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How the residue monitoring program will change

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Introduction

The laws and regulatory system for ensuring food safety that serve as the underpinnings of our food production system have been evolving since 1906. This system has served well to protect the public from foodborne hazards and has resulted in the United States food supply being among the safest in the world. However, maintaining the wholesomeness and safety of the food supply requires continued vigilance and the flexibility to adapt to changing conditions.

The prevention of unsafe levels of chemical residues in the food supply is an integral aspect of maintaining a high level of food safety. High consumer expectations necessitate that the United States be able to thoroughly document the safety of our meat, poultry, and egg products. In addition, issues related to chemical residues in food may be used as trade barriers to hinder the import and export of food products.

There is evidence that human illness such as allergic reactions, hypersensitivity, and toxicity have resulted from drug residues in animal tissues. Similarly, violative levels of pesticide residues are also known to have toxic effects. Expanding scientific evidence demonstrates that antimicrobial-resistant bacteria can result from both subtherapeutic and therapeutic use of antimicrobials in food animals and these antimicrobial-resistant bacteria are subsequently transmitted from animals to humans. A vigilant chemical residue prevention program, therefore, is essential to fostering the prudent use of drugs and pesticides in animals that enter the human food supply.

Elements of the current residue monitoring program

Under the present FSIS national residue program, Agency inspectors collect samples of meat, poultry, and egg products at domestic slaughter establishments and egg processing plants under FSIS and State inspection authority. These samples are then analyzed for violative residue concentrations, either by one of three FSIS technical service laboratories or by a laboratory under contract to FSIS. Violative residue concentrations are determined by reference to residue limits established by the Environmental Protection Agency for pesticides and by the Food and Drug Administration for animal drugs and environmental contaminants. Residue samples may be collected under two separate initiatives, monitoring and enforcement.

Monitoring involves the sampling of specified animal populations to provide information about the occurrence of residue violations on an annual, national basis. Compounds considered usually have established residue limits, that is, tolerances or action levels. Monitoring information is obtained through a statistically based random selection of specimens of normal-appearing tissues from passed carcasses. The carcass is not held after the sample is taken. Specific compounds, or compound classes, are considered in specific slaughter classes. Each combination is known as a compound/slaughter class pair. Generally for a specific pair, the number of specimens chosen provides a 95 percent probability of detecting at least one violation when one percent of the animal population is violative. The results are also used to identify producers or other entities marketing animals with violative concentrations of residues. When such producers subsequently offer animals for slaughter, the animals may be subjected to enforcement testing until compliance is demonstrated.

Enforcement testing consists of the analysis of specimens collected by FSIS inspectors from suspect animals based upon their observations of clinical signs or their knowledge of the history of the animals or the supplier. Testing is performed to detect individual animals with violative concentrations of residues and the number of violative residues does not reflect a statistically valid incidence within the entire slaughter class. In-plant, rapid screening methods are a key tool used in support of enforcement testing. It is emphasized in problem (high prevalence) populations and used as a mechanism to prevent residues from entering the food supply. It is also used to follow up on producers and others who have been identified as marketing animals with violative concentrations of residues.

Slaughter classes now being sampled are horses, bulls, beef cows, dairy cows, heifers, steers, bob veal calves, formula-fed veal calves, non-formula-fed veal calves, heavy calves, sheep, lambs, goats, market hogs, boars, sows, young chickens, mature chickens, young turkeys,

mature turkeys, ducks, rabbits, geese, roaster pigs, and egg products.

Compounds currently sampled under the Monitoring Plan are antibiotics, chlorinated hydrocarbons and chlorinated organophosphates, sulfonamides, arsenicals, halofuginone, carbadox, and ivermectin. The compounds currently sampled as Special Projects are clenbuterol in formula-fed veal calves and tranquilizers in bulls.

Why the program is changing

On July 25, 1996, the sweeping reform of the U. S. Department of Agriculture regulations known as the Final Rule on Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems was published. The principal focus of the rule, which complements existing food safety laws and regulations, is to reduce both the pathogenic organisms on meat and poultry products and the incidence of foodborne illness associated with these products. The rule also provides a new framework for the modernization of the meat and poultry inspection system. The rule requires meat and poultry establishments to develop and implement a system of preventive measures designed to ensure the safety of their products. In their HACCP plans, slaughter establishments must address all chemical, physical, and microbial hazards that are reasonably likely to occur in the animals that enter their plants. Part 417.2 of Title 9 of the Code of Federal Regulations requires that slaughter establishments conduct a hazard analysis to determine the food safety hazards reasonably likely to occur before, during, and after entry into the establishment. These hazards include chemical residues resulting from use of or exposure to animal drugs, pesticides and environmental contaminants. If the hazard analysis identifies chemical residues as a food safety hazard reasonably likely to occur in the production process, then the establishment must have a critical control point to prevent, control or eliminate the hazard. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls. FSIS expects an establishment to consider its history of chemical residue violations and the type of livestock or poultry it is slaughtering in determining whether drug or chemical residues are a food hazard reasonably likely to occur. Failure to develop and implement a HACCP plan or failure to operate in accordance with 9 CFR 417 requirements may make products produced under those conditions adulterated.

