

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

FSIS DIRECTIVE

5500.2
Revision 5

10/18/11

SIGNIFICANT INCIDENT RESPONSE

I. PURPOSE

This directive outlines the procedures that the Food Safety and Inspection Service (FSIS) Emergency Management Committee (EMC) and divisions within FSIS are to follow while managing significant incidents that may adversely affect public health or food defense.

KEY POINTS:

- *Contains information on what developments trigger an FSIS Form 5500-4, Incident Report (IR) or an alert*
- *Provides instructions for completing an IR*
- *Provides information regarding the National Biosurveillance Information System (NBIS)*
- *Provides information on sharing updates to IRs when the FSIS Incident Management System (FIMS) is unavailable*

II. CANCELLATION

FSIS Directive 5500.2, Revision 4 Significant Incident Response, 3/2/10

III. REASON FOR REISSUANCE

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

DISTRIBUTION: Electronic

OPI: OPPD

IV. REFERENCES

9 CFR Part 300 to end

FSIS Directive 5420.5, National Terrorism Advisory System (NTAS) Alert - Intelligence Reports And Communications

V. BACKGROUND

A. A significant incident presents a grave, or potentially grave, threat to public health or to the safety of FSIS-regulated product. Examples of significant incidents include, but are not limited, to the following:

1. Life-threatening or widespread human illnesses potentially implicating FSIS-regulated product that lead to a foodborne incident investigation;
2. Class I recalls resulting from one or more illnesses involving FSIS-regulated product;
3. Deliberate contamination of FSIS-regulated product;
4. An NTAS alert issued, updated, or revised by DHS is determined by the Office of Data Integration and Food Protection (ODIFP) to pose a risk to FSIS personnel or the food and agriculture sector;
5. A Foreign Animal Disease (FAD) as described in FSIS Directive 6000.1 Revision 1, Responsibilities Related to Foreign Animal Diseases and Reportable Conditions, is detected in animals presented for slaughter within the United States
6. Detection of an animal disease with potentially significant public health implications for FSIS-regulated product;
7. Illegally imported or smuggled products in the United States (U.S.) where there is a reasonable probability that the consumption of the product will pose a serious health hazard;
8. High risk FSIS regulated products in the U.S. as identified by Customs and Border Protection;
9. Suspicious activities observed by, or made known (e.g., bomb threats) to, program personnel while performing their normal duties; and
10. Incidents meeting certain criteria reported by member agencies to the NBIS.

B. Additional situations that FSIS may consider to be significant incidents include:

1. Natural disasters (e.g., hurricanes, floods, tornadoes, and earthquakes);
2. Terrorist attacks on the nation's critical infrastructure;
3. Other incidents requiring a national coordinated response that result in the activation of the Emergency Support Function #11 (ESF#11) at the Federal Emergency Management Agency, National Response Coordination Center, which is described in the Agriculture and Natural Resources Annex to the National Response Framework; and
4. Incidents involving FSIS-regulated product and law enforcement or other regulatory agencies for which a coordinated response may be necessary, as well as significant unanticipated expenditure of FSIS resources (e.g., stolen trucks or excessive levels of chemical residues).

VI. FSIS PERSONNEL RESPONSIBILITIES FOR REPORTING A SIGNIFICANT INCIDENT

A. Agency personnel are to immediately report any potentially significant incident as defined in section V. A. through supervisory channels. The information reported, at a minimum, is to include:

1. The name of the person who reported the incident;
2. The date and time of the incident;
3. The location of the incident;
4. The type of threat, hazard, or disease;
5. The type of product involved, and
6. The number of reported illnesses and deaths (if applicable).

B. Designated personnel with access to FIMS are to review the incident information and, if appropriate, develop the IR and submit the report into FIMS for the approving official to review (see attachment 1).

C. For Class I recalls involving one or more illnesses (see section V. 2.), the Office of Public Affairs and Consumer Education (OPACE) are to initiate the IR in FIMS and post the recall release.

D. For significant incidents where the National Response Coordination Center (NRCC) has activated ESF#11 in response to a natural disaster, ODIFP will initiate an IR, if one has not yet been entered by another program area.

