EXHIBIT 40

UNITED STATES
National Residue Program

2011 Scheduled Sampling Plans

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

April 2011

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Preface

The United States National Residue Program (U.S. NRP) Blue Book is a summary of the scheduled domestic and imported meat, poultry, and egg product sampling plans and includes a summary of adjustments to the 2010 NRP. Detailed discussions describing the principles and methods used to plan and design the NRP sampling plans are provided. Development of the sampling plans is divided into individual sections for domestic and imported products and for veterinary drugs, pesticides, and unavoidable contaminants. For convenience, tables that report summaries of FSIS sampling plans are provided before the detailed discussions. Three appendices (I-III) examine tissues required for laboratory analysis; FSIS laboratory analytical methods; and a statistical table that describes the probability of detecting a violation given a specified sample size.

Contacts and Comments

Questions about the U.S. NRP should be directed to the USDA-FSIS-OPHS-Risk Assessment Division (RAD), Chemical Residue Risk Branch (CRRB), 333 Aerospace Center, 1400 Independence Avenue, SW, Washington, DC 20250-3700, telephone (202) 690-6409, fax (202) 690-6565.

Acknowledgements

We would like to acknowledge the following who advised the working team during the execution of this project: Dr. Alice Thaler, Senior Director for Program Services, OPHS; Ms. Janell Kause, Director, RAD; and Dr. Patty Bennett, Chief, CRRB, RAD. We would like to acknowledge also the efforts of Mr. Naser Abdelmajid and Dr. Doritza Pagan-Rodriguez (CRRB), and Dr. Charles Santerre (AAAS Fellow) for their help in preparing this document and the FSIS Laboratory management who finalized Appendix II. Furthermore, we would like to acknowledge the members of the Surveillance Advisory Team, particularly Dr. Joseph Paige, Food and Drug Administration (FDA) and Ms. Susan Hummel, Environmental Protection Agency (EPA), for their extensive contributions to the planning of the 2011 U.S. National Residue Program.

Principal Authors

Alexander Domesle	USDA/FSIS/OPHS/RAD
Margaret O'Keefe	USDA/FSIS/OPHS/RAD

INTRODUCTION

The United States National Residue Program (U.S. NRP) 2011 Scheduled Sampling Plan (Blue Book) provides the scheduled sampling plan for testing chemical compounds in products from food animals and egg products produced domestically or imported into the United States for CY2011. In addition, this book provides detailed information on how the chemical compounds are selected for inclusion in the scheduled sampling plan.

The U.S. NRP is a collaborative interagency program established to protect the public from exposure to harmful levels of chemical residues in meat, poultry, and egg products produced or imported into the United States. The NRP is designed: (1) to provide a structured process for identifying and evaluating chemical compounds of concern in food animals; (2) to analyze chemical compounds of concern; (3) to collect, analyze and report results; and (4) to identify the need for regulatory follow-up when violative levels of chemical residues are found.

The U.S. Department of Agriculture Food Safety and Inspection Service (FSIS), the Environmental Protection Agency (EPA), and the Department of Health and Human Services Food and Drug Administration (FDA) are the federal agencies primarily involved in managing this program. The EPA and FDA have statutory authority for establishing residue tolerances through regulations that limit the quantity of a chemical for the protection of public health.[1] The FDA, under the Federal Food, Drug, and Cosmetic Act, establishes tolerances or action levels for veterinary drugs, food additives, and environmental contaminants. The EPA, under the Federal Insecticide, Fungicide and Rodenticide Act (as modified by the Food Quality Protection Act), establishes tolerance levels for registered pesticides. Through the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, FSIS regulates the safety of meat, poultry, and egg products produced in federally inspected establishments.

