

**FOOD SAFETY AND  
INSPECTION SERVICE**

**2004 FSIS  
NATIONAL RESIDUE  
PROGRAM DATA**

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## **PREFACE**

The “2004 Food Safety and Inspection Service (FSIS) National Residue Program Data” publication (the ‘Red Book’) explains FSIS chemical residue sampling plans and presents National Residue Program (NRP) testing results by calendar year. [For those reading this electronically, this document has been commonly known as the “Red Book” because the covers of the printed versions are red.] In addition, the following appendices are included for the convenience of the reader: Appendix I, *U.S. Residue Limits for Veterinary Drugs, Food Additives and Unavoidable Contaminants in Meat, Poultry, and Egg Products*; Appendix II, *U.S. Residue Limits for Pesticides in Meat, Poultry, and Egg Products*; Appendix III, *Analytical Methods*; and Appendix IV, *Statistical Table* .

## **CONTACTS AND COMMENTS**

The Residue Branch (RB), Zoonotic Diseases and Residue Surveillance Division (ZDRSD), Office of Public Health Science, FSIS, USDA, coordinated this effort and is responsible for the publication of this material. Questions about FSIS NRP should be directed to the USDA, FSIS, ZDRSD, 343 Aerospace Center, 1400 Independence Avenue, SW, Washington D.C. 20250-3700, telephone (202) 690-2683, and 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 contaminant residues in meat, poultry, and egg products. Residue control is a cooperative effort. EPA and FDA have statutory authority for establishing residue tolerances\*, and FSIS, through the National Residue Program (NRP) tests animal tissues and egg products to verify that tolerance levels are not violated.

FDA, under the Federal Food Drug and Cosmetic Act, establishes tolerance levels for veterinary drugs, food additives, and unavoidable 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 or FSIS, based on recommendations that EPA published in the Federal Register. FDA and EPA also have the authority to ensure compliance with established tolerance levels.

FSIS protects consumers from chemical residues by analyzing meat, poultry, and egg products, and by preventing product adulterated with chemical residues from entering the food supply. This authority is provided under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. FSIS regulations are published in Title 9 of the Code of Federal Regulations (9 CFR), chapter III.

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

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

The NRP includes a variety of sampling plans to prevent violative residues from entering the food supply. The range of chemical compounds evaluated for inclusion in the various NRP sampling plans is comprehensive. It includes approved and unapproved veterinary drugs and pesticides known or suspected to be present in domestic food animals and egg products or in imported meat, poultry and egg products. It also includes other xenobiotic and naturally

occurring compounds that may appear in meat, poultry, and egg products 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 found and the residue is in excess of an established tolerance. When a violative chemical residue is detected in an animal presented for slaughter or in an egg product, FSIS condemns the adulterated product. If the product has been distributed into commerce, it is subject to a voluntary recall. FSIS notifies FDA of the violation and assists in obtaining the names of producers and, in the case of food animal products, other parties involved in offering the animals for sale. FDA and cooperating state agencies will follow-up 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 drug, pesticide, or other chemical residue violation in a 12-month period. The list provides information helpful to processors and producers working to avoid residue contamination and serves as a deterrent for violators, while enabling 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.

\*Tolerance levels established by FDA are published in 21 CFR.

Tolerance levels established by EPA are published in Title 40 CFR.

# **COMPONENTS OF THE NATIONAL RESIDUE PROGRAM**

The National Residue Program sampling plans address chemical and veterinary drug residues in domestic and imported food animals and egg products. All products, whether domestic or imported, must fall within tolerance levels set by FDA and EPA.

## **DOMESTIC SAMPLING PLAN**

The domestic sampling plan ensures that egg products and products from food producing animals in the United States comply with residue regulations. Sampling of meat, poultry and egg products also verifies that HACCP systems address residue control.

