

UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC

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# FSIS DIRECTIVE

5420.4  
Revision 6

7/20/11

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**FOOD DEFENSE VERIFICATION AND SURVEILLANCE PROCEDURES  
AND NATIONAL TERRORISM ADVISORY SYSTEM ALERT RESPONSE  
FOR THE OFFICE OF INTERNATIONAL AFFAIRS  
IMPORT INSPECTION DIVISION**

## I. PURPOSE

A. This directive describes the Food Defense Verification Procedures and Food Defense Surveillance Procedures that Food Safety and Inspection Service (FSIS), Office of International Affairs (OIA), Import Inspection Division (IID) personnel are to perform and the frequency with which these procedures are to be performed.

B. On January 27, 2011, the Department of Homeland Security (DHS) announced that it would discontinue the color-coded Threat Conditions of the Homeland Security Advisory System on April 27, 2011, in favor of a new system, the National Terrorism Advisory System (NTAS).

C. This directive also describes additional actions that are required when the DHS issues an NTAS alert.

D. If there is an actual terrorist attack on an in-commerce facility, a facility that handles FSIS-regulated products at a port-of-entry, or an official import inspection establishment, import inspection personnel and Import Surveillance Liaison Officers (ISLOs) will take immediate precautions to ensure their personal safety and to notify appropriate law enforcement officials, their immediate supervisor, and the Assistant Administrator (AA) of OIA. In addition, the OIA senior executive leadership may request the activation of the FSIS Emergency Management Committee (EMC) (see FSIS Directive 5500.2, Significant Incident Response).

### *KEY POINTS:*

- How NTAS alerts are to be communicated;
- How to record any findings and respond to NTAS alerts;
- Procedures to implement Food Defense Verification and Surveillance;
- Procedures and effectively address and resolve noted security concerns to ensure that food is protected, thereby protecting public health; and

- How to determine if a facility has a functional food defense plan.

## **II. CANCELLATION**

FSIS Directive 5420.4, Revision 5, Homeland Security Threat Condition Response – Emergency Procedures for the Office of International Affairs Import Inspection Division, dated 11/17/08.

## **III. REASON FOR REISSUANCE**

FSIS is reissuing this directive to reflect the Department of Homeland Security's National Terrorism Advisory System, which replaced the color-coded Threat Conditions of the Homeland Security Advisory System.

## **IV. REFERENCES**

9 CFR Part 300 to end

FSIS Directive 5420.1, Food Defense Verification Procedures and National Terrorism Advisory System Alert Response for the Office of Field Operations

FSIS Directive 5420.3, Food Defense Surveillance Procedures and National Terrorism Advisory System Alert Response for the Office of Program Evaluation, Enforcement and Review

FSIS Directive 5500.2, Significant Incident Response

FSIS Directive 8010.1, Methodology for Conducting In-Commerce Surveillance Activities

FSIS Directive 8410.1, Detention and Seizure

Homeland Security Presidential Directive/HSPD-9, Subject: Defense of United States Agriculture and Food

Public Health Security and Bioterrorism Act of 2002, Section 332 (21 USC 679C)

Egg Products Inspection Act 21 USC 1048

Federal Meat Inspection Act 21 USC 672

Poultry Products Inspection Act 21 USC 467a

FSIS Directive 9030.1, Targeting for High-Risk Imported Product Shipments

## **V. BACKGROUND**

A. Food defense is the protection of food products from intentional adulteration with chemical, biological, physical, or radiological agents. Food defense is an integral part of FSIS's mission of ensuring that the nation's commercial supply of meat, poultry, and processed egg products is safe, wholesome, and correctly labeled and packaged.

B. Import inspection personnel and ISLOs conduct food defense verification and surveillance tasks to identify potential vulnerabilities in establishments that could lead to or allow deliberate contamination.

C. When the federal government receives information about a specific or credible terrorist threat to food or agriculture, the frequency with which Food Defense Verification and Surveillance Procedures are performed will increase, and additional actions may be

needed to reduce the threat of intentional adulteration of food products. Given what is required to respond to a credible threat of a terrorist attack, import inspection personnel must clearly understand their roles and what will be required of them to respond properly to that threat.

D. Under the new system, DHS coordinates with other federal entities to issue formal, detailed alerts when the federal government receives information about a specific or credible terrorist threat. These alerts include a clear statement that there is an “imminent threat” or “elevated threat.” The alerts also provide a concise summary of the potential threat, information about actions being taken to protect public safety, and recommended steps that individuals, communities, businesses, and governments can take.