The U.S. NRP tests for chemical compounds, including approved (legal) and unapproved (illegal) veterinary drugs, pesticides, hormones, as well as environmental compounds that may appear in meat, poultry, and egg products. FSIS, FDA, EPA, and other federal agencies, including the USDA Agricultural Research Service (ARS) and Agricultural Marketing Service (AMS), as well as the Centers for Disease Control and Prevention (CDC), create an annual sampling plan (per calendar year) using sample results from the U.S. NRP, information that the Agencies have accumulated during investigations, and from FDA veterinary drug inventories completed during on-farm visits. The Agencies create a list of chemical compounds for testing and rank them using mathematical equations that include variables for public health risk and regulatory concern. The Agencies decide which chemical compounds are tested in which food animals and evaluate FSIS laboratory capacity and analytical methods to devise a final sampling plan. FSIS publishes the finalized sampling plan in the Blue Book.

Since 1967, FSIS has administered the U.S. NRP by collecting samples from meat, poultry, and egg products and analyzing the samples at one of three FSIS laboratories. A violation occurs when an FSIS laboratory detects a chemical compound level in excess of an established tolerance or action level in a sample. FSIS shares laboratory findings that exceed established tolerances and action levels with FDA and EPA. FDA has jurisdiction on-farm, and FSIS assists FDA in obtaining the names of producers and other parties involved in offering the animals for sale. FSIS informs producers through certified letters that an animal from their business has tested positive for violative residues.

[1] Title 40 CFR includes tolerance levels established by EPA; Title 21 CFR includes tolerance levels established by FDA.

The FDA and cooperating state agencies investigate producers linked to residue violations. If a problem is not corrected, subsequent FDA visits could result in enforcement action, including prosecution. At the request of industry, FSIS posts the Residue Repeat Violator List weekly. The list includes establishments and producers associated with more than one violation on a rolling 12-month basis. Because FSIS updates this list weekly, FDA may not have investigated each violation. These lists provide helpful information to processors and producers working to avoid illegal levels of residues, serve as deterrents for violators, and enable FSIS and FDA to make better use of resources.

A scientifically sound chemical residue prevention program is essential to encourage the prudent use of veterinary drugs and pesticides in food animals. In the late 1990s, FSIS implemented the Hazard Analysis and Critical Control Points (HACCP) inspection system in all federally inspected establishments to verify chemical residue control under HACCP. The HACCP regulation, (9 CFR 417), requires slaughter and production establishments to identify all food safety hazards, including drug residues, pesticides, and chemical contaminants that are reasonably likely to occur before, during, and after entry into the establishment and determine preventive measures the establishment can apply to control these hazards. FSIS takes regulatory action against establishments that do not have an adequate chemical residue control program in place.

The U.S. NRP requires the cooperation and collaboration of several Agencies for successful design and implementation. The U.S. NRP exists to ensure that chemical compounds are used as intended and that the food supply is safe for consumption.

SAMPLING PLANS OF THE U.S. NATIONAL RESIDUE PROGRAM

The U.S. NRP sampling plans focus on domestic meat, poultry, and egg products and import reinspection of meat and poultry products. These plans are divided further to facilitate the management of chemical residues, such as veterinary drugs, pesticides, and environmental contaminants in meat, poultry, and egg products. The domestic sampling plan includes scheduled sampling and inspector-generated sampling. The import reinspection sampling plan is separated into normal sampling, increased sampling, and intensified sampling.

DOMESTIC SAMPLING PLAN

Scheduled Sampling

Scheduled sampling plans consist of the random sampling of tissue from food animals that have passed ante-mortem inspection. The development of scheduled sampling plans proceeds in the following manner: 1) determine which chemical compounds are of concern to food safety; 2) use algorithms to rank the selected chemical compounds; 3) pair these chemical compounds with appropriate food animal and egg products; and 4) establish the number of samples to be collected. At its annual meeting, the Surveillance Advisory Team (SAT), an interagency committee comprised of representatives from FSIS, FDA, EPA, AMS, ARS, and CDC, determines the compound/production class pairs of public health concern.[1] FSIS calculates the number of samples needed for the scheduled sampling. Since the 2006 NRP, FSIS has sampled 230 or 300 animals for each compound/production class pair. Applying sampling rates of 230 or 300 in food animals and egg products assures a 90 percent and 95 percent probability, respectively, for detecting residue violations if the violation rate is equal to or greater than one percent. The resulting violation data are used to verify whether industry process controls and HACCP plans effectively control residues. The FSIS, FDA, and EPA review and make final adjustments to the sampling plan.