There are four components of the domestic residue sampling plan: Monitoring, Enforcement, Surveillance, and Exploratory sampling (the nomenclature and definitions of these components will be changed for the 2005 National Residue Program). FSIS enters sampling results into the Microbiological and Residue Computer Information System (MARCIS). Data in MARCIS are used to develop future residue testing programs; create educational information for food producers; and provide agencies with information needed to take appropriate action on sample results.

### **Monitoring**

Monitoring samples provide information on the prevalence of chemical residues in domestic food animals and egg products. FSIS schedules inspectors to collect tissue samples from randomly selected food animals that have passed ante- and post-mortem inspections, or from egg products that have passed inspection. Products are not retained pending laboratory analysis. If results indicate a potential public health concern, products may be subject to recall.

Data obtained by monitoring sampling are used to evaluate residue trends. For example, if data indicate a compound is being abused, a targeted sampling program may be instituted.

### **Enforcement**

Enforcement sampling is conducted when an inspector identifies a specific animal as suspect for residue violations. An inspector may deem an animal suspect because of historical information on a production class, or based on ante- and post-mortem inspections.

FSIS inspectors can screen samples for the presence of antibiotics or sulfonamides using two in-plant tests:

- The Swab Test on Premises (STOP) is approved for use in all production classes to detect the presence of antibiotic and sulfonamide drug residues in kidney tissues; and
- The Fast Antimicrobial Screen Test (FAST) is approved for use in bovine to detect the presence of antibiotic and sulfonamide drug residues in kidney tissues.

When an in-plant screen test detects a positive sample, a confirmation test is conducted at an FSIS laboratory. If an in-plant test is not available, or if the presence of a chemical residue that cannot be detected by STOP or FAST is suspected, the appropriate tissue samples are sent directly to the FSIS laboratory. Carcasses sampled for enforcement testing are retained pending laboratory results. If a violative level is found, the carcass is deemed adulterated and is condemned.

## **Surveillance**

Surveillance sampling is scheduled based on a regulation or agency policy implemented to address residue concerns in a specific population. Data collected by surveillance sampling, measures the extent of a chemical residue problem in a suspect population or product. Data are periodically evaluated to determine whether interventions have led to a reduction in the occurrence of residues. Depending on the weight of evidence that led to testing, sampled carcasses may or may not be held pending laboratory results.

## **Exploratory**

Exploratory sampling is for information gathering. Exploratory sampling studies the occurrence of residues for which no tolerance has been established; evaluates new methods and approaches for monitoring sampling; and provides information to supplement the monitoring program.

## **IMPORT SAMPLING PLAN**

Imported meat, poultry, and egg products are sampled at port of entry into the United States to detect chemical residues. Port of Entry Reinspection is a monitoring program conducted to verify the equivalence of inspection systems in exporting countries. The chemical residue sampling program is one of several “types of inspection” (TOI) conducted during FSIS reinspection of imported products. All imported products are subject to reinspection and one or more TOIs are conducted on every lot of product before it enters the United States. The import sampling plan comprises all substance and species combinations included in the domestic sampling plan.

There are three levels of residue reinspection:

- Normal sampling, which is defined as random sampling from a lot;
- Increased sampling, which is defined as above the normal sampling as the result of an agency management decision; and
- Intensified 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 choose to retain the lot pending the laboratory results. For intensified sampling, the lot must be held pending laboratory results. The data obtained from laboratory analysis are entered into the Automated Import Information System (AIIS), an FSIS data base that is designed to generate reinspection assignments, receive and store results, and compiles histories for the performance of foreign establishments certified by the inspection system in the exporting country.

