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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 417

[Docket No. FSIS–2012–0012]

New Analytic Methods and Sampling Procedures for the United States National Residue Program for Meat, Poultry, and Egg Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that it is restructuring the United States National Residue Program (NRP) with respect to how sampling of chemical compounds and animal production and egg product classes is scheduled. To complement this new approach to sampling and scheduling, the Agency is implementing several multi-residue methods for analyzing samples of meat, poultry, and egg products for animal drug residues, pesticides, and environmental contaminants in its inspector-generated testing program. These modern, high-efficiency methods will conserve resources and provide useful and reliable results while enabling FSIS to analyze each sample for more chemical compounds than was previously possible.

DATES: New methods and procedures will be effective 30 days from publication of this notice.

ADDRESSES: FSIS invites interested persons to submit comments on this document. Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to Regulations.Gov at *http://www.regulations.gov/* and follow the online instructions at that site for submitting comments.

Mail, including floppy disks or CD–ROMs, and hand-or courier-delivered items: Send to U.S. Department of Agriculture (USDA), FSIS, Docket Clerk, Patriots Plaza 3, 1400 Independence Avenue SW., Room 8–163A, Mailstop 3782, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2011–0012. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: For information: Contact Rachel Edelstein, Deputy Assistant Administrator, Office of Policy and Program Development, at (202) 720–0399, or by fax at (202) 720–2025.

SUPPLEMENTARY INFORMATION:

I. Background

FSIS administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 453 *et seq.*), and the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) to protect the health and welfare of consumers by regulating the meat, poultry, and egg products produced in federally inspected establishments. Through its inspections, the Agency endeavors to prevent the distribution in commerce of any such products that are adulterated or misbranded, thereby reducing the risk of foodborne illness from FSIS-regulated products. One way in which the Agency effects its regulatory program is through the United States National Residue Program (NRP). The NRP is designed 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 requires the cooperation and collaboration of several agencies for successful design and implementation. FSIS, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) of the Department of Health and Human Services are the Federal agencies primarily involved in managing this program. EPA and FDA have statutory authority to establish residue tolerances through regulations that limit the quantity of a chemical for the protection of public health. FDA, under the Federal Food, Drug, and Cosmetic Act, establishes tolerances or action levels for veterinary drugs, food additives, and environmental contaminants. EPA, under the Federal Insecticide, Fungicide and Rodenticide Act (as modified by the Food Quality Protection Act), establishes tolerance levels for registered pesticides. Title 21 CFR sets out tolerance levels established by FDA; Title 40 CFR sets out tolerance levels established by EPA.

The NRP is designed to provide a structured process for identifying and evaluating chemical compounds of concern in food animals; collecting, analyzing and reporting results; and identifying the need for regulatory follow-up when violative levels of chemical residues are found. The NRP tests for the presence of chemical compounds, including approved (legal) and unapproved (illegal) veterinary drugs, pesticides, hormones, and environmental contaminants that may appear in meat, poultry, and egg products.

A scheduled residue sampling program is developed annually by representatives from FSIS, FDA, EPA, and other Federal agencies, including the USDA Agricultural Research Service (ARS) and Agricultural Marketing Service (AMS) and the Centers for Disease Control and Prevention (CDC). These agencies meet at least once a year as part of the Surveillance Advisory Team (SAT). The SAT creates the annual sampling plan (per calendar year) using sample results from the NRP, information that the agencies have accumulated during investigations, and information from veterinary drug inventories that FDA has compiled 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. In addition to establishing a relative ranking for the chemicals, the SAT determines the compound/production class pairs of public health concern and evaluates FSIS laboratory capacity and analytical

methods to devise a final sampling plan. FSIS publishes the final sampling plan in the *National Residue Program Sampling Plan,* which is traditionally referred to as the Blue Book.

Since 1967, FSIS has administered the NRP by collecting samples from meat, poultry, and egg products and analyzing the samples at one of three FSIS laboratories. A basis for concern appears 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. If the findings are for imported product, FSIS shares them with the competent authority in the foreign country from where the product originated. 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 when an animal from their business has a violative level of a residue. FDA and cooperating State agencies investigate producers linked to residue violations. If a problem is not corrected, subsequent FDA visits could result in an enforcement action, including prosecution.

At the request of industry, FSIS posts a weekly list of repeat residue violators. The Residue Repeat Violators List includes 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. The list provides helpful information to processors and producers who are working to avoid illegal levels of residues, serves to deter violators, and enables FSIS and FDA to make better use of their resources.

