

and Drug Administration and any such drug residues are within tolerance levels approved by the Food and Drug Administration * * *(9 CFR 318.20). FSIS has not strictly applied FDA's marker residue/target tissue approach in determining whether drug residues are within tolerance levels.

Specifically, FSIS has condemned only the organ with a violative residue level and has conducted a laboratory analysis of the muscle tissue to determine whether the muscle portion of the carcass can be salvaged. This has been the practice even for residues of those new animal drugs for which FDA has not established a tolerance or testing methodology for the muscle tissue. Historically, if no drug residue was detected in the muscle, FSIS released the muscle portion of the carcass for human consumption.

FSIS's practice has generated on-going questions regarding whether or not the muscle or other organs are safe. FSIS has referred these questions to FDA, which addresses them on an *ad hoc* basis.

FSIS needs to modify its procedures to be consistent with the determinations that underlie FDA's approach. Therefore, for those new animal drugs for which FDA has established a marker residue tolerance in a specified target tissue without establishing a tolerance for a residue in muscle and an official analytical method for muscle residues, FSIS will only test the target tissue that is identified in FDA regulations. If the residues found in the target tissue exceed the FDA tolerances, FSIS will condemn the entire carcass. If FDA has also established a tolerance for a residue in muscle and an official analytical method for muscle residues, FSIS will test the muscle using the official methodology to determine whether the concentration of residues in the muscle is at or below the muscle tolerance. If acceptable, FSIS will permit the release of the muscle. For those new animal drugs for which a marker residue tolerance in a specified target tissue has not been identified, FSIS will continue to collect and monitor multiple edible tissues.

FSIS is aware that the change in its procedures announced in this notice will affect the industry. To ensure that animals do not have violative amounts of residues, establishments may change their purchasing practices. Establishments should consider incorporating controls into their HACCP plans to avoid exceeding residue tolerances. Exceeding residue tolerances may result in the condemnation of more product than is currently being condemned. FSIS invites comment on

this impact and will welcome any cost data. FSIS will consider these data and consider in what ways it may lessen the impact.

Additional Public Notification

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Done at Washington DC, on: July 31, 2001.

Thomas J. Billy,
Administrator.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 00-051N]

Residue Testing Procedures

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is changing the action it will take when livestock or poultry are presented for slaughter at official establishments that come from producers and others who have previously marketed such animals with violative levels of drug, pesticide, or other chemical residues ("chemical residues"). FSIS will no longer test livestock and poultry carcasses at

official establishments for chemical residues until a specific number of the carcasses consecutively test negative for violative chemical residues (i.e., FSIS "5/15" policy). Instead, FSIS will post on its website the names and addresses of the sellers of livestock and poultry who the Food and Drug Administration has determined are responsible for the repeated sale of livestock or poultry that contain violative levels of chemical residues. FSIS believes that this action will help better ensure that meat and poultry products distributed in commerce are not adulterated with violative residues. FSIS is taking this action partly in response to a request from certain industry groups.

DATES: The new procedures will be effective September 5, 2001.

FOR FURTHER INFORMATION CONTACT: Daniel L. Lazenby, Acting Director, Technical Analysis Staff, Office of Policy, Program Development, and Evaluation, FSIS, U.S. Department of Agriculture, Room 409, Cotton Annex, 300 12th Street, SW., Washington, DC 20250, (202) 205-0210.

SUPPLEMENTARY INFORMATION

Background

The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) to protect the health and welfare of consumers. This program among other things helps to prevent the distribution in commerce of adulterated products of livestock and poultry. Under the FMIA and the PPIA, it is illegal to sell or transport, offer for sale or transportation, or receive for transportation, in commerce, meat and poultry products that are capable of use as human food that are adulterated (21 U.S.C. 458(a)(2)(A) and 610(c)(1)). Meat and poultry products are considered adulterated under the FMIA and PPIA if they bear or contain illegal amounts of drugs, pesticides, and other chemicals (21 U.S.C. 453(g)(1), (g)(2), and (g)(3) and 601(m)(1), (m)(2), and (m)(3)).

Both the FMIA and the PPIA include requirements for Federal inspection. They prohibit the sale, transportation, offer for sale or transportation, or receipt for transportation, in commerce, of meat and poultry products that are required to be inspected unless they have been inspected and passed (21 U.S.C. 458(a)(2)(B) and 610(c)(2)).

Meat and poultry products prepared at establishments that operate solely within a State are effectively subject to the same inspection requirements and

adulteration prohibitions discussed above. These requirements and prohibitions are imposed pursuant to a State inspection program or by the FMIA and PPIA as a result of the designation of a State for Federal inspection (21 U.S.C. 454(c)(1) and 661(c)(1)).

Since the 1960's, the public and private sectors have tried to meet the challenges presented by various types of product adulteration that organoleptic examination generally cannot detect. The control of chemical residues in meat and poultry products is a particularly appropriate subject for an improved regulatory approach that involves a well-integrated and seamless, prevention-oriented farm-to-table strategy.