## ESTIMATED LIVESTOCK, POULTRY, AND EGG PRODUCT CONSUMPTION DATA

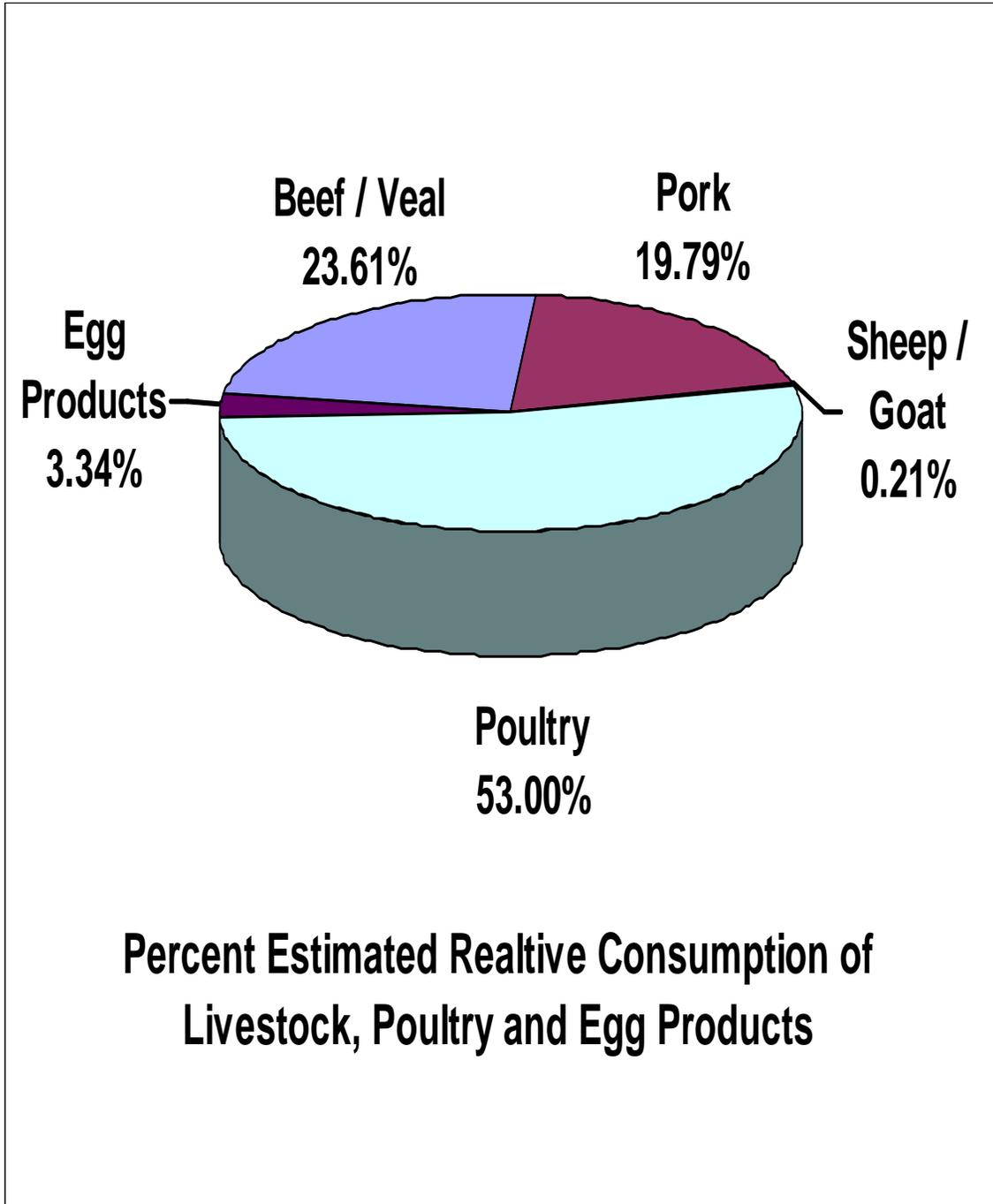
Table 1 and Chart 1 present *2004 Consumption Data*, including the number of head slaughtered or eggs processed, pounds per animal (dressed weight), total pounds (dressed weight), and the percent estimated relative consumption of domestic and exported product for each production class.