The following types of sampling programs are being scheduled:

Exposure Assessments

Exposure Assessments are designed to determine the prevalence of chemical residues in the nation's food supply, and are used to guide:

- FSIS decisions to condemn carcasses with violative levels of residues;
- FDA regulatory decisions when a sample contains violative levels of residues to determine action against producers;
- industry decisions to retain product until the sample has been tested; and
- industry decisions to recall a product that was not retained while the sample was tested and found to contain violative levels of residue.

[1] Compound = chemical compounds; production class =food animals and egg products

Exploratory Assessments

Exploratory Assessments are designed to:

- reinvestigate animal populations from ongoing or previous exposure assessments if the violation rate is confirmed at one percent or greater;
- investigate animal populations when the compounds in question have no established tolerances;
- respond to intelligence regarding use of veterinary drugs, pesticides, and environmental contaminants reported from the field; .
- indicate the prevalence and concentration of residues; and
- evaluate residue trends.

Inspector-Generated Sampling

Public Health Veterinarians (PHVs) conduct inspector-generated sampling in-plant on animals suspected of having violative levels of chemical residues. Currently, inspector-generated sampling targets *individual suspect animals* and *suspect populations of animals* (i.e., show animals). When an inspector-generated sample is collected, the carcass is held pending the results of laboratory testing. If a carcass is found to contain violative levels of residues, the carcass is condemned.

Sampling for individual suspect animals

The in-plant inspector selects a carcass for sampling based on professional judgment and public health criteria outlined in FSIS Directives 10,800.1 and 10,220.3 (i.e., 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 an antibiotic or sulfonamide drug in an animal, then he or she can perform an approved in-plant residue screening test, such as Fast Antimicrobial Screening Test (FAST) or Kidney Inhibition Swab (KIS™) test. If the result of a screening test is positive, then the sample is sent to a FSIS laboratory for confirmation. If the IIC/PHV does not have FAST or KIS™ Test capability, the sample can be sent directly to the FSIS laboratory for testing.

Sampling for suspect animal populations

Sampling for suspect animal populations is generally directed by a FSIS regulation, directive (e.g., FSIS Directive 10,800.1), or notice (e.g., show animals and bob veal).

IMPORT REINSPECTION SAMPLING PLAN

Imported meat, poultry, and egg products are sampled through the Port-of-Entry Reinspection Program, a chemical residue-monitoring program conducted to verify the equivalence of inspection systems in exporting countries. All imported products are subject to reinspection and one or more types of inspection (TOI) are conducted on every lot[2] of product before it enters the United States. Chemical residue sampling is included in the reinspection of imported products. The three levels of chemical residue reinspection include:

- normal sampling, defined as random sampling from a lot;
- increased sampling, defined as above-normal sampling resulting from an Agency management decision; and
- intensified sampling, defined as occurring when a previous sample for a TOI failed to meet U.S. requirements.

For both normal and increased sampling, the lot is not required to be retained pending laboratory results; however, the importer may choose to retain the lot pending the laboratory results. The lot is subject to recall if it is not retained and is found to contain violative levels of residue. For intensified sampling, the lot must be retained pending laboratory results. The data obtained from laboratory analyses are entered into the Automated Import Information System (AIIS), an FSIS database designed to generate reinspection assignments, receive and store results, and compile histories for the performance of foreign establishments certified by the inspection system in the exporting country.

The following summary tables outline the specifics of the sampling programs.

[2] A lot is a group of product defined statistically and/or scientifically by production segments and certified from one country, one establishment, and consisting entirely of the same species, process category, and product standard of identity (sub-category). A single lot can contain shipping cartons with varying sizes of immediate containers.

Summary of the Domestic and Import Reinspection Sampling Plans

U.S. NRP Summary Organized by Compound Class

Summary Tables I–IV provide an overview of both domestic and import sampling organized by chemical compound class. Each of the four tables covers one group of compounds: Animal Medicinal Drug Use Clarification Act (AMDUCA) prohibited drugs, veterinary drugs, pesticides, and environmental contaminants, respectively. The tables also specify which FSIS laboratory conducts the analyses for each compound class.

U.S. NRP Summary Organized by Production Class

Summary Tables V–VII contain the data for the same sampling plans, but reorganized by production class, rather than chemical compound class. Domestic sampling is summarized in Table V and import sampling is summarized in Table VI. In addition, Table VII sorts the import samples by country and production class.

Summary Table I – Summary by Compound Class
Status of the AMDUCA[1]-Prohibited Drugs
2011 U.S. NRP Domestic and Import Scheduled Sampling

AMDUCA[1] Prohibited Drug	Number of Scheduled Samples				
	Domestic		Import		Total
Avoparcin (glycopeptide)	Not in the 2011 NRP		Not in the 2011 NRP		0
Chloramphenicol Analysis by EL	mature chickens (300) young chickens (300)	mature turkeys (300) young turkeys (300) **Total domestic: 1,200**	beef, fresh (91) chicken, fresh (90)	turkey, fresh (16) veal, fresh (89) **Total import: 286**	1,486
Clenbuterol[2] Analysis by WL	steers (300) formula fed veal (230) non-formula fed veal (90)	heifers (300) goats (90) market hogs (300) **Total domestic: 1,310**	pork, fresh (104)	veal, fresh (90) **Total import: 194**	1,504
Diethylstilbestrol	Not in the 2011 NRP		Not in the 2011 NRP		0
Fluoroquinolones[3] Analysis by ML Part of antibiotics 7-plate bioassay analysis	beef cows (300) boars/stags (300) bob veal (300) bulls (300) dairy cows (300) ducks (45) formula fed veal (300) geese (30) goats (90) heavy calves (90) heifers (300) lambs (300)	market hogs (300) mature chickens (300) mature turkeys (300) non-formula fed veal (90) rabbits (30) roaster pigs (300) sheep (300) sows (300) steers (230) young chickens (300) young turkeys (300) **Total domestic: 5,405**	beef, fresh (300) chicken, fresh (90) horse, fresh (8) other fowl, fresh (16)	pork, fresh (230) turkey, fresh (16) varied comb., fresh (8) veal, fresh (90) **Total import: 758**	6,163
Nitrofurans[4] Analysis by WL	dairy cows (230) market hogs (300)	roaster pigs (300) **Total domestic: 830**	No samples scheduled for imports in 2011		830
Nitroimidazoles[5] Analysis by EL	young turkeys (300)	**Total domestic: 300**	chicken, fresh (90)	**Total import: 90**	390
Phenylbutazone	Not in the 2011 NRP		Not in the 2011 NRP		0
Ronidazole	Not in the 2011 NRP		Not in the 2011 NRP		0
Vancomycin	Not in the 2011 NRP		Not in the 2011 NRP		0

EL = FSIS Eastern Laboratory (Athens, GA); ML = FSIS Midwestern Laboratory (St. Louis, MO); WL = FSIS Western Laboratory (Alameda, CA)

[1] Refers to drugs banned by FDA from extralabel use under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). These drugs are not evaluated using the ranking formula. Instead, these drugs are automatically assigned a high sampling priority and will be included in the NRP if methodologies and resources are available.
[2] β-Agonist method is applicable to clenbuterol, salbutamol, cimaterol, zilpaterol, and ractopamine.
[3] The fluoroquinolones, enrofloxacin and danofloxacin, are approved for use in steers and heifers.
[4] Furazolidone and nitrofurazone are antimicrobials.
[5] Nitroimidazoles in the FSIS multi-residue method (MRM) include dimetridazole and ipronidazole; antiprotozoal.