

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

FSIS DIRECTIVE

5420.1,
Revision 4

1/7/08

HOMELAND SECURITY THREAT CONDITION RESPONSE - FOOD DEFENSE VERIFICATION PROCEDURES

I. PURPOSE

A. This directive details the emergency Food Defense Verification Procedures that inspection program personnel will follow when the Department of Homeland Security declares a threat condition Yellow, Orange, or Red.

B. This directive also:

- establishes how threat condition declarations will be communicated to field personnel;
- provides specific instructions to field personnel on how to respond to threat condition declarations;
- identifies procedures to effectively address and resolve noted security concerns in order to ensure that food is protected, thereby protecting public health; and
- provides instructions for the Inspector-in-Charge (IIC) when checking to see if an establishment has developed, implemented, tested, and assessed, and maintains, a food defense plan.

C. If there is an actual terrorist attack on the establishment or surrounding area, the IIC will immediately take measures to make sure inspection program personnel are safe and will notify the District Office (DO). The DO will then notify the appropriate local authorities. In addition, the DO may request the activation of the Food Safety and Inspection Service (FSIS) Emergency Management Committee (EMC) through the senior executive leadership in the Office of Field Operations (OFO) (see FSIS Directive 5500.2, Revision 1, Non-Routine Incident Response).

II. CANCELLATION

FSIS Directive 5420.1, Revision 3, Amendment 1, Homeland Security Threat Condition Response – Food Defense Verification Procedures, dated 9/7/06

III. REASON FOR REISSUANCE

FSIS is reissuing this directive in its entirety to provide inspection program personnel with instructions for documenting food defense verification procedures in the Performance-Based Inspection System (PBIS). The directive also instructs inspection program personnel to update the food defense profile extension when an establishment develops and implements a food defense plan.

IV. REFERENCES

9 CFR part 300 to end
FSIS Directive 5500.2, Non-Routine Incident Response

V. BACKGROUND

In 2002, the White House Office of Homeland Security established a Homeland Security Advisory System based on threat condition color. This System provides a comprehensive and effective means to disseminate information regarding the risk of terrorist acts to Federal, State, and local authorities, and to the American people. A declaration of a Threat Condition Elevated (Yellow) by the Department of Homeland Security indicates there is an elevated risk of terrorist attacks. A declaration of a Threat Condition High (Orange) indicates there is a high risk of terrorist attacks. A declaration of a Threat Condition Severe (Red) reflects a severe risk of terrorist attacks. While the threat may or may not involve the nation's food supply, it is imperative that inspection program personnel take certain actions immediately during any such threat condition to ensure the safety of meat, poultry, and egg products. Given what is required in responding to a credible threat of a terrorist attack, inspection program personnel must clearly understand their roles and what will be required of them to respond properly to that threat.

VI. NOTIFICATION

A. In the event of a declaration of any threat condition:

- Elevated (Yellow), when there is an elevated risk of terrorist attacks
- High (Orange), when there is a high risk of terrorist attacks, or
- Severe (Red), when there is a severe risk of terrorist attacks,

by the Department of Homeland Security, FSIS' Office of Food Defense and Emergency Response (OFDER) will inform the FSIS Administrator and FSIS Management Council. OFDER will issue an e-mail letter to all employees notifying them of the heightened threat condition.

NOTE: IICs are to make sure a copy of the e-mail letter is available to food inspectors.

B. OFDER will issue an e-mail letter to all employees notifying them of the downgrading of a threat condition. The IIC will advise the establishment management that procedures at the lower threat condition have resumed.

VII. SPECIFIC THREAT CONDITION ACTIVITIES

Inspection program personnel in meat, poultry, and egg products establishments are to perform the Food Defense Verification Procedures instead of certain other scheduled non-food safety consumer protection procedures.

NOTE: Inspection program personnel assigned to meat and poultry establishments will continue to perform food safety activities assigned by PBIS. Inspection program personnel assigned to egg products establishments will continue to perform food safety activities as directed by current regulations and policy.

A. Threat Condition Elevated (Yellow), High (Orange), or Severe (Red) with no specific threat to the food and agricultural sector.