E. The NTAS alerts are based on the nature of the threat: in some cases, alerts are sent directly to law enforcement or affected areas of the private sector; while in others, alerts are issued more broadly to the American people through both official and media tools—including a designated DHS webpage ([www.dhs.gov/alerts](http://www.dhs.gov/alerts)), as well as social media channels, including Facebook and Twitter (@NTASAlerts).

F. Additionally, NTAS has a “sunset provision,” meaning that individual threat alerts are issued with a specified end date. Alerts may be extended if new information becomes available or if the threat evolves significantly.

## **VI. NOTIFICATION**

A. If DHS issues an NTAS alert, the FSIS Office of Data Integration and Food Protection (ODIFP) Assistant Administrator (AA) or designee will determine whether the alert affects food or agriculture and, if so, will inform the FSIS Administrator and FSIS Management Council. The ODIFP AA or designee will determine the appropriate distribution of the NTAS alert information and will coordinate with the FSIS Office of Public Affairs and Consumer Education (OPACE) and the other program area AAs or their designees to notify employees, stakeholders, and the public, as appropriate. In the case of a significant incident, the FSIS Emergency Management Committee may be alerted or activated and other response actions taken pursuant to Directive 5500.2.

B. When notified regarding an NTAS alert, the Director of IID or designee will also notify IID personnel (in addition to any notification from ODIFP or OPACE). The Regional Import Field Offices, upon notification by the IID Director or designee of an elevated threat level, will:

1. Ensure that updated personnel contact information is in place and ready for activation;
2. Inform import inspection personnel and the management of official import inspection establishments of the current alert status; and
3. Direct ISLOs to inform management of in-commerce facilities and facilities at ports-of-entry visited during the course of their duties of the current alert status.

C. When an NTAS alert ends, ODIFP will notify the FSIS Administrator and the FSIS Management Council. ODIFP will coordinate with OPACE and the other program area AAs or their designees to notify employees, stakeholders, and the public, as appropriate.

## **VII. FOOD DEFENSE PLAN**

A. FSIS has urged official import inspection establishments, in-commerce facilities, and facilities at ports-of-entry to develop functional food defense plans that set out control measures to prevent intentional adulteration of product. Although a functional food defense plan is not required, FSIS considers these plans to be important preparatory measures. A functional food defense plan has the following characteristics: it is written, the measures described in the plan are implemented, the measures are periodically tested, and the plan is reviewed at least annually and revised if needed. 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/Food\\_Defense\\_&\\_Emergency\\_Response/Guidance\\_Materials/index.asp](http://www.fsis.usda.gov/Food_Defense_&_Emergency_Response/Guidance_Materials/index.asp).

B. When management of in-commerce facilities or facilities (other than official import inspection establishments) at ports-of-entry (“facilities”) develop and implement a new food defense plan, or when management revises an existing food defense plan, ISLOs are to reference this under Block 9 of FSIS Form 5420-3 when they re-visit the facility.

## **VIII. FOOD DEFENSE ACTIVITIES – IMPORT INSPECTORS**

A. Import inspection personnel are to perform one randomly selected Food Defense Verification (08S) Procedure (Inspection System Procedure codes 08S14-08S17) daily as described in Section IX.

B. Import inspection personnel are to record in the Performance-Based Inspection System (PBIS) the 08S procedures as UNSCHEDULED procedures within the established tour of duty.

C. Import inspection personnel assigned to multi-shift establishments are to use the established information sharing practices to ensure that the 08S procedures are performed at the prescribed frequencies.

D. In the case of an NTAS alert identifying an elevated or imminent threat to food or agriculture, the import inspection personnel will receive specific instructions from the Regional Import Field Supervisor (RIFS) 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 RIFS is to deploy import inspection personnel to establishments receiving the products named in the NTAS alert to make sure that FSIS has an on-site presence during any type of operational activity.

E. Should product sampling be warranted, the Office of Public Health Science (OPHS)

will be consulted through proper channels to request laboratory support by the FSIS field labs or the Food Emergency Response Network (FERN) for laboratory testing of product(s) for threat agents.

## **IX. FOOD DEFENSE VERIFICATION PROCEDURES – IMPORT INSPECTORS**

A. The purpose of the following Food Defense Verification Procedures is to identify potential weaknesses in the food defense of an official import inspection establishment that could make it vulnerable to deliberate contamination. A potential weakness can be any part of the system where a measure should be implemented to protect it from deliberate contamination, but where such a measure is found to be missing or not in place. Examples of potential weaknesses include:

1. Unrestricted access to water systems;
2. Unrestricted access to an inspection room; or
3. Uncontrolled access to storage areas.

