

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

FSIS DIRECTIVE	5420.1, Revision 5	7/20/09
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**HOMELAND SECURITY THREAT CONDITION RESPONSE -
RISK-BASED FOOD DEFENSE VERIFICATION PROCEDURES**

I. PURPOSE

This directive establishes a risk-based approach for food defense verification procedures that Inspection Program Personnel (IPP) are to perform when the Department of Homeland Security declares a Threat Condition.

Key Points Covered

- a risk-based approach for scheduling food defense verification procedures
- how Threat Condition declarations will be communicated to field personnel;
- how to respond to Threat Condition declarations;
- how to effectively address and resolve noted security concerns in order to ensure that food is protected, thereby protecting public health; and
- how to determine if an establishment has developed, implemented, tested, and assessed, and maintains, a food defense plan.

II. CANCELLATION

FSIS Directive 5420.1, Revision 4, Homeland Security Threat Condition Response – Food Defense Verification Procedures, dated 1/7/08

III. REASON FOR REISSUANCE

FSIS is reissuing this directive in its entirety to provide IPP with new frequencies for verifying a risk-based approach to Food Defense Verification Procedures.

DISTRIBUTION: Electronic

OPI: OPPD

IV. REFERENCES

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

V. BACKGROUND

In 2002, Homeland Security Presidential Directive 3 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 (DHS) 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. HSPD 3 also prescribes that protective actions be taken at each threat level condition. While the threat may or may not involve the nation's food supply, it is imperative that IPP take certain protective 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, IPP are to understand their roles and what will be required of them to respond properly to that threat.

VI. NOTIFICATION

A. If DHS declares an elevated Threat Condition, FSIS's Office of Data Integration and Food Protection (ODIFP) will inform the FSIS Administrator and FSIS Management Council. ODIFP will issue an e-mail letter to all employees notifying them of the heightened Threat Condition.

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

B. ODIFP will also issue an e-mail letter to all employees notifying them of the downgrading of a Threat Condition. The IIC will advise the establishment management of the change in Threat Conditions.

VII. THREAT CONDITION ACTIVITIES

A. All IPP (e.g., those in meat and poultry establishments and egg product plants) are to perform Food Defense Verification Procedures (08S) listed in Section X., Inspection System Procedure (ISP) codes 08S14-08S17.

B. IPP in meat and poultry establishments are to:

1. perform the 08S procedures at the frequency prescribed in Section VIII, Table 1.
2. record in PBIS, the 08S procedures as UNSCHEDULED procedures within the established tour of duty. If IPP need to replace procedures in order to perform the 08S procedures, first they are to replace scheduled 04 procedures and, if necessary, they are

to replace HACCP 01 procedures to ensure that the number of prescribed 08S procedures are performed. IPP are to refer to the chart in Attachment 1 to prioritize which HACCP procedures to replace, if necessary. If there are multiple scheduled HACCP procedures, select the ones for the lowest risk type of product as listed in the chart in Attachment 1.

C. IPP in egg product plants are to perform the 08S procedures at the frequency prescribed in Section IX., Table 2.

D. All IPP are to enter a result code “3” in PBIS for any scheduled procedure that they replace with a 08S procedure.

E. IICs assigned to multi-shift establishments are to use the established information sharing practices to ensure that the 08S procedures are performed on the prescribed risk-based frequencies. The frequency of alternating the 08S procedure across shifts should be on either a weekly or a bi-weekly basis. The Frontline Supervisor (FLS) will provide any necessary oversight.

F. Under a Threat Condition Red with a specific threat to food or agriculture, the IIC will receive specific instructions from the District Office (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. The DO is to deploy IPP 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. FREQUENCY AND NUMBER OF 08S PROCEDURES IN MEAT AND POULTRY PRODUCTS ESTABLISHMENTS

TABLE 1	Frequency and Number 08S Procedures		
	VULNERABILITY	All Threat Conditions, No Specific Threat to Food or Ag	Threat Condition ORANGE with Specific Threat to Food or Ag
High Risk Products/High Volume	3 per week 1 per week*	4 per day	4 per day
High Risk Products/Low Volume	1 per week 1 every other week*	2 per day	4 per day
Low Risk Products/Any Volume	1 per week 1 every other week*	2 per day	4 per day

*This number and frequency is for establishments that have a functional Food Defense Plan as listed in the plant profile.

NOTE: IPP are to perform one 08S procedure per week in establishments that operate 2 days or less per week.

A. RISK DEFINITIONS FOR TABLE 1

1. High-risk products include all products under 03B, 03C, 03E, 03F, 03G, 03H, and 03I.

2. Low-risk products include all other product categories not listed in 1 above.

B. VOLUME DEFINITIONS FOR TABLE 1

1. High volume establishments are those producing more than 3 million pounds per year (total of meat and poultry products produced).

2. Low volume establishments are those producing less than 3 million pounds per year (total of meat and poultry products produced).

IX. FREQUENCY AND NUMBER OF 08S PROCEDURES IN EGG PRODUCT PLANTS

TABLE 2	Frequency and Number 08S Procedures		
VULNERABILITY	All Threat Conditions, No Specific Threat to Food or Ag	Threat Condition ORANGE with Specific Threat to Food or Ag	Threat Condition RED with Specific Threat to Food or Ag
Egg Products/High Volume	3 per week 1 per week*	4 per day	4 per day
Egg Products /Low Volume	1 per week 1 every other week*	2 per day	4 per day

*This number and frequency is for establishments that have a functional Food Defense Plan as listed in the plant profile.

NOTE: IPP are to perform one 08S procedure per week in establishments that operate 2 days or less per week.