1. When the threat condition is elevated (Yellow), high (Orange), or severe (Red) with no specific threat to the food and agricultural sector, inspection program personnel in meat and poultry establishments are to randomly perform one of the Food Defense Verification Procedures listed in Section IX., Inspection System Procedure (ISP) codes 08S14-08S17, per **day** for the duration of the threat condition. They are to perform this procedure instead of:

a. a scheduled non-food safety 04 procedure; or

b. if an 04 procedure is not scheduled for that day, a scheduled food safety 01 or 02 procedure. To determine the product for which the scheduled 01 or 02 will not be performed, inspection program personnel are to use the chart in Attachment

1. Procedures for products with the lowest risk factor are to be replaced first.

2. Inspection program personnel are to perform and record in PBIS, the Food Defense Verification Procedures as UNSCHEDULED procedures within the established tour of duty.

3. IIC's assigned to multi-shift establishments are to use the established information sharing practices to ensure the 08S procedures are performed only once per day, not once per shift. The frequency of alternating the 08S procedure across shifts should be on either a weekly or a bi-weekly basis. The first-line supervisor will provide any necessary oversight.

4. Inspection program personnel in egg products processing establishments are to randomly perform one of the Food Defense Verification Procedures listed in Section IX. B. of this directive. Inspection program personnel are to perform one verification procedure per shift while the threat condition exists.

B. Threat Condition High (Orange) with a specific threat to the food and agricultural sector.

1. When the threat condition is high (Orange) with a specific threat to the food and agricultural sector, inspection program personnel in meat and poultry establishments are to randomly select and perform three of the procedures from the Food Defense

Verification Procedures (ISP codes 08S14-08S17 identified in Section IX. B.) per **shift** for the duration of the threat condition. They are to perform three of the 08S procedure instead of all the scheduled 04 procedures and the number food safety 01 or 02 procedures to ensure that three 08 procedures are performed (up to three 01 or 02 procedures.) To determine the product for which the scheduled 01 or 02 will not be performed, inspection program personnel are to use the chart in Attachment 1. Procedures for products with the lowest risk factor are to be replaced first.

2. Inspection program personnel are to perform, and record in PBIS, the Food Defense Verification Procedures as UNSCHEDULED procedures within the established tour of duty.

3. Inspection program personnel in egg products processing establishments are to randomly perform three of the procedures from the Food Defense Verification Procedures per shift for the duration of the threat condition within their established tour of duty.

C. Threat Condition Severe (Red) with a specific threat to the food and agricultural sector.

1. When the threat condition is severe (Red) with a specific threat to the food and agricultural sector, inspection program personnel in meat and poultry establishments are to perform ALL of the procedures from the Food Defense Verification Procedures (ISP codes 08S14-08S17) per **shift** for the duration of the threat condition. They are to perform all four 08S procedures instead of all 04 procedures and the number food safety 01 or 02 procedures to ensure that four 08 procedures are performed (up to four 01 or 02 procedures). To determine the product for which the scheduled 01 or 02 will not be performed, inspection program personnel are to use the chart in Attachment 1. Procedures for products with the lowest risk factor are to be replaced first.

2. Inspection program personnel in egg products processing establishments are to perform ALL of the Food Defense Verification Procedures listed in Section IX. B. per shift for the duration of the threat condition within the established tour of duty.

3. The IIC will receive specific instructions from the DO on other measures that he or she is to take based on information received about the specific threat to a product or process. Such measures may include sampling of specific products, if warranted, to protect public health.

4. The DO should deploy inspection program personnel to establishments producing the products named in the threat condition to make sure FSIS has an on-site presence during any type of operational activity.

VIII. FOOD DEFENSE PLAN

A. FSIS has urged establishments to develop functional food defense plans to set out control measures to prevent intentional adulteration of product. Although not required, FSIS considers these plans to be important preparatory measures. The plan should be developed, written, implemented, assessed, and maintained if it is to be functional. The Agency has developed guidelines on the elements of a food defense plan. They are available on the FSIS web site at http://www.fsis.usda.gov/pdf/Elements_of_a_Food_Defense_Plan.pdf.