### **B. Water systems – 08S14**

1. At a minimum, import inspection personnel are to:
  - a. Observe the security of the establishment's water systems, especially well water and ice storage facilities; and
  - b. Pay special attention to water used in defrost tanks and for cleaning and disinfecting.
2. Import inspection personnel should also determine whether the establishment:
  - a. Controls access to private wells;
  - b. Appropriately secures potable water lines or storage tanks; and
  - c. Appropriately secures ice storage facilities.

### **C. Re-inspection/Staging Areas – 08S15**

1. At a minimum, import inspection personnel are to:
  - a. Observe import reinspection areas where exposed products are being handled (e.g., raw and processed product handling); and
  - b. Observe whether the establishment has procedures in place to prevent deliberate contamination (e.g., camera surveillance or restricted access of personnel to areas where food products are stored or handled).
2. Import inspection personnel should also:

- a. Check product for evidence of possible tampering, especially during inspections when product is exposed; and
- b. Check to determine whether the establishment has implemented a system to restrict access to reinspection areas (e.g., camera surveillance, color-coded uniforms, identification badges, or sign-out sheets).

#### D. Storage Areas – 08S16

1. At a minimum, import inspection personnel are to:
  - a. Observe products in cold and dry storage areas for evidence of tampering;
  - b. Pay special attention to bulk products, such as combo bins of meat trim and poultry parts;
  - c. Observe the use and storage of any hazardous materials in the establishment; and
  - d. Verify whether entry into such storage areas is controlled, and that usage logs are maintained and current.
2. Import inspection personnel should also verify that the establishment has implemented:
  - a. Access control procedures to product storage areas;
  - b. Control procedures for access to and use of hazardous chemicals; and
  - c. Observation procedures of all products in storage for evidence of tampering.

#### E. Shipping and Receiving – 08S17

1. At a minimum, import inspection personnel are to:
  - a. Observe loading dock areas and vehicular traffic in and out of the establishment;
  - b. Report immediately to establishment management all unattended deliveries on loading docks and unmarked vehicles parked on the premises;
  - 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 any

suspicious products.

2. Import inspection personnel should also:
  - a. 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;
  - b. Observe incoming raw materials to verify that the establishment checks deliveries against shipping documents. Pay special attention to tanker trucks, combo bins of fresh meat trim or poultry parts, and boxes of frozen trim that the establishment will ship for further processing; and
  - c. Observe outdoor lighting and on-site trailer security, paying particular attention to any unauthorized access.

## **X. FOOD DEFENSE DOCUMENTATION – IMPORT INSPECTORS**

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

1. When import inspection personnel perform a 08S 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 import inspection personnel perform a 08S procedure and find that there is a food defense vulnerability or food defense concern, but that there is no evidence of product adulteration, they are to record the procedure as performed by recording trend indicator “S” and are to:
  - a. Notify the establishment management and discuss the findings (e.g., at the next weekly meeting); and
  - b. Complete FSIS Form 5420-4 (Food Defense Memorandum of Interview) in PBIS, record the establishment response after discussing the findings, and notify the supervisor.
3. When import inspection personnel perform a 08S procedure and find that there is a food defense vulnerability or food defense concern, and that there is evidence of product adulteration, they are to record the procedure as performed by recording trend indicator “T” and are to:
  - a. Immediately notify the establishment management, discuss the findings, and take action as per established policy;
  - b. Immediately report any potential significant incident through supervisory channels in accordance with Directive 5500.2;

- c. Complete a Noncompliance Record (NR) for the product adulteration and cite the appropriate ISP code and regulations; and
  - d. Complete FSIS 5420-4 in PBIS.
4. When trend indicators “S” or “T” are entered in PBIS, the Vulnerability Report section of the screen is activated. Once this screen is activated, import inspection 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 (3rd or more),” indicating the third or greater occurrence.

**NOTE:** For a finding to be reported as the second or greater occurrence of a vulnerability, it is to be for the same vulnerability under the performed O8S procedure as occurred previously.

- b. Verify that the name of the Import Inspector that performed the procedure appears in the Inspector field. To change the name:
    - i. Click the magnifying glass icon next to the name field to open the Change Name Window;
    - ii. Enter the full name or partial name in the fields provided and click the Change Name button;
    - iii. Select the appropriate name from the list, and
    - iv. Click the Select button;
    - v. Select applicable vulnerabilities by clicking the box adjacent to the vulnerability statement;
    - vi. Enter management’s response, if any, to each vulnerability identified in the Est Mgmt Response section; and
    - vii. Review the information entered, make changes if necessary, and then click Save.
5. Import inspection personnel are to provide plant management a copy of the completed Form 5420-4, Food Defense Memorandum of Interview. To print FSIS Form 5420-4 in PBIS, import inspection personnel may:
- a. Print from the Procedure Results screen by highlighting the appropriate O8S Procedure and click the Print button; or



- b. Print from the PBIS pull down menu:
  - i. Select Reports/Results/Vulnerability Report;
  - ii. Select the date range;
  - iii. Select the establishment/shift then click Ok, and a new window will appear;
  - iv. Select one or more vulnerability reports from the list and click Ok; and
  - v. Select the report destination. Enter S for screen, P for printer, or R for an RTF file, and then click OK.

