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. FSIS is reissuing this directive to reflect changes that are the result of FSIS' recent reorganization and to further clarify when a recall would trigger an FSIS Form 5500-4, Incident Report (IR).

KEY POINTS:

- Contains information on what developments trigger an FSIS Form 5500-4, Incident Report (IR)
- Provides instructions for completing an IR
- Defines the EMC and its activities
- Provides information on sharing updates to IRs when the FSIS Incident Management System (FIMS) is unavailable

II. CANCELLATION

FSIS Directive 5500.2, Revision 5 Significant Incident Response, 10/17/11

III. 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 an FSIS foodborne illness investigation, as described in FSIS Directive 8080.3, Food Borne Illness Investigations.

2. Class I recalls resulting from one or more consumer illnesses involving FSIS-regulated product;

3. Class I recalls resulting from one or more consumer injuries involving FSIS-regulated product;

4. Deliberate contamination of FSIS-regulated product;
5. An incident reported in a National Terrorism Alert System (NTAS) alert issued, updated, or revised by the Department of Homeland Security (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;

6. A Foreign Animal Disease (FAD) as described in FSIS Directive 6000.1, Responsibilities Related to Foreign Animal Diseases and Reportable Conditions, is detected in animals presented for slaughter within the United States;

7. Detection of an animal disease with potentially significant public health implications for FSIS-regulated product by FSIS Public Health Veterinarians or other government sources;

8. 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;

9. High risk FSIS-regulated products in the U.S. as identified by Customs and Border Protection;

10. Suspicious activities observed by, or made known (e.g., bomb threats) to, program personnel while performing their normal duties; and

11. Incidents meeting the National Biosurveillance Information Center (NBIC) criteria that are reported by NBIC member agencies.

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

1. Natural disasters (e.g., hurricanes, floods, tornadoes, and earthquakes) with the potential to impact FSIS employees, regulated facilities, or regulated product;

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).

IV. FSIS PERSONNEL RESPONSIBILITIES FOR REPORTING A SIGNIFICANT INCIDENT

A. Agency personnel are to immediately report any potentially significant incident as defined in section III.A. and III.B. 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 (see attachment 1) with access to FSIS’ Incident Management System (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.

C. For Class I recalls involving one or more illnesses or one or more injuries (see section V. 2.), the EMC representative of the Office of Public Affairs and Consumer Education (OPACE) is 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 Investigation, Enforcement and Audit (OIEA), Compliance and Investigation Division (CID), is to be notified by phone and a follow up e-mail by the reporting program office.

F. When the Office of Public Health Science’s (OPHS) Applied Epidemiology Staff (AES) initiates an FSIS foodborne illness investigation per FSIS Directive 8080.3, Foodborne Illness Investigations, the AES lead investigator is to enter information about the investigation into the FIMS.

G. ODIFP may receive notification of a significant incident from the NBIC or one of its member agencies. 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.

V. INCIDENT REPORT

A. The electronic IR 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 by 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 reported on January 30, 2007).

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, as will ODIFP’s Emergency Coordination Staff (ECS).

D. Program offices are to update the IR through FIMS as often as necessary, or as directed in specific agency guidance. 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.

VI. FIMS OR E-MAIL SYSTEM OUTAGE

A. In the event that the FIMS system is non-operational, the person who generates or updates the IR is to send the information about the incident to the ODIFP 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 on 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, 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 area representative is to share this information with his or her program area’s FIMS user community by e-mail, PIN, or fax until FIMS is restored.

C. In the event the e-mail system is also not operational, the person who generates the IR is to send a fax and a PIN message, using a personal digital assistant (e.g., Blackberry), to the ODIFP AA and to his or her AA or designee 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 fax, PIN capabilities, 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.

VII. 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 additional alert or activation 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 is to close the 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 are to consult with other program area representatives as needed to make this final determination. Together, they are to also determine who will have access to the restricted IR.

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 is to 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.

G. If the ODIFP AA and the AA responsible for the IR (or designees) determine that the EMC needs to be activated, ECS is to 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 EMC Duty Officer is to forward a copy of the notification for alerts and activations to 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.