**Table 1**  
**2004 Consumption Data**

Production Class	Number of Head Slaughtered	Pounds per Animal (dressed weight)	Total Pounds (dressed weight)	Percent Estimated Relative Consumption
Bulls	564,374	893	503,985,982	0.493
Beef cows	2,714,939	607	1,647,968,270	1.611
Dairy cows	2,371,693	607	1,439,617,354	1.407
Heifers	10,278,227	733	7,533,940,391	7.366
Steers	16,055,167	801	12,860,188,767	12.573
Bob veal	268,863	75	20,164,725	0.020
Formula-fed veal	488,794	245	119,754,530	0.117
Non-formula-fed veal	30,412	350	10,644,200	0.010
Heavy calves	42,432	400	16,972,800	0.017
<b>SUBTOTAL, CATTLE</b>	<b>32,814,901</b>		<b>24,153,237,019</b>	<b>23.614</b>
Market hogs	97,871,338	195	19,084,910,910	18.659
Roaster pigs	550,243	70	38,517,010	0.038
Boars/Stags	311,394	228	70,997,832	0.069
Sows	3,330,754	314	1,045,856,756	1.023
<b>SUBTOTAL, SWINE</b>	<b>102,063,729</b>		<b>20,240,282,508</b>	<b>19.789</b>
Sheep	2,516,611	69	173,646,159	0.170
Lambs	143,981	66	9,502,746	0.009
Goats	558,703	50	27,935,150	0.027
<b>SUBTOTAL, OVINE</b>	<b>3,219,295</b>		<b>211,084,055</b>	<b>0.206</b>
Horses	65,200	500	32,600,000	0.032
Bison	26,213	610	15,989,930	0.016
<b>TOTAL, ALL LIVESTOCK</b>	<b>138,189,338</b>		<b>44,653,193,512</b>	<b>43.657</b>
Young chickens	8,73,3807,919	Not reported	46,330,185,120	45.296
Mature chickens	142,990,154	Not reported	816,717,608	0.798
Young turkeys	249,359,852	Not reported	6,810,785,188	6.659
Mature turkeys	2,829,373	Not reported	75,276,157	0.074
Ducks	26,003,644	Not reported	174,223,959	0.170
Geese	268,297	Not reported	3,633,664	0.004
Other fowl (includes ratites)	1,381,173	Not reported	2,477,071	0.002
<b>SUBTOTAL, POULTRY</b>	<b>9,156,640,412</b>		<b>54,213,298,767</b>	<b>53.004</b>
Rabbits	340,096	Not reported	1,716,220	0.002
Egg products	Not applicable	Not applicable	3,413,857,390*	3.338
<b>GRAND TOTAL, ALL PRODUCTION CLASSES</b>			<b>102,282,065,889</b>	<b>100</b>