How the residue program is changing

In December of 1997, FSIS convened an inter-agency work group comprised of representatives from the Food and Drug Administration, Centers for Disease Control and Prevention, Environmental Protection Agency, and several USDA agencies to evaluate the national residue program. Their charge was to develop a comprehensive risk-based approach to chemical residues based upon slaughter establishments assuming full responsibility for food safety under HACCP. In May of this year, the work group presented its report, the National Cooperative Residue Program (NCRP), to FSIS management.

In developing the NCRP, the work group accomplished several tasks. First, it conducted a reassessment of FSIS's efforts to prevent and control violative chemical residues; it developed recommendations on how to conduct the residue program in a HACCP environment; and it produced a document which describes for all interested parties how the US carries out its national program. In some respects, the NCRP is not radically different from the current FSIS residue program. It utilizes most of the mechanisms developed to support the existing tissue residue program because they continue to be effective. Some of the procedures have been updated, and, where necessary, new procedures have been developed to address new situations. Some significant aspects of the NCRP are summarized below.

- The identification and selection of slaughter class/compound pairs has been restructured to include unapproved drugs and pesticides, and criteria have been established for prioritizing compounds and compound classes based upon their potential to appear at unsafe levels in meat and poultry. With this information, FSIS can maximize the effectiveness of its limited resources to sample and test for those compounds most likely to be present at violative levels. FSIS has already begun implementing the process defined in the NCRP on a pilot basis to develop the list of priority compounds for the 1999 residue program.
- The NCRP addresses how the results of all FSIS sampling will support verification of both individual establishment's and the entire industry's success in addressing chemical residues. The fact that FSIS will continue to conduct a comprehensive residue program places increased pressure on slaughter establishments to assure that products are not adulterated with chemical residues. This is because an FSIS finding of a violative residue can be an indication of a failure of the establishment's HACCP plan, which can lead to enforcement action.

An analysis of the Agency's need to verify slaughter establishments' HACCP plans for chemical residues and to structure a national residue program based upon public health risk determined that both efforts were complementary and compatible with the basic structure of the current residue effort.

The headquarters initiated monitoring efforts provide a national assessment of the public health risks associated with specific compounds and slaughter classes.

The range of compounds and extent of sampling FSIS is able to conduct far exceed the capability of an individual company, thereby assuring that a more complete picture of residue concerns is obtained.

The inspector-initiated enforcement sampling provides the ability to target suspect animals based upon their clinical signs or supplier/herd history. It also provides FSIS the discretionary ability to evaluate suspect product that may not be detected by an establishment's HACCP plan for chemical residues.

- The NCRP identifies what actions FSIS will take when we detect a residue violation in a product a slaughter establishment has permitted into commerce. Even though each violation will be handled on an individual basis, it also provides fundamental information that will assist both government and industry personnel in determining appropriate resolution of the particular situation.
- The NCRP provides an overview of the requirements from a chemical residue perspective for importing meat, poultry, and egg products into the US.
- The NCRP provides options which slaughter establishments and egg processing plants can take to prevent adulteration of products from chemical residues. This information will be particularly useful to slaughter establishments in determining what actions, if any, may be required in their HACCP plans to address chemical residues. It also will assist FSIS staff in determining when slaughter establishments have taken appropriate corrective actions following detection of a residue violation by FSIS.
- Prevention and control of chemical residues are issues which generate considerable public interest. They are also areas in which increased public participation can benefit FSIS. The NCRP identifies mechanisms for increasing public input into the residue program. These include holding public meetings, including residue issues on the agenda of Federal advisory committee meetings, and participating in conferences, symposia, and seminars such as the Leman Conference.
- The NCRP re-emphasizes the inter-Agency coordination that must take place among FDA, EPA, FSIS, other USDA agencies, and State agencies in order for a national residue program to be effective and successful.
- The NCRP does not require significant changes to existing residue program databases, although several minor modifications were suggested which will significantly improve the effectiveness of these systems.

A significant change that will occur under the NCRP is that enforcement actions can be initiated against slaughter establishments (in addition to the animal supplier) when an FSIS sample contains violative concentrations of residues. In determining the appropriate enforcement actions, FSIS will consider such factors as the historic pattern of violations, the magnitude of the violation, and the extent of potential public health risk. For those slaughter establishments subject to 9 CFR 417, when an unexpected, unforeseen event occurs the requirements of 9 CFR 417.3(b) must be followed. Under these requirements, if an unforeseen hazard arises, the establishment must assess its HACCP plan to determine whether the newly identified hazard should be incorporated into the HACCP plan. With any violative residue, the establishment must perform a review of the affected product to determine its acceptability for distribution and take action to ensure that no adulterated product is distributed. Repeated residue violations indicate a HACCP system failure which could result in suspension or withdrawal of inspection.

