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

FSIS DIRECTIVE	12,700.1 Rev. 1	11/25/08

OPERATIONS OCCURRING OUTSIDE APPROVED HOURS

I. PURPOSE

This directive instructs inspection program personnel (IPP) from the Office of Field Operations (OFO) on how to respond when an official establishment conducts operations or activities that require inspection outside of its approved hours of operation without inspection coverage. This directive also instructs IPP from the Office of International Affairs (OIA) on how to respond when an official import inspection facility operates without inspection.

II. CANCELLATION

FSIS Directive 12,700.1, Operations Occurring Outside Approved Hours, dated 11/6/2008

III. REASON FOR REISSUANCE

FSIS is reissuing this directive in its entirety to correct the statutory citations related to adulteration of products.

IV. REFERENCES

21 U.S.C. 453, 455, 456, 458, 601, 604, 606, 608, 610, 621, 1034, 1035, 1036, and 1037
9 CFR Sections 301.2, 307.4, 317.1, 327.6, 327.10, 381.1, 381.37, 381.136, 381.195(b), 381.199, 381.204, 416.1, 417.2(e), 500, 500.2, 590.22, 590.24, 590.160, 590.124, 590.420, 590.426, and 590.504
FSIS Directive 5000.1, Verifying an Establishment's Food Safety System
FSIS Directive 8080.1, Recall of Meat and Poultry Products
FSIS Directive 8410.1, Detentions and Seizure
FSIS Directive 12600.2, Reimbursable Overtime Inspection Services at Meat and Poultry Establishments

V. BACKGROUND

The Federal Meat Inspection Act, 21 U.S.C. 610(c)(2), the Poultry Product Inspection Act, 21 U.S.C. 458(a)(2)(B)(2), and the Egg Products Inspection Act, 21 U.S.C. 1037(b)(2), prohibit the sale, offering for sale or transportation, or receipt for transportation, in commerce, of any article required to be inspected, unless the article has been inspected and passed or is exempt from the inspection requirements of the statutes.

The District Manager (DM), OFO, or the Regional Import Field Office (RIFO) supervisor, OIA, approves each official establishment's work schedule in accordance with 9 CFR 307.4(d)(1), 381.37(d)(1), or 590.124. The establishment is to consistently maintain the approved work schedule in accordance with 9 CFR 307.4(d)(2), 381.37(d)(2), or 590.124.

IPP are to provide inspection coverage in accordance with 9 CFR 307.4(a), 381.37(a), or 590.24. IPP are to follow the instructions set out in FSIS Directive 12600.2, Reimbursable Overtime Inspection Services at Meat and Poultry Establishments to determine those operations or activities that require inspection coverage. If operations or activities requiring inspection coverage occur outside of approved hours, FSIS may take a withholding action or suspend inspection without providing the establishment prior notification, because products produced without inspection are considered adulterated because they are unfit for human food (21 U.S.C. 453(g)(3); 601(m)(3); and 1033(a)(3)). These products cannot enter commerce because they have not been inspected and found to be not adulterated and capable for use as human food as is required under 21 U.S.C. 604 and 606, 21 U.S.C. 455(b), and 21 U.S.C. 1034(a). Further, if products produced without inspection bear the marks of inspection, they are misbranded under 21 U.S.C. 601(n)(1), 21 U.S.C. 453(h)(1) and 21 U.S.C. 1036.

VI. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. If IPP determine that operations or activities requiring inspection have occurred outside the approved hours without inspection coverage in an official meat or poultry establishment or an official import establishment, they are to take the following steps.

1. Immediately meet with plant management to discuss the issue. Document the conversation and other pertinent facts on a memorandum of interview (MOI). Cite regulations 9 CFR 307.4(a) or 381.37(a), as appropriate, in the MOI.

2. Contact the District Office (DO) or RIFO/OIA, through supervisory channels, to advise them about the situation. The DM or designee will decide whether this violation requires the initiation of a suspension under 9 CFR 500.3(a)(1). The RIFO/OIA is to contact the Deputy Director of Operations (DDO), OIA.

a. If the DM or designee decides to suspend the establishment, it will be notified as set out in 9 CFR 500.5(a). The establishment is then afforded an opportunity to provide immediate and corrective action and further planned preventive action.

b. If the DM or designee decides not to suspend inspection, he or she will provide a letter to the establishment regarding the serious nature of producing products without inspection.

