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

FSIS NOTICE

07-13 | 2/1/13

CONTROL OF AGENCY TESTED PRODUCTS FOR ADULTERANTS

I. PURPOSE

This notice provides inspection program personnel (IPP) and Enforcement Investigation and Analysis Officers (EIAO) with instructions related to the new policy and procedures discussed in the *Federal Register* on 12/10/12, Not Applying the Mark of Inspection Pending Certain Test Results. It instructs IPP to meet with the establishment to make it aware of the new policy and procedures that are effective February 8, 2013. A separate notice will be issued with instructions to import inspection personnel.

II. BACKGROUND

A. FSIS announced in the *Federal Register* that it is changing its procedures and will withhold its determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received. FSIS recognizes that the mark of inspection is pre-printed on the package label of many products, and that it is most efficient to allow the product to be packaged and labeled with the printed mark of inspection as part of the production process (76 FR 19955). FSIS will continue to allow meat and poultry establishments to package and label products sampled and tested for adulterants with the mark of inspection. However, starting February 8, 2013, FSIS will not allow such product to be released into commerce until negative test results for adulterants are available.

B. This policy covers FSIS testing of:

1. Non-intact raw beef product or intact raw beef product intended for non-intact use that is tested for *Escherichia coli* O157:H7 (*E. coli* O157:H7) or shiga-toxin producing *E. coli* (STEC) that FSIS considers to be adulterants;

2. Ready-to-eat products, including product that passed over food contact surfaces tested by FSIS for *Listeria monocytogenes* or *Salmonella*;

3. Livestock carcasses subject to FSIS testing for residues; and

4. Products tested under FSIS Directive 7000.1, Verification of Non-Food Safety Consumer Protection Regulatory Requirements.

C. This policy does not cover FSIS testing of:

1. Raw meat or poultry products tested for *Salmonella* or other pathogens that FSIS has not designated as adulterants in those products; and

2. Poultry tested for residues.

NOTE: As instructed in FSIS Directive 10,800.1, Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program, IPP are to continue to recommend that establishments hold the specific poultry carcasses that are sampled for residues.

III. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. At the next weekly meeting after the receipt of this notice, IPP are to meet with the establishment management and inform it about the new policy and procedures that begin February 8, 2013. At the meeting IPP are to:

1. Inform the establishment that it may control product tested by FSIS for adulterants either by holding the product on premises or by moving the product off site under company control;

2. Remind the establishment that it cannot complete pre-shipment review until negative test results are received; and

3. Inform the establishment that FSIS has prepared FSIS Compliance Guidelines for Controlling Meat and Poultry Products Pending FSIS Test Results.

B. IPP are to document the discussion in a Memorandum of Interview (MOI) as set out in FSIS PHIS Directive 5000.1, Verifying an Establishment's Food Safety System.

C. Each time IPP collect samples tested for adulterants, they are to verify that establishments are holding or controlling product and record the information in Public Health Information System (PHIS) when they collect the sample as:

1. Yes, on-site;

2. Yes, off-site under company control; or

3. No.

D. If an establishment does not hold or maintain control of product tested by FSIS for adulterants, IPP are to immediately contact the District Office (DO). The DO may instruct IPP to write a Non-compliance Record (NR) because the establishment shipped product before FSIS found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as set out in 9 CFR417.5(c).

E. If IPP have concerns regarding how establishments are holding or controlling the product, they are to contact the DO.

F. IPP are to continue to notify establishments about when IPP plan to collect a sample as set out in:

1. FSIS Directive 10,010.1, Verification Activities for *Escherichia coli* O157:H7 in Raw Beef Products;

2. FSIS Notice 40-12, FSIS Verification Testing for Non-O157 Shiga Toxin-Producing *Escherichia Coli* (Non-O157 STEC) under MT60, MT52, And MT53 Sampling Programs;

1. FSIS Directive 10,240.4, Verification Procedures for Consumer Safety Inspectors for the *Listeria monocytogenes* (*Lm*) Regulation and *Lm S*ampling Programs; and

2. FSIS Directive 10,800.1, Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program.

G. Whenever IPP are notified that a sample has been discarded and will not be analyzed by the FSIS laboratory and product is being held on-site or controlled off-site, IPP are to immediately notify the establishment so it can release the product.

IV. EIAO RESPONSIBILITIES

A. Each time EIAOs collect samples (e.g., for the Routine Risk-based Listeria monocytogenes (RLM) Sampling or Intensified Verification Testing (IVT)), they are to determine whether establishments are holding and controlling product that FSIS tested for adulterants.

B. EIAOs are to document in an MOI whether the establishment holds or maintains control of product tested by FSIS.

D. If the EIAO finds that the establishment does not hold or maintain control of product tested by FSIS, he or she is to recommend to the in-plant supervisory personnel that the inspection team issue an NR because the establishment shipped product before FSIS found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as set out in 9 CFR417.5(c). When recommending the issuance of an NR, the EIAO is to follow the instructions in chapters 3, 13, and 15 in FSIS Directive 5,100.1, EIAO Food Safety Assessment Methodology.

C. EIAOs are to continue to notify establishments about when they plan to collect a sample as set out in:

1. FSIS Directive 10,240.5, Verification Procedures for Enforcement, Investigations and Analysis Officers (EIAOs) for the *Listeria monocytogenes* (*Lm*) Regulation and Routine Risk-Based *Lm* (RLm) Sampling Program; and

2. FSIS Directive 10,300.1, Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces, and Environmental Surfaces for *Lm*.

V. OFFICE FIELD OPERATIONS, DO AND OFFICE OF PROGRAM EVALUATION, ENFORCEMENT AND REVIEW (OPEER), COMPLIANCE INVESTIGATION DIVISION (CID), REGIONAL OFFICE (RO) RESPONSIBILITIES

A. If IPP or EIAOs inform the DO that an establishment did not hold or maintain control of product tested by FSIS for adulterants, the DO is to take the appropriate administrative action (i.e., immediately withhold inspection or issue a Notice of Intended Enforcement Action) . Also, the DO is to contact the appropriate OPEER, CID, Regional Director (RD).

B. OPEER, CID RD, in consultation with headquarters, will consider whether additional enforcement actions or sanctions when necessary.

VI. QUESTIONS

Direct all questions regarding this notice to the Risk, Innovations, and Management Division through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter **Notice 07-13 Control of Agency Tested Product for Adulterants**
Question Field:	Enter question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **Sampling** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press the **Submit** button.

Assistant Administrator
Office of Policy and Program Development