\* For Fiscal Year 2004

**Chart 1**  
**2004 Consumption Data**



## **DEFINITIONS OF FSIS PRODUCTION CLASSES**

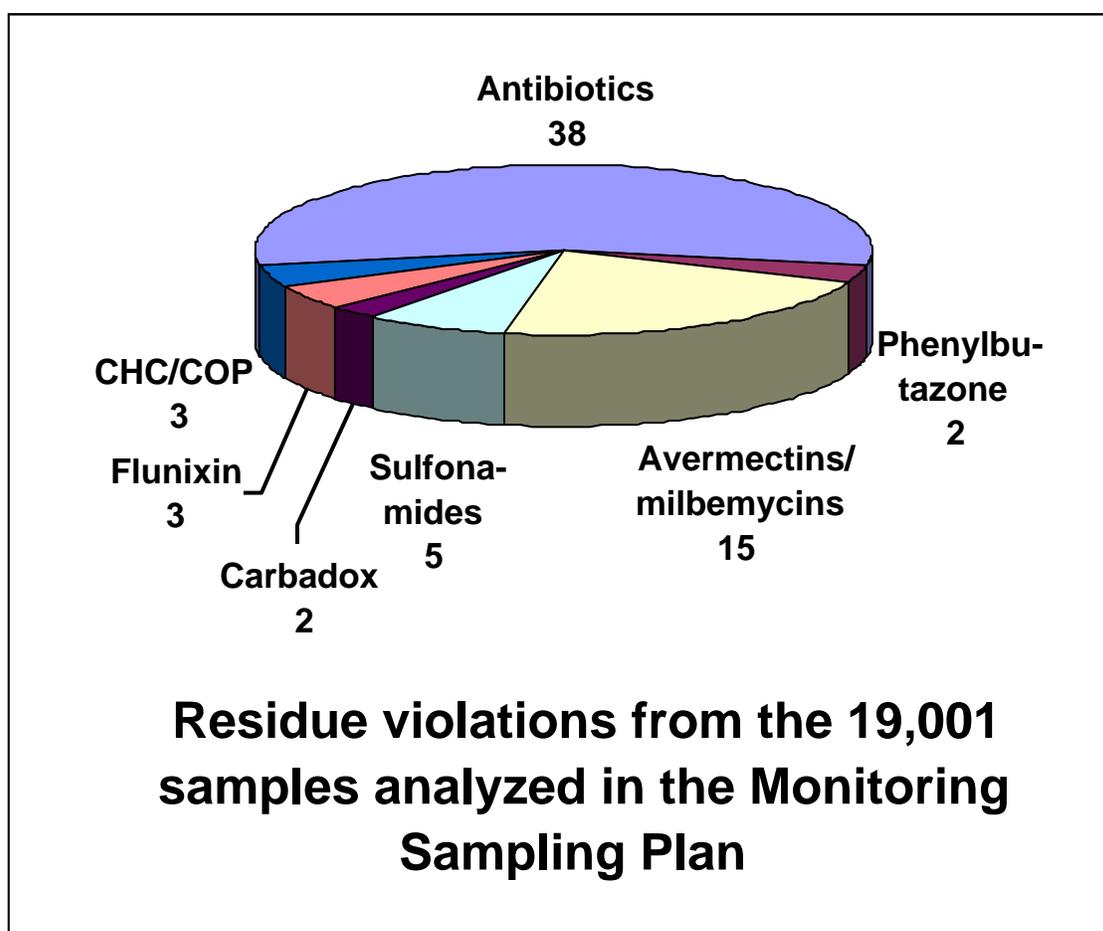
- Bulls are mature, uncastrated male cattle.
- Beef cows are mature female cattle bred for muscle development, ordinarily having given birth to one or more calves.
- Dairy cows are mature female cattle bred for milk production, ordinarily having given birth to one or more calves.
- Heifers are young, female cattle that have not yet given birth to a calf.
- Steers are male cattle castrated before sexual maturity.
- 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 animals castrated after they have reached sexual maturity.
- Sows are mature female swine ordinarily having given birth to one or more litters.
- Sheep are mature animals of both sexes.
- Lambs are generally defined as sheep younger than 14 months and having a break joint in at least one leg.
- Goats are animals of both sexes and any age.
- Horses are animals of both sexes and any age.
- Other livestock include bison, deer, elk, etc.
- Young chickens include: broilers/fryers birds of both sexes that are usually less than 10 weeks of age; roasters, birds of both sexes usually less than 12 weeks of age; and capons, surgically castrated male birds usually less than 8 months of age.
- Mature chickens are adult female birds usually more than 10 months of age.
- Young turkeys include fryer/roaster birds that are of both sexes and usually less than 12 weeks of age, and include turkeys that are birds of both sexes usually less than 6 months of age.
- Mature turkeys are birds of both sexes and usually more than 15 months of age.
- Ducks are birds of both sexes and any age.
- Geese are birds of both sexes 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 of both sexes and any age.
- Egg products are yolks, whites, or whole eggs after breaking and can be processed as dried, frozen, or liquid.