3. For product produced outside of approved hours without inspection coverage that is labeled with the marks of inspection, IPP are to retain the meat or poultry products under 9 CFR 500.2(a)(2) if the products are still at the establishment. Notify the DO or RIFO through supervisory channels, when adulterated or misbranded meat or poultry products may have entered into commerce. FSIS may request a voluntary recall, detain or seize the product in commerce. IPP are to follow the recall instructions found in FSIS Directive 8080.1, Recall of Meat and Poultry Products. For products produced outside the approved hours without inspection coverage which are not labeled with the marks of inspection, verify that the product does not receive the marks of inspection. For products prepared without inspection coverage to which labels are applied bearing the marks of inspection, verify that the marks are removed completely. Verify that any product produced or prepared without inspection coverage is disposed of appropriately. Appropriate disposition includes denaturing and being diverted into inedible rendering, or denaturing and disposal at landfill.

NOTE: Product produced or prepared without inspection coverage is not eligible for donation into human food channels or for sale into pet food or other animal feed channels.

B. If inspection program personnel determine that operations requiring inspection have occurred outside the approved hours in an egg product plant, they are to follow the procedures below.

1. Immediately meet with plant management to discuss the issue. Document the conversation and other pertinent facts on a MOI. Cite regulation 9 CFR 590.24 and attach the completed MOI to PY-203, *Daily Report of Plant Operations,* for liquid egg product processing plants, or PY-159*, Daily Report of Egg Drying Operations,* for dried egg product plants (for noncompliance with 9 CFR 590.160(f)(1)(ii)).

2. Contact the DM, through supervisory channels, to advise him or her about the situation. The DM or designee will decide whether this violation requires the initiation of a suspension under 9 CFR 590.160.

3. Retain egg products under 9 CFR 590.426, if the product is still at the plant. Notify the DO, through supervisory channels, when adulterated or misbranded egg product may have entered into commerce. For products produced outside the approved hours without inspection coverage which are not labeled with the marks of inspection, verify that the product does not receive the marks of inspection. For products prepared without inspection coverage to which labels are applied bearing the marks of inspection, verify that the marks are removed completely. Verify that any product produced or

prepared without inspection coverage is disposed of appropriately. Appropriate disposition includes denaturing and being diverted into inedible product or denaturing and disposal at landfill.

NOTE: The Food Drug Administration (FDA) conducts recalls of egg product in commerce. The DO/OFO will contact the FDA liaison as needed.

C. If IPP become aware that non-official establishments are producing amenable products for commerce without inspection, they are to immediately inform their supervisor of this fact.

VII. FRONTLINE SUPERVISOR OR REGIONAL IMPORT FIELD SUPERVISOR (RIFS) RESPONSIBILITIES

A. Frontline supervisors (FLS) are to ensure that IPP take the appropriate action, document findings on a MOI, and follow the DM's instructions. If FLS are advised by IPP that non-official establishments are producing amenable products for commerce without inspection, they are to contact the appropriate Office of Program Evaluation, Enforcement and Review, Regional Manager.

B. The RIFSs are to ensure that import inspectors take the appropriate action, document findings on a MOI, and follow the DDO's instructions.

VIII. DM or DDO RESPONSIBILITIES

A. After evaluating the circumstances in an incident in which an establishment has been found to be operating outside of official hours, the DM or DDO is to decide whether to notify the establishment that he/she is suspending inspection without notice under 9 CFR 500.3 (a)(1) or 9 CFR 590.160 because the establishment produced and shipped adulterated or misbranded product.

B. The DM and RIFO or designees are to follow the instructions in FSIS Directive 8410.1, Detention and Seizures, and contact the appropriate OPEER Regional Office for product that has entered commerce.

C. The DM, RIFO, and the RM/OPEER, as appropriate, are to collaborate on follow-up investigations or other actions.

Refer questions regarding this directive to the Policy Development Division through askFSIS at http://askfsis.custhelp.com or by telephone at 1-800-233-3935. Direct other questions through supervisory channels.

Assistant Administrator
Office of Policy and Program Development