At the Federal regulatory level, efforts to prevent residue-related food safety problems principally involve, in addition to FSIS, the Food and Drug Administration (FDA), acting under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 321 *et seq.*), and the Environmental Protection Agency (EPA), acting under the FFDCA, the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135 *et seq.*), and the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*). FDA and EPA establish, respectively, what, if any, levels of animal drug and pesticide residues in food are safe, and thus can legally remain in the tissue of livestock and poultry. EPA also may make recommendations regarding what level, if any, of other chemical hazards that may be associated with substances that occur in meat and poultry products as a result of environmental contamination are safe. These levels are known as action or tolerance levels. FSIS enforces the tolerance and action levels set by the EPA and FDA to ensure that meat and poultry products do not contain levels of animal drugs, pesticides, or other chemicals above the level that is considered safe.

At slaughter, FSIS looks for indications of illegal chemical use or exposure and collects livestock and poultry carcass samples for residue analysis. The analytical components of the Agency's residue control activities are collectively known as the "National Residue Program" (NRP). Initiated more than 30 years ago, the NRP has generally been a success. It has been instrumental in reducing the incidence of such residue violations as sulfamethazine in market hogs. The most recent NRP reports are the "1999 FSIS National Residue Program" and the "Domestic Residue Data Book National Residue Program 1998" (referred to informally as

the "Blue Book" and the "Red Book", respectively.)

The prevention of illegal chemical residues in the food supply is an integral aspect of maintaining a high level of food safety. As part of FSIS's inspection program to screen for violative levels of chemical residues in livestock and poultry carcasses to ensure that meat and poultry products are not adulterated, Agency inspection program personnel sample meat and poultry carcasses at official establishments and submit the samples for testing to determine whether they contain violative drug, pesticide, or other chemical residues.

If it is confirmed that a carcass contains a violative drug, pesticide, or other chemical residue, the Slaughter Operations Staff at FSIS' Technical Service Center (TSC) opens a case file about this matter and initiates an investigation to determine who is the violator. A violator is defined as a firm or person, (e.g., farmer, hauler, auction market) who sells livestock or poultry for slaughter that contains violative levels of drugs, pesticides, or other chemical residues. If the TSC staff is able to obtain from the official establishment the name of the producer (e.g. farmer) of the livestock or poultry, the TSC sends an "FSIS Violation Notification Letter" to this person. The letter provides the results of the residue tests taken and requests that the producer submit five animals to FSIS for residue testing at a designated official establishment.

The TSC staff informs the appropriate FSIS personnel at the designated official establishment to sample the carcasses of animals presented for slaughter by the producer. There is no specific time period in which these carcasses must be presented. The case file remains open until five consecutive carcasses from animals presented for slaughter by the producer test negative for violative residues.

If the TSC staff is not able to obtain the name of the producer who supplied the violative livestock or poultry carcass to the official establishment, then inspection program personnel are instructed to sample 15 carcasses from animals provided by the auction, market, or buyer that had previously supplied livestock or poultry to the official establishment that had been found to contain violative chemical residues. Inspection program personnel will select carcasses from three or more different lots for sampling and testing. There is no specific time period in which these carcasses must be presented. The case file remains open until 15 consecutive carcasses from

animals presented for slaughter test negative for violative residues.

The sampling and testing undertaken at official establishments of a specified consecutive number of carcasses of livestock or poultry that contained violative chemical residues is known as FSIS' "5/15" residue policy.

Under an October 1984, Memorandum of Understanding with FDA, when FSIS finds violative drug, pesticide, or other chemical residues in livestock or poultry, FSIS transmits to FDA information, including the name of the official establishment where the livestock or poultry that was presented for slaughter was confirmed positive for violative chemical residues and information about the violator. This information is transmitted via the Residue Violation Information System (RVIS). RVIS is a nationwide interagency computer information system that was designed by FSIS in cooperation with FDA to handle pertinent regulatory information related to residue violations.

FDA uses the information it receives from RVIS to conduct an investigation of the violator to determine whether the violator is a repeat violator. A repeat violator is an individual or firm who sells an animal for slaughter whose carcass is found to contain a violative level of a drug, pesticide, or other chemical residue within a 12-month period after having received a FSIS Violation Notification Letter.

On July 27, 2000, the American Meat Institute, the Livestock Marketing Association, the National Livestock Producers Association, the National Cattleman's Beef Association, and the National Meat Association wrote to FSIS and requested that the Agency make certain changes in how it responded to residue violations by sellers of livestock. The associations stated that they were particularly interested in reducing the sales of market cattle that contained violative levels of animal drug residues. The associations requested that FSIS terminate its "5/15" policy "in favor of a more meaningful cooperative program with FDA." They contended that FSIS' "5/15" policy was not an effective deterrent for firms or persons who knowingly and repeatedly sold medicated livestock.