B. An establishment is not obligated to share a copy of its written plan to inspection program personnel. If an establishment does share the plan, inspection program personnel should only use the plan to help them readily identify how the establishment is addressing food defense. If the establishment is not implementing elements of its plan, inspection program personnel cannot take action on that fact because there are not requirements for such plans. Inspection program personnel are not to show or share the plan with any outside source because it may contain sensitive security information.

NOTE: When establishment management develops and implements a new food defense plan, or when management revises an existing food defense plan, inspection program personnel are to update the responses to the food defense profile extension in PBIS.

IX. FOOD DEFENSE VERIFICATION PROCEDURES

A. The purposes of the following Food Defense Verification Procedures are to identify potential vulnerabilities in the security of an establishment that could lead to deliberate contamination. A potential vulnerability can be any part of the food production system where a measure should be implemented to protect it from deliberate contamination, but such a measure is found to be missing or not in place. Examples of potential vulnerabilities include:

- uncontrolled access to a restricted ingredient area;
- unrestricted access to a processing room; or
- unrestricted access to water systems.

B. At a minimum, the IICs will:

1. Water systems – 08S14

(a) observe the security of the plant's water systems, especially well water, ice storage facilities, and water reuse systems;

(b) pay special attention to water used to prepare injection solutions and water and ice used in emulsification (for the production of deli meats and hot dogs); and

(c) to a lesser extent, check water used to prepare surfactant, antimicrobial agent sprays, and chill tank recharge.

Suggested Activities:

Determine whether the establishment:

- controls access to private wells;
- appropriately secures potable water lines or storage tanks; and
- appropriately secures ice storage facilities.

2. Processing/Manufacturing – 08S15

(a) observe production processes (e.g., raw product handling, processing, and packaging of final product) in which exposed products are being handled for indications of attempts to introduce contaminants into the product;

(b) observe, in particular, operations where the establishment mixes bulk products (e.g., process monitoring by establishment personnel at balance tanks, grinding/emulsification of meat and poultry products, solution injection in preparation areas, and liquid egg product tanker loading areas); and

(c) observe whether the plant has procedures in place to prevent deliberate contamination (e.g., camera surveillance, closed systems, or restricted access of personnel to sensitive production areas.)

Suggested Activities:

- Check a production process (e.g., ground beef production area; egg products breaking room) for evidence of possible intentional product contamination.
- Check to determine whether the plant has implemented a system to restrict access to sensitive processing areas where bulk products are mixed or processed (e.g., camera surveillance, color-coded uniforms, identification badges, and sign-out sheets).
- Check calibration of equipment (if any) used to dispense restricted ingredients.

3. Storage Areas – 08S16

(a) observe products in cold and dry storage areas for evidence of tampering;

(b) pay special attention to bulk product ingredients that will undergo mixing, such as combo bins of meat trim and poultry parts used for grinding or emulsification;

(c) check dry ingredients, including spices, breading materials, and those used in injection solution preparations, for indication of tampering;

(d) observe the use and storage of any hazardous materials in the establishment;

(e) verify whether entry into such storage areas is controlled and that usage logs are maintained and current;

(f) pay special attention to cleaning materials, particularly those used in clean-in-place systems;

(g) pay special attention to areas where bulk products are mixed (e.g., storage silos); and,

(h) verify the control of laboratory reagents and cultures.

Suggested Activities:

Verify that the establishment has implemented:

- access control procedures to dry ingredient areas;
- access control procedures to raw product storage areas;
- access control procedures to finished product storage areas;
- control procedures for access and use of hazardous chemicals; and
- observation procedures of all products in storage for evidence of tampering.

4. Shipping and Receiving – 08S17

(a) observe loading dock areas and vehicular traffic in and out of the establishment;

(b) report immediately all unattended deliveries on loading docks and unmarked vehicles parked on the premises to establishment management;

(c) verify that the establishment secures, when possible, dry and cold products stored in on-site trailers and parks the trailers in a restricted access area of the facility;

(d) verify that the facility security staff routinely check the trailers' physical integrity (e.g., locks, seals, and general condition); and

(e) pay special attention to deliveries of liquid egg products to storage silos, combo bins of meat trim, and dry ingredients.