Recognizing that a scientifically sound chemical residue prevention program is essential to encourage the prudent use of pesticides and veterinary drugs in food animals, in the late 1990s FSIS implemented the Hazard Analysis and Critical Control Points (HACCP) inspection system in all federally inspected meat and poultry establishments to verify that, among other things, the establishments have effective residue controls in their food production systems. In pertinent part, the HACCP regulations (9 CFR Part 417) require that FSIS-inspected slaughter establishments identify all food safety hazards, including drug residues, pesticide residues, and chemical contaminants, that are reasonably likely to occur before, during, and after entry into the establishment and establish preventive measures to control these hazards. FSIS will take regulatory action against an establishment that does not have an adequate chemical residue control program in place.

NRP Operating Structure

In practice, the NRP consists of three separate but interrelated chemical residue testing programs: Scheduled sampling, inspector-generated sampling, and import sampling. This basic structure has been in existence since 1967, though modified over the years to adjust to emerging and reemerging chemical residue concerns and to improvements in testing methodologies.

Under the current scheduled sampling program, FSIS calculates the number of samples needed for the scheduled sampling as part of a ''paired sampling'' protocol. Since the 2006 residue program, FSIS has sampled 230 or 300 animals for each chemical compound/production class pair. For instance, if FSIS scheduled heifers to be tested for four different chemical compound classes (for example, antibiotics, chlorinated hydrocarbons, β-agonists, and sulfonamides), FSIS inspectors would collect approximately three hundred samples for each of the chemical compound classes. Therefore, FSIS inspectors would collect samples from approximately 1,200 heifers (300 samples by four chemical compound classes = 1,200 samples collected). Applying sampling rates of 230 or 300 in food animals and egg products assures FSIS a 90 percent and 95 percent probability, respectively, of detecting chemical residue violations if the violation rate is equal to or greater than one percent. For the Calendar Year (CY) 2011 domestic scheduled sampling program, FSIS laboratories completed 21,555 analyses across multiple production classes and chemicals. Several of the analytical methods tested for multiple compounds.

New NRP Structure

During CY 2012, in contrast, FSIS is significantly modifying the scheduled sampling approach by eliminating the ''paired sampling'' protocol. FSIS will be analyzing fewer samples but by using multi-residue methods will actually be assessing more compounds per sample. As part of this new approach, FSIS is establishing three tiers of sampling for the NRP.

Tier 1—New Scheduled Sampling Program

The new Tier 1 resembles the current scheduled sampling program and should be understood as an exposure assessment. Where the current scheduled sampling program has collected samples from each production class, the new FSIS program will rotate production classes through Tier 1. Where FSIS has allocated a maximum of 300 samples per chemical compound class in the traditional program, the new structure will allocate approximately 800 samples per chemical compound class for each of the production classes tested in Tier 1.

Under Tier 1 during CY 2012 domestic scheduled sampling program, FSIS will run 6,400 samples through 12 multi-residue methods across nine production classes of meat and poultry, which represent 95 percent of the meat and poultry consumed domestically. Eliminating the ''paired sampling'' protocol will result in more samples run per production class and more analytes targeted. Samples from Tier 1 will be analyzed at either the FSIS Eastern or Western laboratories.

New Scheduled Sampling Program Tier 2

The new Tier 2 will resemble the traditional inspector-generated sampling program at the establishment level. The inspector-generated program is a targeted testing program in which field public health veterinarians make the determination to perform in-plant screens on carcasses because they suspect that animals or carcasses contain higher than allowable levels of chemical residues. Samples from carcasses having positive in-plant screens are sent to the FSIS Midwestern Laboratory for confirmation, and the carcass is held pending results. In 2010, field personnel completed more than 200,000 in-plant screens resulting in almost 7,000 positive samples submitted to the FSIS Midwestern Laboratory for confirmation. FSIS implemented the newest in-plant screen (Kidney Inhibition Swab (KIS™) test) in 2009, and since then, the Midwestern Laboratory has instituted a policy of repeating the KIS™ test on positive in-plant KIS™ screens received from the field. In 2012, FSIS will begin using a multi-analytic screening method discussed below on inspector-generated in-plant screen positives submitted to the Midwestern Laboratory.