E. For all incidents that involve law enforcement agencies or the need to notify the Office of Inspector General (OIG), the Office of Program Evaluation, Enforcement, and Review (OPEER), Compliance and Investigation Division (CID), is to be notified by phone and followed up via e-mail by the reporting program office.

F. The Office of Public Health Science (OPHS) Applied Epidemiology Division is to send an alert through FIMS when it initiates a foodborne illness investigation per FSIS Directive 8080.3, Foodborne Illness Investigations. Alerts provide early notification of investigations that will likely necessitate Agency action or commitment of resources.

G. ODIFP may receive notification of a significant incident from the NBIS or one of its member agencies. The significant incident would meet NBIS' own activation criteria as defined in the NBIS Protocol managed by the DHS.

H. Once the information is received, ODIFP's AA or designee is to discuss the information with the relevant program area to determine whether an alert notification through FIMS to the EMC and Management Council is warranted.

VII. INCIDENT REPORT

A. The electronic IR form can be accessed on an FSIS issued computer through FIMS via the following intranet link: <http://FIMS.fsis.usda.gov>

B. The electronic IR in FIMS automatically saves the IR as its case number. The case number is derived using the following format: year, month, day, number of IR entered that day, e.g., 20070130-01 means this is the first IR in 2007 reported on Jan. 30.

C. All approved IRs in FIMS are automatically forwarded to the AA or designee of ODIFP and the originating program's AA or designee for review, following the automated process outlined in attachment 1. EMC members on duty also will get a copy.

D. Program offices are to update the IR as often as necessary through FIMS. The most recent information will appear first on the IR. Whenever certain fields in the IR are updated, an e-mail notification will be sent to all FIMS users, unless the override selection is used.

VIII. FIMS OR E-MAIL SYSTEM OUTAGE

A. In the event that the FIMS system is non-operational, the person who generates the IR is to send the information about the incident to the ODIFP Assistant Administrator (AA) or designee and his or her AA or designee as an attachment to an e-mail or via fax. The ODIFP fax information is in the EMC roster. If e-mail is available the information can also be sent to ERI-Mail@fsis.usda.gov.

B. Upon receipt of the information, ODIFP Emergency Coordination Staff (ECS) is to manually, through a Word document or by attaching the faxed information, update an IR. This information is to be shared with the EMC representative of each program area. The EMC program representative is to share this information with the FIMS user community by e-mail, PIN, or fax until FIMS is restored.

C. In the event the e-mail system is not operational, the person who generates the IR is to send a PIN message, using a personal digital assistant (e.g., Blackberry), to the ODIFP AA and to his or her AA or designees with the information. The two AAs are to review the information and make a determination regarding the IR in accordance with this directive.

D. In the event that both fax and e-mail systems are not operational, the person who generates the IR is to orally notify his or her AA, his or her program EMC representative, and the ODIFP EMC representative. The AA is to share the information immediately with the ODIFP AA or designee and decide whether further action is warranted.

E. When the FIMS system becomes operational, the person who initiated the IR during the outage is to enter the information about the incident into FIMS.

IX. REVIEWING THE IR

A. The ODIFP AA and the AA responsible for the IR, or their designees, are to review the submitted IR and, as appropriate, determine:

1. That no action is required;
2. That the EMC is to be alerted; or
3. That the EMC is to be activated.

B. The ODIFP AA and the AA responsible for the IR (or designees) are also to determine, as appropriate, what further actions need to be taken on the open IR.

C. If, after the ODIFP AA or designee and representatives of the program areas relevant to the IR discuss the status of the significant incident and determine that the incident is resolved, and no further actions or monitoring are required, the Duty Officer on duty will close the IR. They will also determine who will have access to the restricted IR

D. An IR is to be archived when the ODIFP AA or designee in consultation with the program area with primary responsibility for the IR determines that the incident will take an extended period of time to resolve, such as a pending criminal investigation. Once the investigation is complete, an IR that has been archived is to be closed.