Suggested Activities:

- Check to determine whether the plant has procedures in place to restrict or control access to the loading dock area and verify that the plant has implemented these access control procedures.
- Observe incoming raw materials to verify that the establishment checks deliveries against shipping documents. Pay special attention to tanker trucks and totes of liquid egg products, dry ingredients, combo bins of fresh meat trim or poultry parts, and boxes of frozen trim that the establishment will ship for further processing.

X. DOCUMENTING FOOD DEFENSE VERIFICATION ACTIVITIES

PBIS

A. Inspection program personnel are to record the performance of the ISP procedures listed in Section IX. and document findings in the following manner:

1. When inspection program personnel perform an O8S procedure and do not find a food defense vulnerability or concern, they are to record the procedure as performed by recording trend indicator “A.”

2. When inspection program personnel perform an O8S procedure and find that there **is** a food defense vulnerability or food defense concern, but that there is **no** evidence of consequential product adulteration, they are to record the procedure as performed by recording trend indicator “S.” If there **is** evidence of product adulteration, inspection program personnel are to record trend indicator “T.” After recording the “S” or “T” trend indicator, inspection program personnel are to:

- a. verbally notify establishment management and discuss the findings;

NOTE: This can take place at the next weekly meeting.

- b. if “T” is recorded under the appropriate ISP code, complete an NR for the product adulteration; and

- c. complete FSIS Form 5420-1, Food Defense Memorandum of Interview, in PBIS and record the plant response after discussing the findings.

3. When trend indicator “S” or “T” is entered in PBIS, the Vulnerability Report section of the screen is activated. Once this screen is activated, inspection program personnel are to:

- a. click on the down arrow next to the Occurrence field and select:
 - i. “1 (First)”, if this is the first occurrence of this vulnerability,
 - ii. “2 (Second)”, if this is the second occurrence, or
 - iii. “3 (Third)”, indicating the third occurrence;

NOTE: For a finding to be reported as the second or third occurrence of a vulnerability, it must be for the same vulnerability under the performed 08 food defense procedure as occurred previously.

b. verify the name of the inspection program personnel that appears in the Inspector field to ensure that it is the name of the person who performed the procedure. To change the name:

i. click the magnifying glass icon next to the name field to open the Change Name Window,

ii. click the Browse button,

iii. select the appropriate name from the list, and

iv. click the Select button;

c. select applicable vulnerabilities by clicking the box adjacent to the vulnerability statement;

d. enter management's response to each vulnerability selected in the Est Mgmt Response section; and

NOTE: The changes to the form can be made and saved.

e. review the information entered, make changes if necessary, and then click Save.

B. Inspection program personnel are responsible for providing plant management with a copy of the completed FSIS Form 5420-1, Food Defense Memorandum of Interview. To print FSIS Form 5420-1 in PBIS, inspection program personnel are to:

1. Print from the Procedure Results screen by highlighting the appropriate 08 procedure and click the Print button; or

2. Print from the PBIS pull-down menu:

a. select Reports/Results/Vulnerability Report;

b. select the date range;

c. select the establishment/shift, then click OK, and a new window will appear;

d. select one or more vulnerability reports from the list and click OK; then

e. select the report destination. Enter S for screen, P for printer, or R for an RTF file, then click OK.

Daily Report of Plant Operations (egg products establishments)

A. Inspection program personnel assigned to egg products establishments are to:

1. record the performance of the food defense verification activities in the "Remarks" section of the "Daily Report of Plant Operations" (PY-203 for liquid egg products and PY-159 for dried egg products);

2. complete FSIS Form 5420-1, Food Defense Memorandum of Interview (found at: Outlook/Public Folders/All Public Folders/Agency Issuances/Forms/FSIS Forms 5,000 series) and record the plant response after discussing the findings;

3. provide a copy of the form to plant management;

4. electronically send a copy to the district analyst and the IF-OFDER mailbox in Outlook, or Fax a copy to OFDER at 202-690-5634; and,

5. attach a copy of the form to the "Daily Report of Plant Operations" and maintain it in the file.

B. The establishment is not under any regulatory obligation to respond. After meeting with plant management and completing FSIS Form 5420-1, inspection program personnel do not need to verify how the establishment addresses the situation. Inspection program personnel are to continue the random selection of food defense procedures as instructed in Section VIII.