## **XI. MULTIPLE OCCURRENCES OF THE SAME FOOD DEFENSE VULNERABILITY – IMPORT INSPECTORS**

A. If import inspection 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 FSIS Form 5420-4 regarding this vulnerability. Import inspection personnel are to note on the FSIS Form 5420-4 that this is the second occurrence of this vulnerability, and notify the supervisor.

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

B. If import inspection personnel encounter the potential food defense vulnerability or concern for a third time, they are to meet again with the establishment management, complete a third FSIS Form 5420-4, 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, import inspection personnel are to notify the RIFS of this situation. Import inspection personnel are not to further review or document the specific potential vulnerability identified in the three issuances of FSIS Form 5420-4 until the RIFS provides further instructions. If the procedure is randomly selected, import inspection personnel are to direct Food Defense Verification Procedures to establishment activities other than the one identified in the third FSIS Form 5420-4.

D. Import inspection personnel are to provide a copy of the third FSIS Form 5420-4, the discussion notes, and a copy of the weekly meeting memorandum documenting that the establishment developed a functional food defense plan (if applicable) to the RIFS. If the RIFS determines that it is appropriate, the RIFS will forward a copy of the documentation to the ERI-Mail mailbox in Outlook and request an assessment of the reported vulnerability.

E. If requested by the RIFS, ODIFP will prepare an assessment within 30 days. The 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 RIFS 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 import inspection personnel 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 RIFS will forward ODIFP's recommendation to the establishment and inform the import inspection personnel at the establishment that ODIFP's recommendation was forwarded.

H. If ODIFP provided guidance on how the establishment can address the vulnerability, import inspection personnel are to meet with the establishment management at the next weekly meeting to inquire about the establishment's next steps, if any. Import inspection personnel are to document what was discussed at this meeting on the third FSIS Form 5420-4.

## **XII. FOOD DEFENSE ACTIVITIES – ISLOs**

A. ISLOs are to conduct Food Defense Surveillance Procedures when the facility is reviewed for the first time or during a follow-up surveillance review where Food Defense Surveillance Procedures have not been conducted within the previous 12 months.

B. When there are no active NTAS alerts, or active alerts with no specific threat to food or agriculture:

1. ISLOs are to conduct Food Defense Surveillance Procedures described in Section XIII.

C. When there is an NTAS alert of an elevated threat to food or agriculture:

1. RIFSs, upon notification by the Director of IID or designee of the threat level, will:
  - a. Direct ISLOs to perform Food Defense Surveillance Procedures described in Section XIII;

- b. Coordinate with OPHS for FSIS field laboratory or FERN laboratory support in testing of surveillance samples;
  - c. Direct the collection of product samples as needed; and
  - d. Coordinate activity at in-commerce facilities with Office of Program Evaluation, Enforcement and Review (OPEER) personnel.
2. ISLOs, upon notification by the RIFS of an elevated threat to food or agriculture, will:
- a. Conduct Food Defense Surveillance Procedures listed in Section XIII; and
  - b. Inform management of facilities visited during the course of their duties of the current NTAS alert.

D. When there is an NTAS alert of an imminent threat to food or agriculture:

- 1. RIFSs are to instruct ISLOs to carry out any additional activities as directed by Director of IID or designee, through emergency response issuances, or by incident command.
- 2. ISLOs, when notified by the RIFS of an imminent threat to food or agriculture, are to:
  - a. Conduct procedures listed above under Section XII E above (NTAS alert with elevated threat to food or agriculture); and
  - b. Conduct any additional activities as directed by the Director of IID or designee, through emergency response issuances, or by incident command.

### **XIII. FOOD DEFENSE SURVEILLANCE PROCEDURES – ISLOs**

A. ISLOs conduct surveillance reviews in accordance with FSIS Directive 8010.1, Methodology for Conducting In-Commerce Surveillance Activities, at warehouses, distributors, and other in-commerce facilities, and facilities located at ports-of-entry to verify that persons and firms whose business activities involve FSIS-regulated products prepare, store, transport, sell, or offer for sale or transportation such products in compliance with FSIS statutory and regulatory requirements. These surveillance reviews include procedures for food defense surveillance as well as for food safety, imported products, and other in-commerce surveillance activities.