NOTE: Closed IRs and Archived IRs can still be updated with new information if necessary.

E. An IR can be classified as “restricted” when it contains sensitive information that is not to be shared with all FIMS users. The ODIFP AA or designee will work with the program area with primary responsibility for the IR to determine whether access to the IR should be restricted. They will consult with other program area representatives as needed to make this final determination.

F. If the ODIFP AA and the AA responsible for the IR (or designees) determine that an incident may warrant further discussion by the EMC, ECS will send a notification (alert) through FIMS to the EMC representatives. This notification alerts the EMC representatives that there is a significant incident that may warrant EMC activation. The alert notification is to include information on how and when the discussion will take place.

G. If the ODIFP AA and the AA responsible for the IR (or designees) determine that the EMC needs to be activated, ECS will send an activation notification through FIMS to the EMC representatives on duty for each program area. The message is to provide instructions on where to convene, or how to participate in, a conference call. The FSIS Management Council, the Office of the Under Secretary for Food Safety, the Office of the Administrator, and the USDA Office of Homeland Security and Emergency Coordination are also to receive a copy of the notification for alerts and activations.

X. EMERGENCY MANAGEMENT COMMITTEE

A. The EMC is comprised of senior management personnel (AA or designee) from each of the FSIS program offices. Each program office EMC representative is to have the authority to commit, as necessary, the resources of his or her respective program office in responding to the incident. The EMC duty roster is available in FIMS and also is issued by e-mail weekly to all program areas. The list contains on-call members and contact information for each program area member.

B. The EMC may be alerted or activated at any time, on any day of the year, to address and manage the Agency’s response to a significant incident involving potentially-adulterated or adulterated, FSIS-regulated product, or an incident that could have a significant impact on FSIS employees or regulated establishments. As described in FSIS Directive 8080.1, the EMC can also be activated if the Recall Committee is unable to reach consensus on whether the Agency should request that a company conduct a recall. In the event the incident does not result in adulteration of FSIS-regulated product, the purpose of the EMC activation would be to determine how to work with other involved agencies, to assign responsibilities for any information gathering, and to decide how best to provide the public with information about the safety of the product.

C. The AA or the EMC representative from ODIFP serves as the Incident Commander (IC). The IC coordinates the work of the EMC in response to a specific significant

incident. Depending on the nature, scope, and complexity of the incident, the IC may designate any member of the EMC as IC to coordinate key activities critical to the management of the incident.

D. The Duty Officer for the EMC maintains an up-to-date roster of on-call EMC members, including home, work, cell/Blackberry phone numbers, PINs, and e-mail addresses. The Duty Officer also manages incident reports, monitors FIMS readiness, and prepares situation and spot reports to the USDA's Operations Center as information becomes available, or as requested by the Department.

E. ODIFP maintains the FSIS Situation Room and FSIS preparedness plans in conjunction with the Department's Continuity of Operations Plans (COOP). In conjunction with the Department's Office of Homeland Security and Emergency Coordination, ODIFP is FSIS' emergency incident liaison with other Federal agencies through the Multi Agency Coordination (MAC) structure.

XI. THE WORK OF THE EMC

A. Upon alert or activation, the EMC evaluates the information provided in the IR and determines what information is needed to complete the assessment of the significant incident. The EMC also develops and implements an incident action plan, the execution of which is monitored by the IC through FIMS.

B. The EMC coordinates the development of responses to questions about the incident, including responses to questions about illness prevention, hazard detection, incident containment, and remediation. The EMC also recommends Agency actions to detect and mitigate the hazard that caused the incident, including the formation of an Incident Investigation Team (see FSIS Directive 5500.3) to investigate matters, such as why FSIS-regulated product is causing illnesses.

C. The IC provides progress reports to the FSIS Management Council (i.e., Office of the Administrator and AAs), as requested. All relevant program areas are to routinely provide updates through FIMS to assist the IC in tracking the incident response, reporting progress, and maintaining relevant documents and a chronology of events.

