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Done at Washington, DC on July 31, 2001.

F. Edward Scarbrough,

U.S. Manager for Codex Alimentarius.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 00-026N]

Residue Policy

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing its intention to harmonize its procedures with those of the Food and Drug Administration (FDA) with respect to the target tissue/marker residue policy in testing animal tissues for residues of new animal drugs. FSIS has reviewed its approach regarding the disposition of carcasses containing residues and has determined that its approach is not consistent with FDA's approach. To ensure that meat containing unsafe levels of chemical residues is not being released into commerce, FSIS intends to modify its approach to testing and disposition of carcasses for violative residues to be more consistent with FDA's target tissue/marker residue policy.

DATES: Comments may be submitted by no later than September 5, 2001. FSIS will review comments and address them

in another notice. That notice will announce when the procedural changes addressed in this notice are effective.

ADDRESSES: Submit one original and two copies of written comments to: FSIS Docket Clerk, Docket # 00-026N, Room 102, Cotton Annex Building, 300 12th Street, SW., Washington, DC 20250-3700. All comments received in response to this notice will be considered part of the public record and will be available for viewing in the FSIS Docket Room between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Daniel L. Lazenby, Acting Director, Technical Analysis Staff, Office Policy, Program Development and Evaluation; (202) 205-0210.

SUPPLEMENTARY INFORMATION:

Background

When a new animal drug is given to an animal, some of the parent drug and resulting metabolites remain in the animal as residues. A new animal drug is defined under 21 CFR 510.3(g) and examples of "newness" are specified in 21 CFR 510.3(i).

For new animal drugs approved prior to 1976, tolerances were assigned for each of the edible tissues. Collection and testing of multiple tissues is routine for these new animal drugs. As each tissue is tested, it is either released or condemned, depending on whether it is found to have an acceptable level of residue.

Since 1976, FDA has been establishing tolerance levels for new animal drugs using a "marker residue." The term "marker residue" is defined in the Food and Drug Administration's (FDA) Center for Veterinary Medicine's Guideline, "*General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals*," (CVM Guideline #3, <http://www.fda.gov/cvm/guidance/guideline3toc.html>) as being the residue selected for assay whose concentration is in a known relationship to the total residue of toxicological concern in the last tissue to deplete to its permitted concentration.

These marker residues serve as a sentinel for the levels of all residues associated with that drug (parent and metabolites) in all edible tissues of the food animal. CVM's Guideline 13 defines target tissue as being the edible tissue selected to monitor for residues in the target animals, including, where appropriate, milk or eggs. When the FDA-approved conditions of use for a new animal drug are followed, the concentration of marker residue in the target tissue should be below the target

tissue tolerance when the animal is sent to slaughter. To establish an appropriate tolerance for the marker residue, FDA must know the relationship between the concentration of the marker residue in the target tissue and the concentrations of total residues in each of the edible tissues (CVM Guideline 13). FDA obtains this information from the drug's sponsor who, in submitting a New Animal Drug Application (NADA), includes total residue depletion and metabolism studies with radiolabeled compound in species for which approval is sought (CVM's Guideline #3). The target tissue is usually liver, kidney, or fat because residues generally deplete from these tissues more slowly than from other tissues, i.e., muscle tissue.

In those cases where FDA has established a marker residue tolerance in target tissue, when the marker residue in the target tissue depletes to a concentration equal to or less than the target tissue tolerance (based on the total residue depletion and metabolite data), it can be reliably anticipated that the concentration of total residue in each edible tissue has reached its respective permitted safe concentration. In other words, when the concentration of the marker residue is at or below its tolerance in the target tissue, the entire carcass is considered safe to eat, without additional testing of the individual edible parts of the animal carcass. Similarly, if the level of the marker residue in the target tissue exceeds the tolerance, FDA will consider the entire carcass to be adulterated, because the residue in the target tissue is imputed to the rest of the animal.

In addition, for 15 new animal drugs FDA has specifically established tolerances for residues found in muscle tissue and analytical methods for detecting those residues. Therefore, the muscle tissue may be released for human consumption if it meets the muscle residue tolerance level. This is true even when the marker residue tolerance in the target tissue has been exceeded. The target tissue, however, would be condemned. In this situation, documenting that the drug residues in muscle are less than the muscle tolerance will only demonstrate that the muscle tissue is safe, and does not imply that any other part of the animal carcass is safe, except in those few instances where muscle has been designated to be the target tissue.

FSIS Practice

FSIS regulations regarding residues state that " * * * Animal drug residues are permitted in meat and meat food products if such residues are from drugs which have been approved by the Food

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

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on-line through the FSIS web page located at <http://www.fsis.usda.gov>. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720-5704.

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