A. VOLUME DEFINITIONS FOR TABLE 2

1. High volume establishments are those producing more than 2 million pounds per year (total of all egg products produced).

2. Low volume establishments are those producing less than 2 million pounds per year (total of egg products produced).

X. 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 with IPP. If an establishment does share the plan, IPP are only to 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, IPP cannot take action on that fact because there is no regulatory requirement for such plans. IPP 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, IPP are to update the responses to the food defense profile extension in PBIS.

XI. FOOD DEFENSE VERIFICATION PROCEDURES

A. The purpose of the following Food Defense Verification Procedures is to identify potential weaknesses in the food security of an establishment that could make it vulnerable to deliberate contamination. A potential weakness 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 weaknesses include:

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

B. At a minimum, IPP are to:

1. Water systems – 08S14

(a) observe the security of the establishment'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

(c) observe whether the establishment 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) for evidence of possible intentional product contamination.
- Check to determine whether the establishment 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, 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 storage silos, combo bins of meat trim, and dry ingredients.

Suggested Activities:

- Check to determine whether the establishment has procedures in place to restrict or control access to the loading dock area and verify that the establishment 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, dry ingredients, combo bins of fresh meat trim or poultry parts, and boxes of frozen trim that the establishment will ship for further processing.

XII. DOCUMENTING FOOD DEFENSE VERIFICATION ACTIVITIES

PBIS

A. IPP are to record the performance of the O8S procedures and document findings in the following manner:

1. When IPP 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 IPP 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, IPP are to record trend indicator “T.” After recording the “S” or “T” trend indicator, IPP are to:

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

b. verbally notify establishment management and discuss the findings;

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

c. complete FSIS Form 5420-1, Food Defense Memorandum of Interview, in PBIS and record the establishment 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, IPP 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 is to be for the same vulnerability under the performed O8S procedure as occurred previously.

b. verify the name of the IPP 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, if any, to each vulnerability selected in the Est Mgmt Response section; and

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

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

1. Print from the Procedure Results screen by highlighting the appropriate O8S 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.

XIII. MULTIPLE OCCURRENCES OF THE SAME FOOD DEFENSE VULNERABILITY

A. If IPP encounter a second occurrence of a potential food defense vulnerability or concern, they are to meet with the establishment management and complete a second FSIS Form 5420-1 regarding this vulnerability. IPP are to note on the FSIS Form 5420-1 that this is the second occurrence of this vulnerability.

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

B. If IPP 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 FSIS Form 5420-1, and note on the form that it is the third occurrence of this vulnerability.

C. If the establishment expresses no intention to address the vulnerability or concern, IPP are to notify the DO of this situation through the FLS. IPP are not to further review or document the specific potential vulnerability identified in the three issuances of FSIS Form 5420-1 until the DO provides further instructions. If the procedure is randomly selected, IPP are to direct verification procedures to establishment activities other than the one identified in the third FSIS Form 5420-1.

D. IPP are to provide a copy of the third FSIS Form 5420-1 and the discussion notes to the DO through the FLS. The DO will forward a copy to the IF-ODIFP mailbox and request an assessment of the reported vulnerability.

E. Within 30 days, ODIFP'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 represent; and
3. a determination as to whether the establishment has been afforded sufficient time to mitigate the vulnerability.

F. ODIFP 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 IPP are to no longer consider the situation a vulnerability; or
2. that ODIFP will provide the establishment with specific guidance on how it can address the vulnerability.

G. After consideration of ODIFP's assessment and any accompanying materials, the DO will forward ODIFP's recommendation to the establishment and inform the IPP at the establishment that ODIFP's recommendation was forwarded.

H. If ODIFP provided guidance on how the establishment can address the vulnerability then at the next weekly meeting, IPP are to meet with the establishment management to inquire about the establishment's next step, if any. IPP are to document what was discussed at this meeting on the third FSIS Form 5420-1.

XIV. DATA ANALYSIS

ODIFP-HQ personnel will analyze the data collected by IPP through this directive to track trends in the types of verification activities resulting in an FSIS Form 5420-1. The analyses will include examining trends in the rate of FSIS Forms 5420-1 and will assess follow-up activities conducted by districts to any FSIS Form 5420-1. The analyses will inform future guidance and policy regarding performing food defense verification activities. At least annually, ODIFP will provide a summary of this analysis to the Assistant Administrator, Office of Field Operations.

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.



Assistant Administrator
Office of Policy and Program Development

Attachment 1

NOTE: Replace scheduled HACCP procedures based on product type beginning at the top and moving downward.

FINISHED PRODUCT TYPE	ISP Codes
Thermally processed, commercially sterile	03D
RTE meat, fully-cooked, without subsequent exposure to the environment	03G
RTE poultry, fully-cooked, without subsequent exposure to the environment	03G
RTE fully-cooked meat	03G
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 poultry	03G
RTE fermented meat (without cooking)	03E
RTE fermented poultry (without cooking)	03E
Raw intact pork	03C, 03J
Raw intact beef	03C, 03J
Raw intact meat – other	03C, 03J
Raw ground, comminuted, or otherwise non-intact pork	03B, 03C
Raw ground, comminuted, or otherwise non-intact meat – other	03B, 03C
Raw otherwise processed meat	03E, 03H,03I
Raw otherwise processed poultry	03E, 03H,03I
Raw intact chicken	03C
Raw intact turkey	03C
Raw intact poultry – other	03C
Raw ground, comminuted, or otherwise non-intact beef	03B, 03C
Raw ground, comminuted, or otherwise non-intact poultry -- other	03B, 03C
Raw ground, comminuted, or otherwise non-intact turkey	03B, 03C

Raw ground, comminuted, or otherwise non-intact chicken

03B, 03C