Potential impact of the proposed changes

Responsibility for residue prevention begins with animal production. The presence in food of chemical residues above permitted levels causes the food to be adulterated under the Federal Food, Drug, and Cosmetic Act (FFDCA). The Food and Drug Administration regards live animals raised for food as "food" under the FFDCA. Everyone involved in the production, handling, transporting, or manipulating of "food animals," and the animals themselves, come under the jurisdiction of the FFDCA. A supplier who has shipped an animal with illegal tissue residues to slaughter has violated the FFDCA, even if the slaughter establishment rejects the animal for processing. If a slaughter establishment has knowledge that an animal or carcass contains violative levels of chemical residues, it should report that information to the FSIS inspector. The inspector will collect tissue samples (a live animal may be held until the residues deplete to the tolerance) which will be forwarded to an FDA laboratory to support possible enforcement action against the supplier of the animal.

FSIS has identified some potential options that slaughter establishments may consider to assist them in preventing

violative chemical residues in animals they accept for processing. Plants are not required to implement the options presented here and may institute other options they believe to be appropriate to prevent violative residues. A key element in determining that an animal is free of violative residues is knowledge about its production history. The 90 days immediately before slaughter is a critical period for most residues. Slaughter establishments need to take strong, affirmative action to ensure that the animals they slaughter do not bear violative residues. The following procedures are offered for consideration:

- Rejecting animals that are assessed to be at risk of having violative residues.
- Clearly defining the slaughter establishment's specifications for animals suitable for processing for human consumption. Providing this information to food animal producers and animal suppliers will reinforce the message regarding the importance of maintaining product safety.
- Purchasing from suppliers who have implemented proper animal drug and pesticide use procedures including animal identification and record keeping as identified in commodity quality assurance and good production practices programs. To convince suppliers of the importance of preventing violative residues, periodically visit suppliers or obtain independent third party verification that good production practices are being implemented.
- Refusing to purchase animals from suppliers who have a history of providing animals with violative residues.
- Requiring written assurance from suppliers that all animals meet the plant's contract specifications. Each lot or shipment of animals may need a separate assurance, depending on the source of supply.

  Market animals from a known source may be identified by a document covering the status of the entire lot. For feedlots and regular producer sources, a certification program could be tied into a national quality assurance program.

  In cases of animals from order-buyers, dealers, or others, when there is a non-uniform lot without knowledge of individual sources, documentation would be required for each individual animal/producer lot or an affidavit that such documentation is in the possession of the seller and available for review.
- Periodically using analytical tissue residue tests that are appropriate for the treatment history of the animals to be slaughtered to verify that the supplier information is correct.

  Analytical tests are a reasonable technique to verify that residue critical control points are under control. If a slaughter establishment decides to perform analytical testing, only reliable methods should be used. Determination of tolerances set by FDA/CVM for animal drugs is dependent upon a specific analytical method, target compound, and target tissue. Determinations of residues of approved animal drugs should be performed using the methods prescribed by the FDA, or by methods that have been demonstrated to be comparable to the FDA or FSIS method.

  EPA sets tolerances for pesticides in meat, poultry and egg products using methods that are performance-based. Methods used to determine residues of pesticides should be FSIS methods or must be shown to provide results comparable to FSIS methods.

  There are some cases when unapproved drugs, pesticides, or new environmental contaminants may be detected. In such a case, sound science is the only basis for choice of an analytical method.

Methods used by FSIS are detailed in the Analytical Chemistry Laboratory Guidebook and the Microbiology Laboratory Guidebook published respectively by the Chemistry and Toxicology Division and Microbiology Division within OPHS, FSIS. The criteria used by FSIS for performance of chemical methods are outlined in the FSIS Quality Assurance Manual and FSIS Directive 10,110.1 Rev 1.

While the final rule on Pathogen Reduction and HACCP has no direct effect on animal producers, we believe that the adoption of HACCP and food safety performance standards within the slaughter establishments will have a ripple effect on the food animal production industry. As plants begin to implement HACCP plans, we believe that they will need more information on incoming animals. Exactly what information suppliers will need to provide and how they should make it available needs to be worked out by animal producers and the plants that receive animals.

Pork producers are fortunate to have the guidance they will need to react to any of these changes readily available to them. The National Pork Producers Council's Pork Quality Assurance program contains state-of-the-industry information to address food safety concerns at the production level. Producers who implement the practices described in the program will be doing the types of things that can provide slaughter establishments with the assurance of the safety of incoming animals.

Future options for consideration

Although there is not any mandatory requirement for slaughter establishments to conduct analytical tests on meat and poultry products, some may choose to do so.

The results of these tests could potentially be used to supplement government testing programs and help provide a more complete picture of the safety of the US food supply. Such an initiative would require coordination and planning to ensure that the data derived would be of acceptable quality to support claims about product safety. Potential benefits would be increased consumer confidence in the safety of meat, poultry, and egg products, and improved export markets.