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GENERAL REVIEW AND ENFORCEMENT POLICIES

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TISSUE RESIDUE REPORTING

1. **Purpose:**

This guide identifies the procedures for reporting and processing violations involving illegal residues of drugs in edible tissue of meat and poultry products.

2. **Reporting:**

The Food Safety Inspection Service (FSIS) of the United States Department of Agriculture (USDA) is responsible for inspecting the edible tissues of meat and poultry for illegal drugs. The Memorandum of Understanding (MOU) (Compliance Policy Guide 7155a.19) between the Food and Drug Administration (FDA), Environmental Protection Agency (EPA), and USDA, requires FSIS to notify the appropriate FDA District Office of all findings of illegal residues. In the case of chemical residue findings which may indicate that an emergency exists, the FSIS, through the Chemical Response System, also notifies the Division of Emergency and Investigational Operations, Office of Regional Operations (ORO), and the Center for Veterinary Medicine's (CVM) Division of Animal Feeds. See Feed Contaminants Compliance Program 7371.003.

3. **Processing Procedures:**

a. The FDA District Office considers each FSIS report and initiates the follow-up investigation on the illegal residues in accordance with instructions in the Compliance Program 7371.006. After completion of the Field investigation, the report and any supporting evidence are reviewed by the District Compliance Officers and any regulatory action is completed by the District Office (applicable to certain Warning Letters only) or forwarded to CVM for concurrence.

(1) A copy of the completed investigation report, program evaluation form, FSIS Producer Warning Letter, FSIS Laboratory Form, and District recommendation is forwarded to the Compliance Information Management Team, (HFV-235). A separate copy may also be forwarded to the Division of Compliance for review and proposed action.

- (2) Hard copy reports of the field investigation are provided to the FSIS Regional Office by the FDA District Office.
- b. Information obtained from the investigations is periodically tabulated and evaluated by CVM for program guidance or issuance of specific field follow-up assignments.
- c. Compliance Program 7371.006, Part II, provides guidance on managing follow-up investigations to tissue residue violations reported by FSIS. The District Offices have the discretion on whether or not to follow-up on routine first-time violators. State agencies with cooperative agreements or contracts may be assigned these follow-up investigations. The District Offices are instructed to conduct follow-up investigations of all repeat violators and certain first-time violators meeting one of four criteria specified in the Compliance Program.
- d. Regulatory actions against the culpable parties in tissue residue situations may include:
  - (1) Warning Letters (some of which may be issued without CVM concurrence).
  - (2) Injunction.
  - (3) Citation followed by prosecution, and
  - (4) Recall (are voluntary actions by the industry).