## SUMMARY OF DOMESTIC DATA

### MONITORING

Fifty nine (59) chemical residues from 13 compound classes of veterinary drugs and pesticides were analyzed. Of the 19,001 samples analyzed in 2004, 68 chemical residue violations were found. There were 38 antibiotics, 5 sulfonamides, 15 avermectins/milbemycins, 3 chlorinated hydrocarbons /chlorinated organophosphates, 2 carbadox, 2 phenylbutazone, and 3 flunixin residue violations (see Chart 2). There were no residue violations in the testing for arsenic, chloramphenicol, florfenicol, *beta*-agonists, and melengestrol acetate.

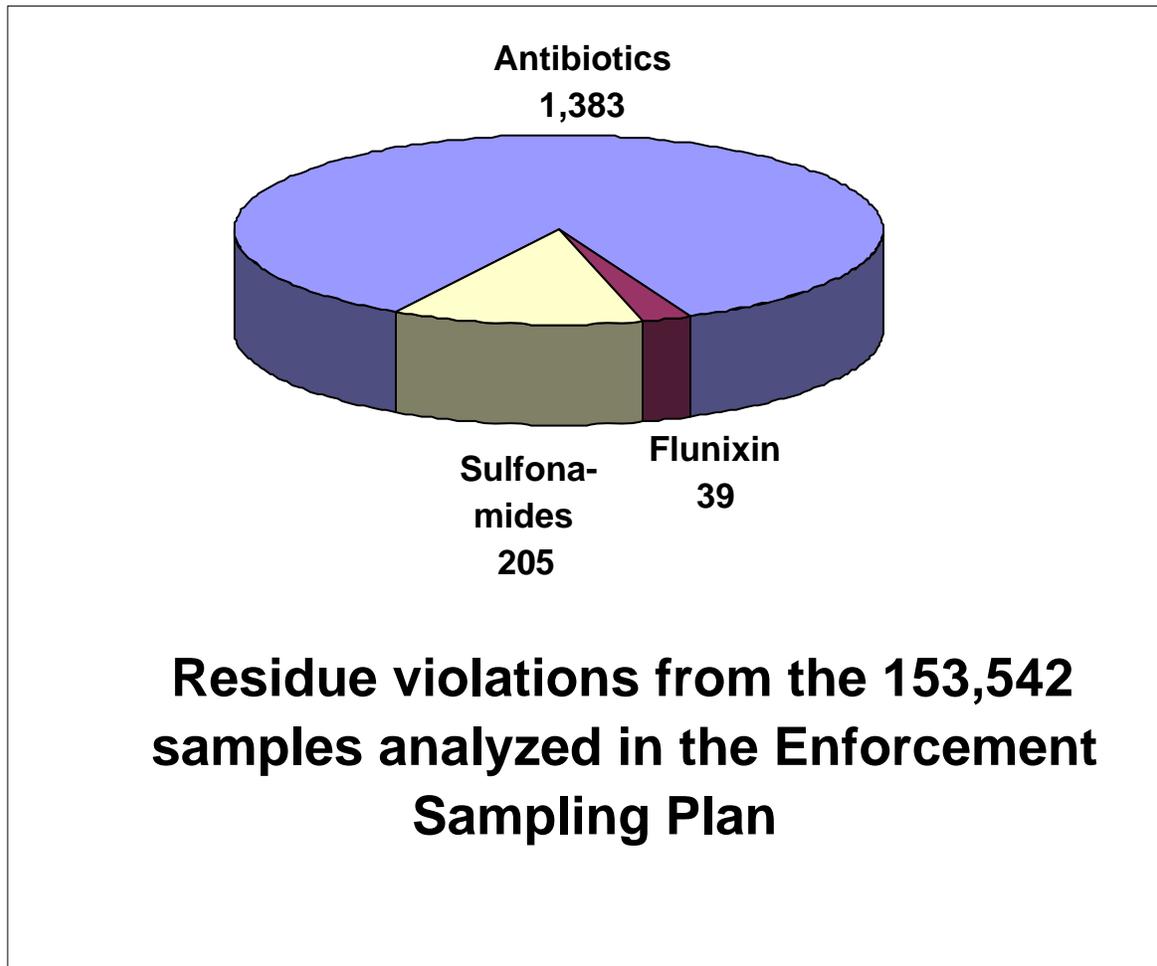
Chart 2



## ENFORCEMENT

Seventy three (73) chemical residues from 8 compound classes of veterinary drugs and pesticides were analyzed. Of the 153,542 samples analyzed in 2004, 1,627 residue violations were found. There were 1,383 antibiotics, 39 flunixin, and 205 sulfonamides residue violations (see Chart 3). No violations were found in the testing for arsenicals, chlorinated hydrocarbons, chlorinated organophosphates, phenylbutazone, ractopamine, diethylstilbestrol, and zeranol.

Chart 3



## **SURVEILLANCE**

**Market Hogs** – The Sulfa-On-Site (SOS) test was used to screen 141 market hogs for sulfonamides. There was 1 sulfamethazine residue violation.

**Bob veal** – The Fast Antimicrobial Screen Test (FAST) was used to screen 46,775 bob veal for antibiotics and sulfonamides. The total bob veal tested included both surveillance sampling (testing of a suspect population) and enforcement sampling (testing of suspect animals). Of the animals tested, 821 FSIS laboratory confirmed violations were found in 744 animals. There were 1 chlortetracycline, 48 penicillin, 5 tetracycline, 1 tylosin, 655 neomycin, 15 oxytetracycline, 31 gentamicin, 3 tilmicosin, 28 sulfadimethoxine, 26 sulfamethazine, 7 sulfamethoxazole, and 1 sulfathiazole residue violations.