XI. MULTIPLE OCCURRENCES OF THE SAME FOOD DEFENSE VULNERABILITY

A. If inspection program personnel encounter a second occurrence of a potential food defense vulnerability or concern, they are to meet with the establishment management and complete a second MOI on this vulnerability. Inspection program personnel are to note on the MOI that this is the second occurrence of this vulnerability.

NOTE: As stated above, the occurrence must be for the same vulnerability under the performed 08 procedure.

B. If inspection program personnel encounter the potential food defense vulnerability or concern for a third time, they are to meet once again with the establishment management, complete a third MOI, and note on the MOI that it is the third occurrence of this vulnerability.

C. If the establishment expresses no intention to address the vulnerability or concern, inspection program personnel are to notify the DO of this situation through the Front-line Supervisor. Inspection program personnel are not to further review or document the specific potential vulnerability identified in the three repeat MOIs until the DO provides further instructions. If the procedure is randomly selected, inspection program personnel are to direct verification procedures to establishment activities other than the one identified in the third MOI.

D. The DO will request OFDER to conduct an assessment of the repeat findings.

E. OFDER's assessment will include:

1. a review of the results of the Food Defense Plan Survey to determine whether the establishment has a functional food defense plan in place;

2. an assessment of the level of concern that the repeat findings present; and

3. a determination as to whether the establishment has been afforded sufficient time to mitigate the vulnerability.

F. OFDER will provide the DO with the results of its assessment and a recommendation as to what further action is necessary. The results and recommendations may be:

1. that, because of the nature of the vulnerability, no specific action by the Agency is needed, and inspection program personnel are to no longer consider the situation a vulnerability; or

2. that OFDER will provide the establishment with specific guidance on how it can address the vulnerability.

G. The DO is to forward OFDER's results, recommendation, and any accompanying materials to inspection program personnel through the Front-line Supervisor.

H. Inspection program personnel are to meet with the establishment management to discuss OFDER's results and recommendation. If OFDER provided guidance on how to address the vulnerability more effectively, inspection program personnel are to present that and any material forwarded by OFDER to the establishment. Inspection program personnel are to document what was discussed at this meeting on the third MOI.

I. Inspection program personnel will provide a copy of the third MOI and the discussion notes to the DO through the Front-line Supervisor. The DO will forward a copy to the IF-OFDER mailbox.

XII. ANALYSIS OF THE DATA

OFDER-HQ personnel will analyze the data collected by inspection program personnel through this notice to track trends in the types of verification activities resulting in an MOI. The analyses will include examining trends in the rate of MOIs and will report follow-up activities conducted by districts to any MOIs. Furthermore, the analyses will inform future guidance and policy regarding performing food defense verification activities.

Refer questions to the Policy Development Division at 1-800-233-3935.



Assistant Administrator
Office of Policy, Program, and Employee Development

Product/Process Risk

NOTE: The products are listed in descending order of risk.

FINISHED PRODUCT TYPE	ISP Code
Raw intact beef	03C
Raw intact pork	03C
Raw intact meat – other	03C
Raw intact chicken	03C
Raw intact turkey	03C
Raw intact poultry – other	03C
Raw ground, comminuted, or otherwise non-intact beef	03B
Raw ground, comminuted, or otherwise non-intact pork	03B
Raw ground, comminuted, or otherwise non-intact meat – other	03B
Raw ground, comminuted, or otherwise non-intact chicken	03B
Raw ground, comminuted, or otherwise non-intact turkey	03B
Raw ground, comminuted, or otherwise non-intact poultry - other	03B
Raw otherwise processed meat	03E, 03H,03I
Raw otherwise processed poultry	03E, 03H,03I
RTE fermented meat (without cooking)	03E
RTE fermented poultry (without cooking)	03E
RTE dried meat	03E, 03F
RTE dried poultry	03E, 03F
RTE salt-cured meat	03E, 03I
RTE salt-cured poultry	03E, 03I
RTE fully-cooked meat	03G
RTE fully-cooked poultry	03G
RTE meat, fully-cooked, without subsequent exposure to the environment	03G
RTE poultry, fully-cooked, without subsequent exposure to the environment	03G