

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

04-09

1/6/09

**HOW TO PROCEED IN ESTABLISHMENTS THAT HAVE
MULTIPLE FSIS LABORATORY CONFIRMED RESIDUE VIOLATIONS
FROM THE SAME SOURCE SUPPLIER**

I. PURPOSE

This notice advises Public Health Veterinarians (PHVs) about their responsibilities when they are informed by the District Office or otherwise determine that an establishment has more than one FSIS laboratory-confirmed residue violation from the same source supplier.

II. BACKGROUND

Establishments that slaughter livestock are expected to identify the foodborne hazards, including chemical hazards, identified in animals offered for slaughter and to address those hazards in their Hazard Analysis and HACCP plan. Under 9 CFR 417.2, establishments are to identify the hazards that are reasonably likely to occur in their production processes and to establish steps to prevent, eliminate, or reduce those hazards to an acceptable level.

In the Federal Register Notice, "Residue Control in a HACCP Environment" (70 FR 70809, November 28, 2000, see link below), FSIS informed establishments that if their HACCP plans include residue controls that constitute the best available preventive practices for slaughter establishments, if they implement those controls effectively, and if they supply FSIS with information about residue violators, then the Agency will not treat violative residue findings as noncompliances, as long as the finding of a violative residue is followed by appropriate corrective actions.

<http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-043N.htm>

However, since that Federal Register Notice was published, FSIS has come to recognize that certain establishments have multiple residue violations because they repeatedly purchase animals from the same sources and do not use the information about the residue violations to reassess the adequacy of their hazard analysis. These establishments do not have an adequate HACCP plan with respect to a potential residue hazard that may be reasonably likely to occur.

DISTRIBUTION: Electronic

NOTICE EXPIRES: 1/1/2010

OPI: OPPD

III. OFFICE OF POLICY AND PROGRAM DEVELOPMENT RESPONSIBILITIES

The Office of Policy and Program Development (OPPD) receives the FSIS Weekly Residue Violator Report from USDA's National Information Technology Center. This FSIS-RVIS report identifies establishments that, on more than one occasion, have purchased animals with violative residues from the same source supplier as confirmed by FSIS laboratories. OPPD informs the FSIS District Offices weekly of establishments listed more than once in the FSIS-RVIS report through the shared outlook residue mailbox files.

IV. DISTRICT OFFICE RESPONSIBILITIES

When a District Office (DO) is advised by OPPD of an establishment that has had more than one FSIS laboratory-confirmed residue violation from the same source supplier, the DO is to notify the Inspector in Charge (IIC) at that establishment and the Front-line supervisor of this fact.

If the DO is aware of any other establishments in the District that purchase animals from this supplier, it is to make the IICs at these establishments and their Front-line supervisors aware that the supplier is a repeat source for animals with violative residues. The DO is to instruct these PHVs to advise the establishments of this development at the next weekly meeting and to document this weekly meeting in a Memorandum of Interview (MOI) that is shared with plant management.

V. PUBLIC HEALTH VETERINARIAN RESPONSIBILITIES

When a PHV is notified that an establishment to which he or she is assigned has more than one FSIS laboratory-confirmed residue violation from animals purchased from the same source supplier, he/she is to discuss this finding with the establishment at the next weekly meeting. The "same source supplier" is any person, farm, sale barn, or other firm from which the establishment has received or purchased animals with violative residue levels of the same or different chemical compounds.

The PHV is to inform the establishment that FSIS is implementing a more focused approach on same source suppliers to ensure that the establishment is notified of the residue history of its suppliers and to recommend that the establishment adopt corrective and preventive measures. The PHV will document the meeting using a MOI and provide a copy to the establishment as well as to the Front-Line Supervisor and the District Office.

Under usual circumstances when a violative result is reported, per instructions in FSIS Directive 10,800.1, Chapter 6, under Noncompliance Documentation (<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10800.1.pdf>), the PHV also reviews the establishment's residue control program.

If the establishment addresses residue control in its HACCP plan or Sanitation Operating Procedures (Sanitation SOP) or other prerequisite program, the PHV is to perform an O3J01 procedure. If the HACCP system is in compliance, the PHV does not write a noncompliance record (NR). If the establishment has a residue control program

but has failed to take corrective actions, or the corrective actions are ineffective, the PHV is to issue an NR using 9 CFR 417.5(a)(1) if the establishment addresses residue control in its prerequisite program or 9 CFR 416.15 if the establishment addresses residue control in its Sanitation SOP. If the establishment addresses residue control in its HACCP plan, the PHV will issue an NR citing 9 CFR 417.3(a). However, if the establishment has not incorporated residue control in its HACCP plan or Sanitation SOP or other prerequisite program, the PHV is to document the noncompliance as an unforeseen hazard, 9 CFR 417.3(b), and use the “verification” trend indicator.

The PHV is also to inform the establishment that the PHV will increase testing of animals that the establishment receives from this same source supplier. As part of the Entry Training for PHV, in the section Residue Detection Program (http://www.fsis.usda.gov/PDF/PHVt-Residue_Detection_Program.pdf), PHVs are instructed to consider increasing scrutiny and testing of animals from a particular supplier when they have knowledge of findings of residue violations in animals from that supplier. PHVs are expected to follow this training.

The PHV is to test two or more animals each time the establishment receives animals from the supplier and use his or her professional judgment to determine whether additional samples are necessary including up to 100% testing of animals from the supplier to ensure that product from animals with violative residues is not introduced into the human food supply. The PHV is to continue this level of residue testing until the tests for four consecutive, separate shipments from the supplier are negative. These consecutive findings are necessary to demonstrate that the establishment’s determination that it can rely on the supplier to provide animals that do not contain violative residues is justified.

If, after the MOI is issued, the PHV is made aware that the establishment has another FSIS laboratory-confirmed residue violation from an animal purchased from the same source supplier, either through increased testing by the PHV or other notification, in addition to issuing noncompliances (NR) as described above, the PHV is to issue an NR citing 9 CFR 318.20 to document the establishment’s failure to prevent animals with violative residue levels from entering slaughter as indicated by the multiple residue violations reported from the same source supplier.

The PHV is to discuss all new noncompliances with the establishment at the first weekly meeting after the PHV is made aware of the finding. The PHV is to point out to the establishment that its failure to prevent this hazard from recurring raises questions about the adequacy of the establishment’s HACCP system.

If the Agency finds additional residue violations between an establishment and a same source supplier, the PHV is to issue noncompliances, as described above, for each occurrence. The PHV is to link the NRs in accordance with FSIS Directive 5000.1, Chapter IV, to document that there is a trend occurring.

With multiple or recurring noncompliances, the PHV is to assess whether the establishment’s HACCP system is inadequate under 9 CFR 417.6. If the PHV determines that the HACCP system is inadequate, and that enforcement is warranted, he or she is to contact the District Office to discuss whether to issue a Notice of

Intended Enforcement to the establishment (see 9 CFR 500.4). The PHV is also to keep his or her supervisor apprised of the situation.

Attachment 1 provides potential scenarios and resulting actions that can be taken by the PHV for multiple laboratory confirmed residue violations and same source supplier.

Refer questions regarding this notice to the Policy Development Division through askFSIS at <http://askfsis.custhelp.com> or by telephone at 1-800-233-3935.



Assistant Administrator
Office of Policy and Program Development

Attachment