FOOD SAFETY AND INSPECTION SERVICE

2005 FSIS NATIONAL RESIDUE PROGRAM DATA

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PREFACE

The "2005 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, *Analytical Methods;* Appendix II, *Statistical Table;* and Appendix III, *Summary of Scheduled Sampling Data from 2002 to 2004.*

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 Service's, Food and Drug Administration (FDA), to control veterinary drug, pesticide, and environmental contaminant residues in meat, poultry, and egg products. Residue control is a cooperative effort. EPA* and FDA** have statutory authority for establishing residue tolerances or action levels, and FSIS, through the National Residue Program (NRP) tests animal tissues and egg products to verify that tolerances or action levels are not violated.

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

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

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

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

* Tolerance levels established by EPA are published in 40 CFR.
** Tolerance levels established by FDA are published in Title 21 CFR.

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

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

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

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

SAMPLING PLANS OF THE NATIONAL RESIDUE PROGRAM

The National Residue Program (NRP) consists of two primary sampling plans: domestic and import. These plans are further divided to facilitate the management of chemical residues such as veterinary drugs, pesticides, and environmental contaminants in food animals and egg products. The domestic sampling plan includes scheduled sampling and inspector generated sampling. The import reinspection sampling plan is separated into normal sampling, increased sampling, and intensified sampling.

DOMESTIC SAMPLING PLAN

Scheduled Sampling

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

Exposure Assessments

Exposure Assessments are used:

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

Exploratory Assessments

Exploratory Assessments are designed by Residue Branch:

- To reinvestigate animal populations from an ongoing or previous exposure assessments if the violation rate is confirmed at 1% or greater;
- To investigate animal populations when the compounds in question have no established tolerances; and
- To respond to intelligence reports from the field.

All products are FSIS retained and subject to condemnation.

Inspector Generated Sampling

Inspector generated sampling is conducted by in-plant Public Health Veterinarians (PHVs) using FSIS Form 10,000-2. This occurs when the in-plant PHV suspects that an animal may have violative level of chemical residues. Currently, inspector generated sampling targets *individual suspect animals* and *suspect populations of animals*. When an inspector generated sample is collected, the carcass is held pending the results of laboratory testing and if a carcass is found to contain violative levels of residues the carcass is condemned.

Sampling for individual suspect animals

The in-plant inspector selects a carcass for sampling based on professional judgment and public health criteria developed by FSIS. These criteria include but are not limited to the following: animal disease signs and symptoms; producer history; or results from random scheduled sampling. Some samples are screened in the plant by the Inspector In Charge (IIC) and verified when necessary by a PHV. Other samples are sent directly to the laboratory for analysis. For example, if the IIC suspects the misuse of either an antibiotic or sulfonamide residue in an animal, then he or she can perform one of the following in-plant screening tests: Fast Antimicrobial Screening Test (FAST) or Swab Test On Premises (STOP). If the result of

a screening test is positive, then the sample is sent to an FSIS laboratory for confirmation.

Sampling for suspect animal populations

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

IMPORT REINSPECTION SAMPLING PLAN

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

- Normal sampling, 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. The lot is subject to recall if it is not retained and is found to contain violative levels of residue. For intensified sampling, the lot must be retained pending laboratory results. The data obtained from laboratory analysis are entered into the Automated Import Information System (AIIS), a FSIS data base that is designed to generate reinspection assignments, receive and store results, and compile histories for the performance of foreign establishments certified by the inspection system in the exporting country.