D. When the incident has been resolved, the IC, in conjunction with the EMC members, is to deactivate the EMC and advise the Administrator and FSIS Management Council. The ODIFP Duty Officer on duty will notify all EMC representatives and other parties through FIMS, and the IR will be closed.

XII. COMPLETING FSIS FORM 5500-8, IMPACT OF SIGNIFICANT INCIDENTS ON ESTABLISHMENTS, WAREHOUSES, AND IMPORT ESTABLISHMENTS

A. The EMC is to coordinate the collection and submission of information necessary to complete an FSIS Form 5500-8 in FIMS about the operational status of official establishments, facilities that handle FSIS-regulated products (e.g., large warehouses),

import facilities, FSIS offices, and laboratories affected by a significant incident, such as an earthquake, flooding, fire, or hurricane. All FSIS program areas can submit a program specific 5500-8 using FIMS.

NOTE: Authorized users can access the form through FIMS at <http://FIMS.fsis.usda.gov> . For those individuals without access to FIMS, the form is available in inside FSIS at <http://inside.fsis.usda.gov> .

B. ODIFP is to notify the appropriate EMC representatives from the relevant offices to collect information about the operational status of establishments or facilities in the affected areas by contacting their local program offices.

C. The EMC representative is then to notify the appropriate personnel within his or her program, for example, the District Manager (DM), Import Inspection Division's (IID) Deputy Director (DD), or CID Regional Director (RD), to collect the information and complete FSIS Form 5500-8, in FIMS. FSIS field personnel may need to supply information on whether official establishments or facilities are operational as a result of the significant incident, so that the DM, RD, or the IID DD can complete the form in FIMS.

D. To complete FSIS Form 5500-8 in FIMS, the DM, RD, or the IID DD or their designees may need to contact other personnel, such as Front-line Supervisors; Consumer Safety Officers; Enforcement, Investigations, and Analysis Officers; Investigators; Regional Import Field Officers; Import Surveillance Liaison Officers; or Import Inspectors. The following information is needed to complete FSIS Form 5500-8:

1. The specific IR # that relates to the incident requiring a FSIS Form 5500-8 to be filled out.
2. For the Office of Field Operations (OFO), the Office of International Affairs (OIA), and OPEER the official identification numbers for establishments or facilities that are not operating;
3. For OPEER, the addresses, contact information, square footage, and number of buildings impacted at high volume distribution points (e.g., wholesale grocery suppliers or transportation centers) that are not operating need to be entered. In addition, poundage of product impacted, detained, or seized also needs to be entered; and
4. For all three offices, the reason why the establishment or facility is not operational:
 - a. no establishment or facility personnel present;
 - b. damage from flooding;

- c. building destroyed;
 - d. no electricity; or
 - e. other (specify).
5. For all program areas reporting on damage to or closure of FSIS leased office space, you will need to have the name of the building, address, and reason for its non-operation.

E. After the initial submission of a completed FSIS Form 5500-8, the form will be automatically attached to the IR. Program areas will edit the form attached to the IR in FIMS each time there is a change to any of their entries' operational status, or if additional entries need to be made. After saving the changes to FSIS Form 5500-8 in FIMS, a new FSIS Form 5500-8 will be created, and ECS will be notified by FIMS that it is available for review. Daily updates are not needed if there is no change in status.

XIII. DATA ANALYSIS

The information collected about significant incidents in FIMS, including operational status of establishments, will be evaluated and analyzed by ODIFP, at a minimum, on a quarterly basis. Results of the analysis will be used to inform new or existing data initiatives, to develop enhanced capabilities of FIMS to effectively manage significant incidents, and to provide input into DHS reports on suspicious activities.

Refer questions through supervisory channels.