Simultaneously, FSIS will discontinue the use of the 7-plate bioassay in the Midwestern Laboratory as a primary screen for field positive samples. Inspector-generated samples will be tested using the updated multi-residue analytic screening method on in-plant samples described below in the section on New Methodology. Because the multi-analytic method is significantly superior to the KIS™ test, it will be unnecessary to repeat the

KIS™ test on field-screen positive samples submitted to the Midwestern Laboratory. Hence, the turnaround time for availability of regulatory results will be reduced.

FSIS will continue, however, to use the bioassay for quantification of those veterinary drugs having tolerances associated with the bioassay as required by FDA New Animal Drug Applications (NADA).

The new Tier 2 also will absorb the traditional exploratory assessment program at the production class and compound class level. Exploratory assessments are targeted sampling plans designed, for example, in response to information gained from previous exposure assessments and intelligence from other agencies. Consequently, FSIS may use the data results from Tier 1 sampling to inform the type of sampling that will occur in Tier 2.

New Scheduled Sampling Program Tier 3

FSIS is further planning a Tier 3 level, which the Agency anticipates will be similar in structure to the exploratory assessment program in Tier 2, with the exception that Tier 3 will encompass targeted testing at the herd or flock level. FSIS anticipates that certain chemical exposures may occur that involve more than one animal or bird. For instance, producers may administer some veterinary drugs to a herd or a flock (for example, growth promotants or antibiotics given in the feed) in a way that involves misuse. In addition, livestock and birds may be exposed unintentially to an environmental contaminant. Therefore, a targeted testing program designed for livestock or flocks originating from the same farm or region may be necessary on occasion to determine the level of a chemical or chemicals to which the livestock or the birds in the flock have been exposed. Tier 3 will provide a vehicle for developing information that will support future policy development within the NRP. FSIS is evaluating implementation issues and requirements for Tier 3 activities.

Import Sampling

The import-sampling program will be structured using the Tier 1 and 2 frameworks. In CY 2012, FSIS intends to collect approximately 1300 import samples—500 samples under Tier 1 and 800 samples under Tier 2. It also intends to screen a subset of these samples for unknown compounds in the FSIS Food Emergency Response Network (FERN) laboratory.

New Methodology and Sampling Procedures

The analytical methods that have been used for many years in the NRP to measure veterinary drug residues in meat, poultry, and egg products are laborious, expensive, and time consuming and, as a result, sometimes prevent the timely testing of food products before they are released into the marketplace. More modern, performance-based analytical methods can reduce cost, increase the number of analytes that can be measured, and improve precision and accuracy while also shortening turn-around time. Modern methods use multi-residue techniques to quantify a larger number of analytes with greater precision (repeatability) and accuracy (degree of closeness to actual value). Such methods can often be performed with faster throughput and at lower cost than conventional single residue methods. In the food regulation arena, improved analytical methods are necessary if regulatory agencies are to effectively monitor for the increasing number of chemical residues and to protect public health.

This notice announces the adoption by FSIS of a new screening method for antibiotics and environmental contaminants. The current official FSIS screening methodology for antibiotics is a 7-plate bioassay. The 7-plate bioassay screen has several drawbacks: (1) It only works for microbial growth-inhibiting residues (certain antibiotics within and among classes); (2) it is not sensitive enough for sulfonamides and fluoroquinolones in relation to their tolerances, but it is much too sensitive as a screen for tetracyclines and certain aminoglycosides with high tolerances; (3) it does not distinguish one drug from another in the same class; (4) the results can be difficult to interpret, especially when multiple drugs are present; (5) it is prone to unknown microbial inhibition responses; (6) it takes a team of personnel to set up the assay and more than 16 hours to obtain the results; and (7) the measurement uncertainty associated with the 7-plate bioassay is large compared with other methods.

The new multi-residue method (MRM) being implemented by FSIS provides significant improvements: (1) It can screen for a variety of analytes, not just antibiotics; (2) the method can be validated at levels appropriate in relation to tolerances; (3) because of the power of mass spectrometry, it can clearly distinguish individual analytes, even if multiple drugs are present in the same sample; (4) unknown microbial inhibition responses would be mitigated; and (5) the time and personnel needed to obtain results is reduced.

The 52 analytes shown in the following table are appropriate for inclusion in the new MRM at and above the level specified. Analytes that were not analyzed during the 2011 NRP sampling plan and had not been included for testing in previous years are in italics.