**Show animals** - Sixty (60) show animals were tested. No violations were found in the 44 animals tested for *beta*-agonists. Eight (8) animals were tested for ractopamine (2 lambs and 6 market hogs) and no violations were found. Seven animals were tested for antibiotics and sulfonamides (2 lambs and 5 market hogs) and no violations were found. One (1) steer was tested for flunixin and no violation was found.

## **EXPLORATORY**

**Market Hogs** – Antibiotic and sulfonamide testing was conducted on 675 market hogs. There were 5 sulfamethazine and 1 penicillin residue violations.

**Horses** – Seventeen (17) horses were sampled and tested for different analytes, including: antibiotics, avermectins, CHCs, COPs, phenylbutazone, flunixin, and sulfonamides. There were 2 penicillin and 1 phenylbutazone residue violations.

**FAST-Flunixin** – A total of 330 bovine samples, including bulls, beef cows, heifers, dairy cows, and bob veal, were tested for antibiotics, sulfonamides and flunixin. There were 5 gentamicin, 1 neomycin, 13 penicillin, 1 tilmicosin, 7 sulfamethoxine, and 14 flunixin residue violations.

**Non-Steroidal Anti-inflammatory Drugs (NSAID) Compounds** – One hundred and forty four (144) dairy cows were tested for NSAIDs (dipyrrone, flunixin, and phenylbutazone). There were 7 flunixin residue violations.

**Lead and Cadmium** – Lead and cadmium testing was conducted on 507 dairy cows, 122 boars/stags, and 600 chickens. The results of the analyses are found on pages 132 to 149.

# COMPARISON OF NUMBER OF TESTS PERFORMED UNDER MONITORING, ENFORCEMENT, SURVEILLANCE, AND EXPLORATORY

## COMPARISON BY PRODUCTION CLASS

Table 2, *Comparison by Production Class*, presents the number of animals tested under monitoring, enforcement, surveillance, and exploratory sampling for each production class.