Assistant Administrator
Office of Policy and Program Development

IR Process Via the FIMS Based on Incident Information

Program Area	Incident Information Sources	FSIS Personnel with Access to the FIMS for IR Development	FSIS Personnel Responsible for IR Review	FSIS Personnel Responsible for Approving IR	FIMS, E-mail notification of an Approved IR
OA	External Federal Agencies	ODIFP - Recorder	ODIFP – AA or Designee	ODIFP – AA or Designee	ODIFP AA/Designees/ECS Staff/EMC Reps
ODIFP	OA External Agencies Other Program Offices	ODIFP - Recorder	ODIFP-AA or Designee	ODIFP-AA or Designee	ODIFP- AA/Designee/EMC Reps
OIA	Field & External Agencies IES IEPS IAS IID	IES Director IEPS Director IAS Director IID Director	IES Director IEPS Director IAS Director	IES Director IEPS Director IAS Director * *cc: DAA, Directors: IES, IEPS, IID, IAS	OIA AA ODIFP AA/Designees ECS EMC Reps
	Foreign Governments	IID Deputy Director	Directors: IES,IEPS, IAS, IID	Directors: IES, IEPS, IAS * *cc: DAA, Directors: IES, IEP, IID, IAS	OIA AA/ODIFP AA/Designees ECS Staff EMC Reps
	External - (Others) ISLOs	IID Deputy Director ISLOs	Director IID	Director- IID* *cc: DAA, Directors: IES,	OIA AA/ODIFP AA/Designees ECS Staff EMC Reps

Program Area	Incident Information Sources	FSIS Personnel with Access to the FIMS for IR Development	FSIS Personnel Responsible for IR Review	FSIS Personnel Responsible for Approving IR	FIMS, E-mail notification of an Approved IR
				IEPS, IID, IAS	
OPEER	External Agencies or CID	CID-Director, Deputy Director, Compliance Specialist, Regional Director, Supervisory Compliance Investigator, Sr. Compliance Investigator, Compliance Investigator	Regional Director	Regional Director* *cc: CID Director	OPEER AA/ODIFP AA Designees ECS Staff EMC Reps
	ICAD External - State MPI Programs	Director ICAD	Director ICAD	Director ICAD	OPEER AA/ODIFP AA/Designees ECS Staff EMC Rep
OPACE	Hot Line Information	Hot Line Specialist and Manager	FSES Director	OPACE AA/ Designee	OPACE AA/ Designee /ODIFP AA/Designee ECS Staff/EMC Rep
	External Sources	Director: ECIMS, CPAO, FSES	Director: ECIMS, CPAO, FSES	OPACE AA/ Designee	OPACE AA/ Designee /ODIFP AA/Designee ECS Staff/EMC Rep
OFO	External Agencies IICs FLS	District Manager or Designee, DDM, Case Specialist, Director RMD or Designee	District Manager or Designee	District Manager or Designee	OFO AA/ODIFP AA/Designee ECS Staff/EMC Rep

Program Area	Incident Information Sources	FSIS Personnel with Access to the FIMS for IR Development	FSIS Personnel Responsible for IR Review	FSIS Personnel Responsible for Approving IR	FIMS, E-mail notification of an Approved IR
OPPD	IICs Industry FLS	Director: PDD, PAD, LPDD	OPPD AA/ Designee	OPPD AA/ Designee	OPPD AA/ODIFP AA/Designees ECS Staff EMC Rep
OPHS	External Agencies, State and Local Partners, PHELS, CCMS FDIB illness investigation	AED Director or Designee CCMS staff FDIB Branch Chief PHELS	AED Director or Designee	AED Director or Designee	OPHS AA/ODIFP AA/Designees ECS Staff EMC Rep
	Laboratories, CDC Liaison	OPHS AA Lab Directors	OPHS AA	OPHS AA	OPHS AA/ODIFP AA/Designees ECS Staff EMC Rep
OOEET	Regional Trainers and Field personnel	OOEET AA Outreach and Partnership Division Staff	OOEET AA or Designee	OOEET	OOEET AA/ODIFP AA/Designees ECS Staff EMC Rep
OM	Field Personnel (FPC, Urbandale, IA & HRFO, Minneapolis MN); Field Safety and Health (SH) Specialists	OM AA & DAA; OCHCO & Deputy Division Directors & Deputies; CFO & Deputy; EHSB Chief; SH Specialists	OM AA/DAA or Designee	OM AA/DAA or Designee	OM AA/ODIFP AA/Designees ECS Staff EMC Rep