ANALYTES AND APPLICABILITY LEVEL

[(μ g/g) for MRM]

Analyte	Bovine kidney	Porcine kidney	7-plate bioassay (ppm)
Ampicillin	0.02	0.02	0.05
Beta-dexamethasone	0.05	0.05	.....
Cefazolin	0.2	0.2	.....
Chloramphenicol	0.006	0.006	20
Chlortetracycline	1	1	0.05
Cimaterol	0.012	0.003	.....
Ciprofloxacin	0.025	0.025	.....
Clindamycin	0.05	0.05	.....
Cloxacillin	0.02	0.02	1.6
Danofloxacin	0.025	0.025	.....
DCCD (marker for Ceftiofur)	0.2	0.2	.....
Desthylene Ciprofloxacin	0.025	0.025	.....
Dicloxacillin	0.2	0.2	.....

ANALYTES AND APPLICABILITY LEVEL—Continued

[(μ g/g) for MRM]

Analyte	Bovine kidney	Porcine kidney	7-plate bioassay (ppm)
Difloxacin	0.025	0.025	.....
Enrofloxacin	0.025	0.025	.....
Erythromycin A	0.05	0.05	0.25
Florfenicol	0.1	0.1	.....
Florfenicol Amine *	.....	0.15	.....
Flunixin	0.0125	0.0125	.....
Gamithromycin	0.05	0.05	.....
Lincomycin	0.05	0.05	1.5
Nafcillin	0.2	0.2	.....
Norfloxacin	0.025	0.025	.....
Oxacillin	0.2	0.2	.....
Oxyphenylbutazone *	0.05	.....	.....
Oxytetracycline	0.5	0.5	0.4
Penicillin G	0.1	0.1	0.05
Phenylbutazone *	.....	0.05	.....
Pirlimycin	0.25	0.25	.....
Prednisone	0.05	0.05	.....
Ractopamine	0.003	0.003	.....
Salbutamol	0.006	0.003	.....
Sarafloxacin	0.025	0.025	.....
Sulfachloropyridizine	0.05	0.05	.....
Sulfadiazine	0.05	0.05	.....
Sulfadimethoxine	0.05	0.05	.....
Sulfadoxine	0.05	0.05	.....
Sulfaethoxypyridazine	0.05	0.05	.....
Sulfamerazine	0.05	0.05	.....
Sulamethazine	0.05	0.05	150
Sulfamethizole	0.05	0.05	.....
Sulfamethoxazole	0.05	0.05	.....
Sulfamethoxypyridazine	0.05	0.05	.....
Sulfanilamide *	0.1	.....	.....
Sulfanitran	0.05	0.05	.....
Sulfapyridine	0.05	0.05	.....
Sulfaquinoxaline	0.05	0.05	.....
Sulfathiazole	0.05	0.05	.....
Tetracycline	0.5	0.5	0.4
Tilmicosin	0.12	0.24	0.5
Tylosin	0.1	0.2	1
Zearalanol *	.....	0.012	.....

* This analyte is not applicable for bovine kidney in the MRM.

With the new sampling and analytic methods, approximately 6,400 samples of two pounds of muscle and one pound each of kidney and liver will be collected, in contrast to approximately 20,000 samples collected per year under the current system in which the Agency collects one pound each of muscle, kidney, and liver. Although FSIS inspectors will be collecting more muscle with every sample, they will be collecting far fewer samples.

Cost-Benefit Analysis

The new methodologies will result in additional costs for the Agency only for the purchase and maintenance of new equipment that will enable the FSIS laboratories to use the new multi-residue method. Equipment for the Midwestern Laboratory was replaced and charged under the old program. The additional purchase of the same equipment for the Eastern and Western Laboratories is anticipated to cost $250,000 per instrument, resulting in a total cost in the second year of implementation of $550,000 for two instruments and service maintenance. (Maintenance of the 2 instruments is at the rate of 10 percent of the cost of each instrument.) FSIS is exploring the possibility of leasing this equipment, which would significantly reduce the startup cost and eliminate the maintenance cost. The annualized cost of the instruments plus maintenance over 6 years at 7 percent equals approximately $112,000 and, if discounted at 3 percent, equals about $108,000. The Agency does not expect a significant impact on other laboratory resources because of the instrument purchases. In sum, FSIS sees only a small cost to the taxpayer in implementing the new methodology.

As stated above, under the new system approximately 6,400 samples of two pounds of muscle and one pound each of kidney and liver will be collected, in contrast to approximately 20,000 samples collected per year under the current system in which the Agency collects one pound each of muscle, kidney, and liver. The muscle samples will be larger, but the total number of samples collected will be much smaller. The smaller number of samples required will result in cost savings to FSIS that will be realized through reductions in special delivery shipments and in inspector time spent collecting samples. At approximately $20 a shipment, a reduction of approximately 13,600 samples that will not need to be collected will equal approximately $272,000 saved annually. At approximately 30 minutes allowed for an inspector to collect and package a

sample, the savings for 13,600 samples will equal approximately $218,280.