**Table 2**  
**Comparison by Production Class**  
**2004 Domestic Sampling Plan**

<b>Production Class</b>	<b>Number of Tests under Monitoring</b>	<b>Number of Tests under Enforcement</b>	<b>Number of Tests under Surveillance</b>	<b>Number of Tests under Exploratory</b>
Horses		117		69
Bovine				2
Bulls	857	682		1
Steers	1,101	5,241	14	2
Beef cows	1,407	6,656		6
Heifers	1,240	2,781	2	1
Dairy cows	1,757	85,067		1,473
Bob veal	741	46,776 <sup>1</sup>		1
Formula-fed veal	950	692		
Non-formula-fed veal	474	49		
Heavy calves	728	573		
Calves				
Mature sheep	229	16		
Lambs	697	267	12	
Goats	522	31		
Porcine				

<sup>1</sup> The total analyzed includes both surveillance testing (testing of a suspect population) and enforcement testing (testing of suspect animals)

**Table 2 – continued**  
**Comparison by Production Class**  
**2004 Domestic Sampling Plan**

<b>Production Class</b>	<b>Number of Tests under Monitoring</b>	<b>Number of Tests under Enforcement</b>	<b>Number of Tests under Surveillance</b>	<b>Number of Tests under Exploratory</b>
Market hogs	2,577	3,490	173	1,349
Boars/Stags	816	45		244
Sows	504	1,046		
Roaster pigs	188	2		
Bison				
Chickens		9		
Young chickens	1,677			
Mature chickens	486			1,200
Turkeys				
Young turkeys	887			
Mature turkeys	275			
Ducks				
Geese				
Squab				
Ratites				
Rabbits				
Egg products	888	2		
Other				
<b>Total</b>	<b>19,001</b>	<b>153,542</b>	<b>201</b>	<b>4,348</b>

## COMPARISON BY COMPOUND CLASS

Table 3, *Comparison by Compound Class*, presents the number of tests performed under monitoring, enforcement, surveillance, and exploratory sampling for each compound class.

**Table 3**  
**Comparison by Compound Class**  
**2004 Domestic Sampling Plan**

Compound Class	Number of Tests under Monitoring	Number of Tests under Enforcement	Number of Tests under Surveillance	Number of Tests under Exploratory
Antibiotics	4,270			689
Antibiotics and Sulfonamides		51	7	
Antibiotics, Sulfonamides, and Non-steroidal anti-inflammatory drugs		153,406		330
Sulfonamides	3,981	5	141	692
Arsenic	1,293	5		
Cadmium				1,228
Lead				1,228
CHCs/COPs/PCBs/Phenylbutazone	5,272	1		15
Phenylbutazone (with ELISA Method)	702	1		48
Dipyrrone				49
Avermectins/Milbemycins	931			17
Chloramphenicol	1,024			
Melengestrol acetate	238			
<i>Beta</i> -agonists	776		44	
Carbadox	188			
Ractopamine		2	8	
Flunixin	213	1	1	52

**Table 3 - *continued***  
**Comparison by Compound Class**  
**2004 Domestic Sampling Plan**

<b>Compound Class</b>	<b>Number of Tests under Monitoring</b>	<b>Number of Tests under Enforcement</b>	<b>Number of Tests under Surveillance</b>	<b>Number of Tests under Exploratory</b>
Florfenicol	113			
DES/Zeranol		70		
<b>Total</b>	<b>19,001</b>	<b>153,542</b>	<b>201</b>	<b>4,348</b>

## **SUMMARY OF IMPORT DATA**

The United States imported approximately 4,214,561,463 pounds of fresh and processed meat, poultry, and egg products. These products were imported from 24 of the 28 countries eligible for exportation to the United States. The import testing program included analysis of 50 chemical residues from 9 compound classes of veterinary drugs and pesticides. No violations were found in the 3,413 reported results.

### **NORMAL**

Nine (9) compound classes of veterinary drugs and pesticides were tested. From these nine compound classes approximately 50 residues were analyzed. No violations were found in the 3,380 samples analyzed.

### **INCREASED**

Three (3) compound classes of veterinary drugs and pesticides were tested. From these three compound classes approximately 40 residues were analyzed. No violations were found in the six samples analyzed.

### **INTENSIFIED**

Seven (7) compound classes of veterinary drugs and pesticides were tested. From these seven compound classes approximately 50 residues were analyzed. No violations were found in the 27 samples analyzed.