ESTIMATED LIVESTOCK, POULTRY, AND EGG PRODUCT CONSUMPTION DATA

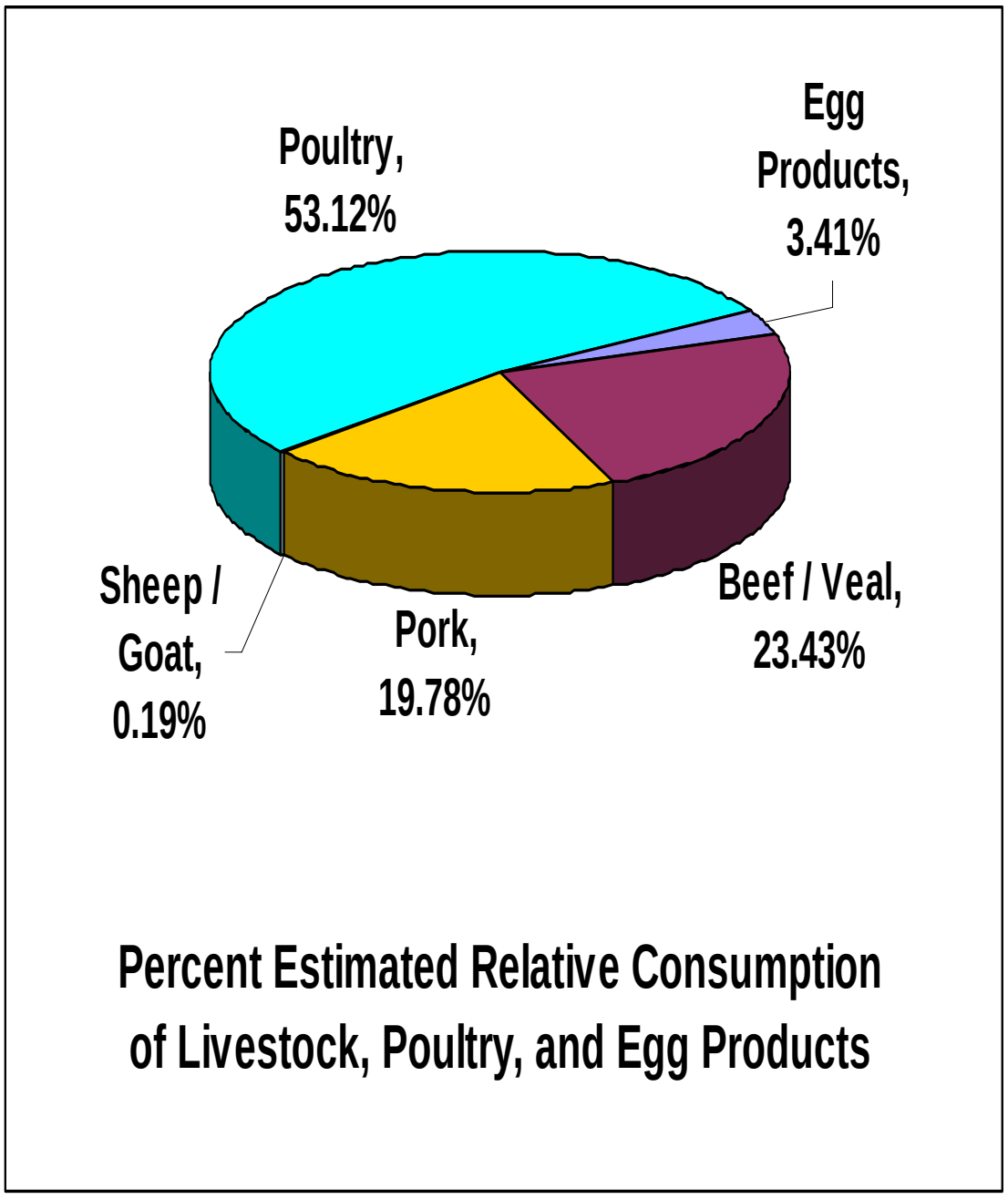
Table 1 and Chart 1 present, *2005 Consumption Data*, including the number of head slaughtered or pounds of eggs processed, pounds per animal (dressed weight), total pounds (dressed weight), and the percent estimated relative consumption of domestic and exported product for each production class.

