Year) = Violation Rate (2000-2002) is 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).

UNS. = Unadjusted number of samples, which is obtained from last column of Table 4.7

Adj. = Adjustment based on FSIS Historical Testing Information (refer to text discussion in Section 4); +1 level, +2 levels, -1 level = There are four different sampling levels: 90, 230, 300 and 460. Sampling levels were increased or decreased (e.g., changed from 300 samples to 230 samples) based on the rules described in Section 4.

IA. = Number of samples proposed following adjustment for historical violation rate information or lack of testing information

ALC. = Adjustment for Laboratory Capacity (refer to text discussion in Section 4)

APV. = Adjustment for Production Volume (refer to text discussion in Section 4)

FA. = Final Adjustment. Finalized sample numbers, obtained following adjustments based on production volume, laboratory capacity, and 3 year violation rates

NA = Not applicable

NT = Not tested.