In place of FSIS' "5/15" policy, the associations requested that FSIS publish and disseminate a list that contains the names and addresses of the sellers of livestock that FDA has investigated and determined to be responsible for more than one residue violation in a 12-month period (repeat violators). The associations recommended that these violators remain on the published list

for a period of one year following a "responsible party" designation by FDA, and that this time period be extended another twelve months for each subsequent residue violation for which the seller was determined to be responsible.

FSIS has reviewed the associations' request. FSIS has determined that the list requested may more effectively prevent, than its current "5/15" policy does, the distribution of meat products that are adulterated with violative levels of chemical residues. FSIS has also determined that this type of list may also more effectively prevent, than the current "5/15" policy does, the distribution of poultry products that contain violative chemical residues. FSIS believes that its current "5/15" policy may not be the best way to deter the repeated sale of livestock and poultry with violative chemical residues because, once a producer is notified about a residue violation, it is not difficult for a seller of livestock and poultry to temporarily present animals for slaughter that do not contain violative drug, pesticide, or other chemical residue levels. FSIS also believes that the suggested approach is more consistent with the approach embodied in HACCP than is the "5/15" policy.

Therefore, FSIS will implement the change requested by the associations not only in regard to persons who have marketed livestock with violative chemical residues, but also in regard to persons who have marketed poultry that contain violative chemical residues. In cooperation with FDA, FSIS will make a list of repeat chemical residue violators publicly available by posting a list of repeat violators on the FSIS Homepage (www.fsis.usda.gov). The list will contain the names and addresses of the sellers of livestock and poultry that FDA has investigated and determined to be responsible for more than one drug, pesticide or other chemical residue violation in a 12-month period. The names and addresses of violators will remain on the list for a year from the time of being listed. For any subsequent violation, the time period will be extended by a year from the time of that subsequent violation.

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Done at Washington, DC on: July 31, 2001.

Thomas J. Billy,

Administrator.

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DEPARTMENT OF AGRICULTURE

Forest Service

American Electric Power (Formerly Appalachian Power Company) Transmission Line Construction—Jackson's Ferry (Cloverdale), Virginia, to Oceana, West Virginia. George Washington and Jefferson National Forests, Appalachian National Scenic Trail, the New River, and R.D. Bailey Lake Flowage Easement Land. Virginia Counties of Botetourt, Roanoke, Craig, Montgomery, Pulaski, Bland, Tazewell, Wythe and Giles and the West Virginia Counties of Monroe, Summers, Mercer, McDowell and Wyoming

AGENCY: Forest Service, USDA.

ACTION: Revised Notice—Revises the proposed action based on the application submitted by the proponent (American Electric Power) to include a different federal land crossing; identifies a new construction endpoint; identifies three new counties in Virginia and West Virginia affected by the transmission line proposal; notifies interested parties of the federal agencies' intent to prepare a supplemental draft environmental impact statement; establishes the date, time and location of 3 public meetings; and provides the dates for the publication of the supplemental draft and final environmental impact statements.

SUMMARY: On June 28, 1996 the Forest Service published a draft environmental impact statement for American Electric Power's (AEP's) proposed crossing of federal lands with a 765,000-Volt transmission line. AEP has since revised their preferred route for the line and changed the location of the endpoint of the transmission line from Cloverdale to Jackson's Ferry, Virginia. The Virginia State Corporation Commission and the West Virginia Public Service Commission have approved the private land components (79 miles) of the proposed transmission line. The Commissions do not have the authority to approve transmission line corridors across federally administered lands.

The actions and assessments of the two Commissions represent significant new information for the federal agencies to consider. They also present a substantial change in the proposed action. Accordingly, the Forest Service will prepare a supplemental draft environmental impact statement, before publishing a final environmental impact statement, on a proposed action to authorize American Electric Power (formerly the Appalachian Power Company) to construct a 765,000-volt transmission line across approximately 11 miles of the George Washington and Jefferson National Forests, as well as portions of the Appalachian National Scenic Trail, the New River (at Bluestone Lake) and R.D. Bailey Lake Flowage Easement Land (at Guyandotte River).

The revised proposal by American Electric Power (AEP) crosses federal lands outside the area analyzed by the federal agencies in the draft environmental impact statement published in July of 1996. The revised AEP proposal includes the previously unaffected Virginia Counties of Wythe and Tazewell, and the West Virginia County of McDowell in addition to the Virginia Counties of Bland and Pulaski and the West Virginia County of Wyoming. The total length of the revised AEP proposal is approximately 90 miles.

The American Electric Power (AEP) proposal involves federal land under the administrative jurisdiction of the USDA Forest Service (George Washington and Jefferson National Forests and the Appalachian National Scenic Trail) and the US Army Corps of Engineers (New River and R.D. Bailey Lake Flowage Easement Land).

The Forest Service is the lead agency and is responsible for the preparation of the environmental impact statement. The National Park Service and the US