Table 1
2005 Consumption Data

Production Class	Number of Head Slaughtered [A]	Pounds per Animal (dressed weight) [B]	Total Pounds (dressed weight)	Percent Estimated Relative Consumption
Bulls	518,294	901	466,982,894	0.444
Beef cows	2,531,618	622	1,574,666,396	1.498
Dairy cows	2,262,651	622	1,407,368,922	1.339
Heifers	9,772,241	748	7,309,636,268	6.955
Steers	16,845,446	814	13,712,193,044	13.047
Bob veal	196,868	75	14,765,100	0.014
Formula-fed veal	492,645	245	120,698,025	0.115
Non-formula-fed veal	7,245	350	2,535,750	0.002
Heavy calves	29,822	400	11,928,800	0.011
SUBTOTAL, CATTLE	**32,656,830**		**24,620,775,199**	**23.427**
Market hogs	99,963,248	197	19,692,759,856	18.738
Roaster pigs	691,901	70	48,433,070	0.046
Boars/Stags	343,849	213	73,239,837	0.070
Sows	3,152,299	310	977,212,690	0.930
SUBTOTAL, SWINE	**104,151,297**		**20,791,645,453**	**19.783**
Sheep	127,079	69	8,768,451	0.008
Lambs	2,418,268	69	166,860,492	0.159
Goats	541,109	50	27,055,450	0.026
SUBTOTAL, OVINE	**3,086,456**		**202,684,393**	**0.193**
Horses	93,768	500	46,884,000	0.045
Bison	35,763	610	21,815,430	0.021
TOTAL, ALL LIVESTOCK	**140,024,114**		**45,683,804,475**	**43.469**
Young chickens	8,993,871,716	Not reported	47,847,682,669	45.528
Mature chickens	147,672,050	Not reported	836,851,344	0.796
Young turkeys	248,086,640	Not reported	6,881,881,088	6.548
Mature turkeys	2,469,651	Not reported	63,895,888	0.061
Ducks	27,974,170	Not reported	188,873,897	0.180
Geese	252,462	Not reported	3,526,215	0.003
Other fowl (includes squab)	1,299,089	Not reported	2,457,011	0.002
SUBTOTAL, POULTRY	**9,421,625,778**		**55,825,168,112**	**53.118**
Rabbits	384,863	Not reported	1,972,516	0.002
Egg products	Not applicable	Not applicable	**3,584,984,108** [C]	3.411
GRAND TOTAL, ALL PRODUCTION CLASSES			**105,095,929,211**	**100**

(A) Number of heads is obtained from the Animal Disposition Reporting System (ADRS). (B) Average dressed weights are obtained from the publication: "Livestock Slaughter", National Agricultural Statistics Service (NASS), March 2005. In instances when the average weight is not available, an average weight based on previous calendar years data was imputed. (C) For Fiscal Year 2005

Chart 1
2005 Consumption Data*



*FSIS employs techniques and principles from the field of risk assessment to determine the relative public health concerns represented by the results from the scheduled sampling plan-exposure assessments. The information on the residue levels detected in the scheduled sampling plan is combined with consumption data to estimate exposure.

Exposure = Consumption Data x Residue Levels

DEFINITIONS OF FSIS PRODUCTION CLASSES

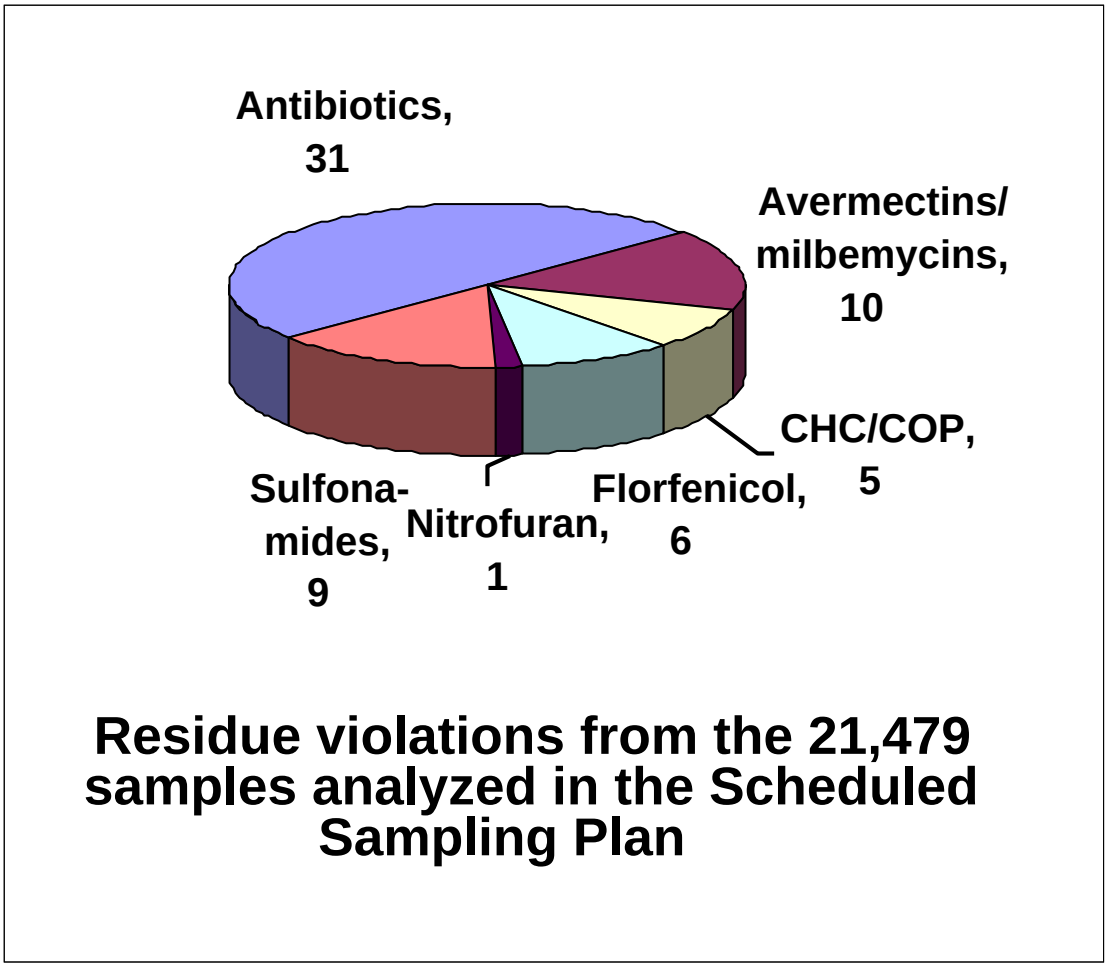
- Bulls are mature, uncastrated male cattle.
- Beef cows are mature female cattle bred for muscle development, ordinarily having given birth to one or more calves.
- Dairy cows are mature female cattle bred for milk production, ordinarily having given birth to one or more calves.
- Heifers are young, 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 are processed as dried, frozen, or liquid.
- Roaster pigs are animals of both sexes and any age that are marketed with the carcass unsplited and with the head on.

SUMMARY OF DOMESTIC DATA

SCHEDULED SAMPLING – Exposure Assessments

Seventeen (17) compound classes of veterinary drugs and pesticides comprised of approximately 80 compounds were analyzed. Of the 21,479 samples analyzed, 62 chemical residue violations were found. The number of residue violations for each compound or compound class is presented in Chart 2. The residue violations consisted of 31 antibiotics, ten (10) avermectins/milbemycins, five (5) chlorinated hydrocarbons/chlorinated organophosphates, six (6) florfenicol, one (1) nitrofuran, and nine (9) sulfonamides. There were no residue violations in the testing of arsenic, *beta*-agonists, carbadox, chloramphenicol, melengestrol acetate, nitroimidazoles, phenylbutazone, ractopamine, thyreostats, trenbolone, and zeranol.

Chart 2
Residue Violations
2005 Scheduled Sampling Plan



SCHEDULED SAMPLING - Exploratory Assessments

Lead and Cadmium – Lead and cadmium testing was conducted on 238 steers. The results of the analyses are found on pages 124 to 129.

Horses – Ten (10) 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.

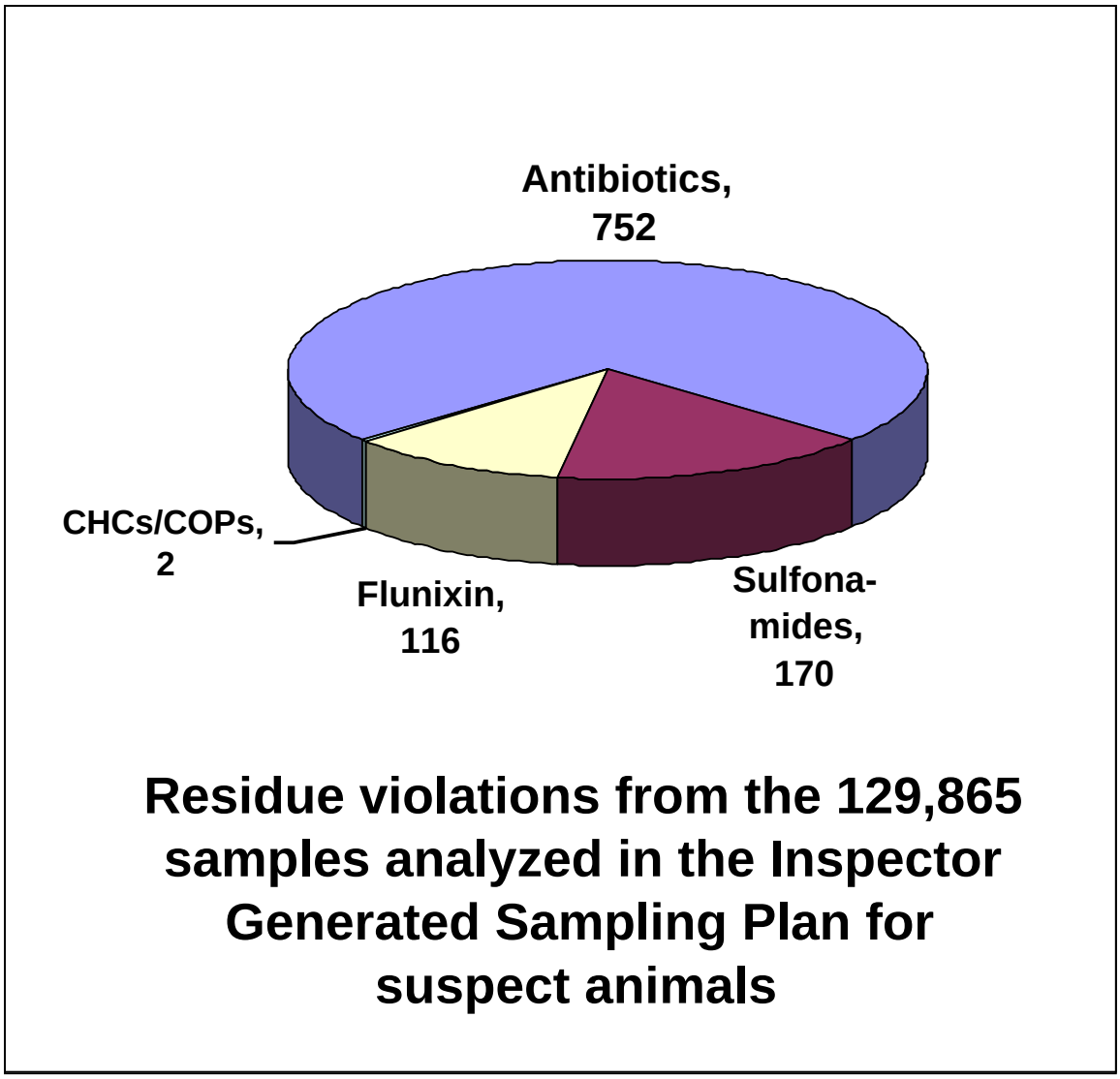
Market Hogs – Antibiotic and sulfonamide testing was conducted on 318 market hogs. There were 2 sulfamethazine residue violations.

Non-Steroidal Anti-inflammatory Drugs (NSAID) Compounds – One hundred and fifty nine (159) dairy cows and two (2) market hogs were tested for NSAIDs (dipyrone, flunixin, and phenylbutazone). There were 15 flunixin and 2 phenylbutazone residue violations in dairy cows.

INSPECTOR GENERATED SAMPLING - Sampling for individual suspect animals

Twelve compound classes (12) of veterinary drugs and pesticides comprised of approximately 75 compounds were analyzed. Of the 129,865 samples analyzed, 1,040 chemical violations were found. The number of residue violations for each compound or compound class is presented in Chart 3. The residue violations consisted of 752 antibiotics, two (2) chlorinated hydrocarbons/chlorinated organophosphates, 116 flunixin, and 170 sulfonamides. No violations were found in the testing for avermectins/milbemycins, *beta*-agonists, carbadox, chloramphenicol, florfenicol, and non-steroidal anti-inflammatory drugs.

Chart 3
Residue Violations
2005 Inspector Generated Sampling Plan



INSPECTOR GENERATED SAMPLING- Sampling for suspect animal populations

Bob veal – The Fast Antimicrobial Screen Test (FAST) was used to screen 16,643 bob veal for antibiotics and sulfonamides. The bob veal tested with FAST included two types of sampling: suspect population (by FSIS directive) and suspect animals [see page roman numeral ten (x), Inspector Generated Sampling]. Of the animals tested, 155 FSIS laboratory confirmed violations were found in 131 animals. There were one (1) chlortetracycline, one (1) dihydrostreptomycin, seven (7) gentamicin, 105 neomycin, eight (8) oxytetracycline, 16 penicillin, one (1) tetracycline, one (1) spectinomycin, five (5) sulfadimethoxine,two (2) sulfamethazine, seven (7) sulfamethoxazole, and one (1) sulfathiazole residue violations.

Show animals – Forty five (45) show animals were tested. Forty (40) animals were tested for ractopamine [12 steers, two (2) heifers, 13 market hogs, two (2) goats, and 11 lambs] and no violations were found. Five animals were tested for antibiotics and sulfonamides [two (2) lambs, one (1) heifer, and two (2) market hogs] and no violations were found.

NUMBER OF SAMPLES TESTED BY PRODUCTION AND COMPOUND CLASSES FOR SCHEDULED AND INSPECTOR GENERATED SAMPLING PLANS

NUMBER OF SAMPLES TESTED BY PRODUCTION CLASS

Table 2, *Number of Samples Tested by Production Class*, presents the number of animals tested under scheduled and inspector generated sampling plans for each production class.

Table 2
Number of Samples Tested by Production Class
2005 Domestic Sampling Plan

Production Class	Number of samples tested under Scheduled - exposure assessment	Number of Samples tested under Scheduled – exploratory assessment	Number of samples tested under Inspector Generated – suspect animals	Number of samples tested under Inspector Generated – suspect populations
Beef cows	986	--	6,031	--
Boars/Stags	361	--	41	--
Bob veal[1]	748	--	16,645	16,643
Bovine	--	--	16	--
Bulls	924	72	653	--
Calves	--	--	--	--
Chickens	--	--	1	--
Dairy cows	1,461	159	94,983	--
Ducks	--	--	--	--
Egg products	392	--	--	--
Formula-fed veal	3,082	--	475	--
Geese	--	--	--	--
Goats	379	--	11	2
Heavy calves	810	--	373	--

[1] The total analyzed includes both testing of a suspect population and testing of suspect animals

Table 2 – *continued*
Number of Samples Tested by Production Class
2005 Domestic Sampling Plan

Production Class	Number of samples tested under Scheduled - exposure assessment	Number of samples tested under Scheduled – exploratory assessment	Number of samples tested under Inspector Generated – suspect animals	Number of samples tested under Inspector Generated – suspect populations
Heifers	1,970	--	2,175	3
Horses	230	34	117	--
Lambs	549	--	216	13
Market hogs	1,254	631	1,999	15
Mature chickens	163	--	--	--
Mature sheep	167	--	121	--
Mature turkeys	257	--	--	--
Non-formula-fed veal	700	--	54	--
Ostrich	--	--	10	--
Other	--	--	846	--
Porcine	--	--	1	--
Roaster pigs	426	--	16	--
Sows	444	--	481	--
Steers	4,927	340	4,594	12
Young chickens	637	--	--	--
Young turkeys	612	--	6	--
Total	**21,479**	**1,236**	**129,865**	**16,688**

NUMBER OF SAMPLES TESTED BY COMPOUND CLASS

Table 3, *Number of Samples Tested by Compound Class,* presents the number of tests performed under scheduled and inspector generated sampling plans sampling for each compound class.

Table 3
Number of Samples Tested by Compound Class
2005 Domestic Sampling Plan

Compound Class	Number of Tests under Scheduled - exposure assessment	Number of Tests under Scheduled – exploratory assessment	Number of Tests under Inspector Generated – suspect animals	Number of Tests under Inspector Generated – suspect populations
Antibiotics	2,370	319	--	--
Antibiotics and Sulfonamides	--	--	83	16,648
Antibiotics, Sulfonamides, and Flunixin◊	--	--	129,730	--
Arsenic	25	--	--	--
Avermectins/Milbemycins	2,098	7	2	--
Berenil		72		
Beta-agonists	1,020	--	--	40
Cadmium	--	170	--	--
Carbadox	243	--	5	--
CHCs/COPs/PCBs/Phenylbutazone	5,272	9	34	--
Chloramphenicol	893	--	1	--
Florfenicol	355	--	1	--
Lead	--	170	--	--
Melengestrol acetate	350	--	--	--

◊ In the Inspector Generated Sampling plan, samples that are found to be FAST positive in the plant are further analyzed for flunixin (a non-steroidal anti-inflammatory compound) in the laboratory.

Table 3 - *continued*
Number of Samples Tested by Compound Class
2005 Domestic Sampling Plan

Compound Class	Number of Tests under Scheduled - exposure assessment	Number of Tests under Scheduled – exploratory assessment	Number of Tests under Inspector Generated – suspect animals	Number of Tests under Inspector Generated – suspect populations
Nitrofurans	1,052	--	--	--
Nitroimidazoles	251	--	--	--
NSAID (dipyrone, flunixin, phenylbutazone)		161		
Phenylbutazone (with ELISA method)	874	--	--	--
Ractopamine	423	--	--	--
Ractopamine (using eyeballs)	8		--	--
Sulfonamides	3,425	328	9	--
Thyreostats	638	--	--	--
Trenbelone	1,076	--	--	--
Zeranol	1,106	--	--	--
Total	**21,479**	**1,236**	**129,865**	**16,688**

SUMMARY OF IMPORT DATA

The United States imported approximately 4,246,457,697 pounds of fresh and processed meat, poultry, and egg products. These products were imported from 18 of the 33 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 5,372 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 5,321 samples analyzed.

INCREASED

Six (6) compound classes of veterinary drugs and pesticides were tested. From these six compound classes approximately 50 residues were analyzed. No violations were found in the 29 samples analyzed.

INTENSIFIED

Four (4) compound classes of veterinary drugs and pesticides were tested. From these four compound classes approximately 40 residues were analyzed. No violations were found in the 22 samples analyzed.