Thus, given annualized costs of approximately $112,000 (7 percent) or $108,000 (3 percent) and annual recurring benefits of $490,280, net annual benefits exceed the costs by approximately $378,280.

Benefits to the public health are likely to occur because the Agency will be able to test for more residues with the additional new methods, but those benefits cannot be quantified at this time.

Impact on Small Entities

The new sampling program will operate according to a scheduling algorithm that will ensure that establishments are sampled in proportion to their production volume, and the Agency expects no negative impact on small businesses. Because of the design of the algorithm used for the new sampling program, small businesses may be sampled less frequently than is the case under the current system. This differential in frequency of sampling is likely to offset any economic losses conceivably resulting from the increased size of an individual sample.

Expected Changes in Violation Rates

The nine classes to be sampled for CY 2012 under the new program are specified as Bob Veal, Beef Cows, Dairy Cows, Steers, Heifers, Market Swine, Sows, Young Chicken, and Young Turkey. The number of samples taken for nine species classes for CY 2012 will be 800 per class except for steers and heifers, which have 400 each. The total allocation per species class and the number of samples allocated per species class may change, as will the species classes sampled in successive years. Assuming a constant rate of violations estimated from those in CY 2011, the number of expected violations will tend to increase in some but not all cases even though the total number of samples will decrease. This is because the number of analyses run per sample will be increased in CY 2012 compared to CY 2011. Specifically, based on historical data on chemical residue violations, the Agency expects that Bob Veal, Beef Cows, and Sows may show some increase in violations, while Dairy Cows, Steers, Heifers, Market Swine, Young Chicken, and Young Turkey may show no change in violations. The total net increase in violations expected is unlikely to have a significant impact because the residue violative rate is very low.

Impact on Foreign and State Stakeholders

The proposed plan remains statistically structured relative to sample collection of imported products. FSIS and other federal agencies will continue to select chemicals tested within the U.S. program using a risk-based approach. FSIS expects countries exporting meat, poultry, and egg products to the United States to control chemical residues in the products that they export. FSIS will continue to require foreign countries to maintain equivalent residue control programs (9 CFR 327.2(a)(2)(iv)(C)). Therefore, FSIS does not anticipate any trade issues or international consequences.

States that administer ''at least equal to'' cooperative State meat or poultry inspection (MPI) programs need to complete and sign an ''Annual Statement of Defensible Laboratory Results'' as part of their annual ''at least equal to'' self-assessment. States under the Cooperative Interstate Shipment Program must demonstrate that their laboratory services used to analyze regulatory samples are capable of producing results that are the ''same as'' those obtained by FSIS laboratories. Requirements for demonstrating ''same as'' status can be found at *http://askfsis.custhelp.com/app/answers/detail/a_id/1622/related/1.* State laboratories operating under the Cooperative Interstate Shipment Program need to use the protocols for analytical tests required for FSIS regulatory activities on meat and poultry and egg products described in the FSIS Chemistry, Microbiological, and Pathology Laboratory Guidebooks. The authorities of affected States should take note of the methodological developments described in this notice.

Additional Public Notification

FSIS will announce this document online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp.* FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/News_&_Events/Email_Subscription/.* Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on June 29, 2012.

Alfred V. Almanza,

Administrator.

[FR Doc. 2012–16571 Filed 7–5–12; 8:45 am]

BILLING CODE 3410–DM–P

NUCLEAR REGULATORY COMMISSION

10 CFR Chapter I

[NRC–2012–0092]

RIN 3150–AJ16

Technical Corrections

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is amending its regulations to make technical corrections, including updating the street address for its Region I office, correcting authority citations and typographical and spelling errors, and making other edits and conforming changes. This document is necessary to inform the public of these non-substantive changes to the NRC's regulations.

DATES: This rule is effective August 6, 2012.

FOR FURTHER INFORMATION CONTACT: Jennifer Borges, Rules, Announcements, and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–492–3675, email: *Jennifer.Borges@nrc.gov.*

ADDRESSES: Please refer to Docket ID NRC–2012–0092 when contacting the NRC about the availability of information for this final rule. You may access information and comment submittals related to this final rulemaking, which the NRC possesses and are publicly available, by any of the following methods: