2006 FSIS National Residue Program Scheduled Sampling Plans

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

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Preface

The Food Safety and Inspection Service (FSIS) National Residue Program (NRP), *Blue Book* is a summary of the scheduled domestic and import sampling plans and includes a summary of adjustments to the 2006 NRP. Detailed discussions describing the principals and methods used to plan and design the NRP sampling plans are provided. Development of the sampling plans is divided into individual sections for domestic and import products for veterinary drugs, pesticides, and environmental contaminants. For convenience, tables that report summaries of FSIS sampling plans are provided before the detailed discussions. Four appendices (I-III) are also provided: tissues required for laboratory analysis; FSIS laboratory analytical methods; and a statistical table that describes the probability of detecting a violation given a specified sample size.

Contacts and Comments

Questions about the FSIS NRP should be directed to the USDA-FSIS Zoonotic Diseases and Residue Surveillance Division, Residue Branch, 344 Aerospace Center, 1400 Independence Avenue, SW, Washington, DC 20250-3700, telephone (202) 690-6566, fax (202) 690-6565.

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Introduction

The Food Safety and Inspection Service (FSIS), the U.S. Department of Agriculture's public health regulatory agency, works with the Environmental Protection Agency (EPA) and the Department of Health and Human Service's Food and Drug Administration (FDA), to control animal 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 animal 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 prevents 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) analyzing compounds of concern; (3) appropriate regulatory follow-up of reports of violative tissue residues; and (4) collection, statistical analysis, and reporting 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 animal drugs and pesticides known or suspected to be present in domestic food animals and egg products or in countries exporting products to the U.S. It also includes any other xenobiotic or endogenous substance that may appear in meat, poultry, and egg products and 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 follow-up with on-site visits to these firms for an educational visit.

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 aids FSIS, FDA, and EPA to enforce Federal laws and regulations, and assists the agencies to design 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 NRP is comprised of sampling plans to address chemical and drug residues in domestic and imported food animals and egg products. All products, whether domestic or imported, must fall within the tolerance levels set by Food and Drug Administration (FDA) and Environmental Protection Agency (EPA).

I. Domestic Sampling Plan

- *Scheduled sampling* is a process for the determination of compounds of concern, pairing compounds of concern with production classes, and sample numbers for compound-production class pairs. Compound-production class pairs are determined at Surveillance Advisory Team (SAT) and FSIS Residue Branch determines sample numbers. Residue Branch staff employ modern statistical analysis techniques to calculate sample numbers. Beginning with the 2006 NRP, FSIS uses sample sizes of either 230 or 300 for each compound-production class pair. Statistically, applying sampling rates of 230 and 300 assures a probability of detecting a residue violation (if the true violation rate among healthy appearing animals is 1 percent) of 90 and 95%, respectively. Residue Branch has adopted a sample size of 300 as a public health standard for determining if HACCP is effective. FSIS Senior Management, FSIS Laboratories, the FDA, and the EPA review and make a final determination of sample numbers. Scheduled sampling is applied to healthy appearing food animals for the following types of assessments:
    - *Exposure Assessments* are used to determine the prevalence of residues in the nations food supply. Residue samples collected for exposure assessments are subject to voluntary retention by industry, condemnation by FSIS, and voluntary recall by industry, and by FDA for regulatory action when a sample contains violative levels of residues.
    - *Exploratory Assessments* are designed by Residue Branch to investigate violations identified in exposure assessments, compounds that have no established tolerances, and when suggested by intelligence from the field. Exploratory assessments are subject to mandatory retention by FSIS, condemnation by FSIS, and voluntary recalls by FSIS.

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

- *Inspector generated sampling* is not scheduled and is not directed by FSIS Headquarters. Inspector generated sampling is conducted by in-plant public health veterinarians, using FSIS Form 10,000-2, when there is reason to believe that an animal may have violative levels of residues. Currently, inspector generated sampling targets *individual suspect animals* and *suspect populations of animals*. In inspector generated sampling, the carcass is retained pending the results of laboratory testing and a carcass that is found to contain violative levels of residues is condemned.

    - *Sampling for individual suspect animals* is performed in-plant using residue screening tests: Fast antimicrobial screening test (FAST) and swab test on

premises (STOP). The FAST and STOP tests are used only for the detection of antimicrobial and sulfonamide residues. If the result of a screening test is positive, the sample is sent to an FSIS laboratory for confirmation. The in-plant inspector selects a carcass for sampling based on professional judgment and public health criteria developed by FSIS. These criteria include animal disease signs and symptoms, producer history, and results from random scheduled sampling.

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

II. Import Sampling Plan

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

- *Normal sampling*, which is defined as random sampling from a lot;
- *Increased sampling (random sampling)*, which is defined as above the normal sampling as the result of an Agency management decision; and
- *Intensified sampling (biased sampling)*, which is defined as occurring when a previous sample for a type of inspection failed to meet U.S. requirements.

For both normal and increased sampling, the lot is not required to be retained pending laboratory results; however, the importer may retain the lot pending the laboratory results. For intensified sampling, the lot must be held pending laboratory results. The level of reinspection that is applied depends on the country's performance history. The data obtained from laboratory analysis are entered into an FSIS Data Base System, the Automated Import Information System (AIIS). Import sampling is designed to verify that the chemical residue programs in countries exporting meat, poultry, or egg products to the U.S. are equivalent to those in the U.S.