B. ISLOs conduct Food Defense Surveillance Procedures to identify potential security vulnerabilities at facilities that increase the risk of intentional product tampering and adulteration of meat, poultry, and egg products. A potential vulnerability can be any part of the food continuum system identified at the facility where measures can be taken to protect food products from intentional product tampering and adulteration. Examples of potential vulnerabilities include:

1. Unrestricted access to product storage and staging areas;
2. Unrestricted access to product processing areas;
3. Unrestricted access to shipping/receiving areas; or
4. Unrestricted access to water systems.

C. When ISLOs conduct Food Defense Surveillance Procedures, they are to:

1. Determine whether the facility has a written food defense plan that consists of standard operating procedures for preventing intentional product tampering and adulteration; and contact information (e.g., police, state and local health agencies) to be used if product is intentionally adulterated.
2. Determine whether the facility has a means to protect the outer perimeter and outside premises of the facility (e.g., cameras, security guards, lighting, alarm system, and locks).
3. Observe and determine whether the facility has:
  - a. A surveillance system (e.g., cameras, security guards, lighting, and alarm system) to secure the inside premises;
  - b. Measures in place to ensure that all persons (e.g., employees, contractors, and construction or maintenance personnel) in the facility are authorized, properly identified, and restricted from areas as appropriate;
  - c. A process for the use, storage, and controlled access of hazardous materials in the facility to prevent product adulteration; and
  - d. A process to protect food or food ingredients, including water used in products prepared by the facility, especially if it is well water.

**NOTE:** this question applies to facilities that store products only (e.g., distributors and warehouses) and facilities that process products (e.g., retail stores and restaurants).

4. Observe and determine whether the facility has:
  - a. A process that restricts access to the receiving/shipping areas to authorized personnel;
  - b. A process to verify that incoming/shipped products are consistent with shipping documents;
  - c. A process to examine all incoming products for indications of apparent tampering or adulteration (e.g., opened or resealed boxes; the presence of an unidentified substance on packaging or product; or questionable products, packaging, or labeling); and

- d. A process for maintaining security of products during loading/shipping, (e.g., trucks and trailers are locked or sealed while not under the direct supervision of company personnel).
- 5. Determine whether there are any indications of apparent product tampering or adulteration for products currently held in storage by the facility.

#### **XIV. FOOD DEFENSE SURVEILLANCE PROCEDURE DOCUMENTATION – ISLOs**

- A. ISLOs will conduct the Food Defense Surveillance Procedures listed in Section XII above and will document the findings in the In-Commerce System (ICS).
- B. If ISLOs find food defense vulnerabilities, they are to provide a hard copy of the completed FSIS Form 5420-3 to management at the time of the visit or subsequently via fax or regular mail.

**NOTE:** ISLOs are to complete FSIS Form 5420-3 and print it using ICS. The form can be found at: <https://inside.fsis.usda.gov/fsis/emp/static/global/forms/forms.jsp>.

- C. If ISLOs do not have access to ICS while conducting the Food Defense Surveillance Procedures, they are to document findings on FSIS Form 5420-3 and enter the information from the Form into ICS as soon as possible.
- D. IID supervisors, as well as other OIA and designated ODIFP personnel, will have access to the data entered by ISLOs, in addition to having access to summary reports of the data in the ICS application.

#### **XV. ADULTERATED PRODUCT OR POSSIBLE TAMPERING**

- A. ISLOs are to immediately follow the established policy described in FSIS Directive 8410.1, Detention and Seizure, when they have reason to believe that meat, poultry, or processed egg products in commerce are adulterated, misbranded, or otherwise in violation of the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act.
- B. ISLOs are to follow procedures defined in FSIS Directive 5500.2, Significant Incident Response, when they have evidence or information that indicates that product may have been tampered with or other findings that may require completion of an Incident Report (IR).

#### **XVI. ANALYSIS OF THE DATA**

On at least an annual basis, ODIFP will review food defense verification and surveillance activity data to evaluate the overall frequency and number of Food Defense Surveillance and Verification Procedures performed by import inspection personnel and ISLOs, as well as potential trends in vulnerabilities or food defense concerns. The analyses will inform future guidance and policy regarding performance food defense

verification and surveillance activities. At least annually, ODIFP will provide a summary of this analysis to the OIA AA.

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.

A handwritten signature in black ink, appearing to read "David Josephson". The signature is written in a cursive style with a prominent initial "D".

Assistant Administrator  
Office of Policy and Program Development