VIII. 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 employees who serve on the EMC, as well Office of the Under Secretary for Food Safety, the Office of the Administrator, and the USDA Office of Homeland Security and Emergency Coordination. 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 as defined in section III of this directive. As described in FSIS Directive 8080.1, Recall of Meat and Poultry Products, the EMC can also be activated if the Recall Committee or the AA’s are unable to reach consensus on whether the Agency should request that a company conduct a recall, or when there may be need for a public health alert related to a foodborne illness investigation.

C. The AA or the EMC representative from ODIFP serves as the initial 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 initial or current IC may designate any program area representative as IC to coordinate key activities critical to the management of the incident. The IC is to ensure that Agency subject matter experts are included in EMC meetings.

D. The Duty Officer for the EMC maintains an up-to-date roster of on-call EMC members, including home, work, and 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 USDA Office of Homeland Security and Emergency Coordination, ODIFP is FSIS’s emergency coordination liaison with other Federal agencies through the Multi Agency Coordination (MAC) structure.

IX. 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, which is posted to the IR in FIMS. The execution of the incident action plan 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, Incident Investigations Team Reviews) 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 using the IR in 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 will notify all EMC representatives and other parties through FIMS, and the IR will be closed.

X. COMPLETING FSIS FORM 5500-8, IMPACT OF SIGNIFICANT INCIDENTS ON ESTABLISHMENTS, WAREHOUSES, AND IMPORT ESTABLISHMENTS, AND THE AUTOMATED EMPLOYEE TRACKING SHEET

A. EMC representatives are to coordinate the collection and submission of information necessary to complete an FSIS Form 5500-8 and Automated Employee Tracking Sheet in FIMS. These forms track the operational status of official establishments, in-commerce facilities that handle FSIS-regulated products (e.g., distributors, warehouses), import facilities, FSIS offices, laboratories, and FSIS employees affected by a significant incident, such as an earthquake, flooding, fire, or hurricane. All FSIS program areas are to submit a program specific 5500-8 using FIMS for establishments/firms that have their operational status affected by a significant incident.

NOTE: Authorized users can access the forms through FIMS at http://FIMS.fsis.usda.gov. For those individuals without access to FIMS, Form 5500-8 is available on 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 status of their employees and 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) or CID Regional Director (RD), to collect the information and complete FSIS Form 5500-8, and if necessary the Automated Employee Tracking Sheet, in FIMS. FSIS field personnel may need to supply information on employee status, and whether official establishments or firms are operational as a result of the significant incident, so that the DM or RD or their designee can complete the forms in FIMS.

D. To complete FSIS Form 5500-8 in FIMS, the DM or RD 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; 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) and OIEA the official identification numbers for establishments or firms that are not operating;

3. For OIEA, 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 into the FSIS Form 5500-8. In addition, poundage of product impacted, detained, or seized also needs to be entered; and
4. For both offices, the reason why the establishment or firm is not operational:
   a. No establishment or firm 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, the person reporting needs to have the name of the building, address, and reason for its non-operation.

E. FSIS Program Offices are to enter the following information to complete the Automated Employee Tracking Form if necessary: Number of employees that normally work in their program area broken down by State; Number of employees from their program area that are working broken down by State; Number of employees from their program area that are absent for any reason broken down by State; Number of employees from their program area that are not accounted for broken down by State; and the Number of employees from their program area that are deceased or ill.

F. After the initial submission of a completed FSIS Form 5500-8 and the Automated Employee Tracking Sheet, the forms will be automatically attached to the IR. Program areas are to edit the forms attached to the IR in FIMS each time there is a change to any of their entries, or if additional entries need to be made. After saving the changes to FSIS Form 5500-8 or to the Automated Employee Tracking Sheet in FIMS, ECS will be notified by FIMS that the information is available for review. Daily updates are not needed if there is no change in status unless otherwise requested.

XI. OIEA RESPONSIBILITIES

A. OIEA personnel are to develop a response plan and to submit it to the IR within 12 hours, or when the IR is approved for food safety or food defense events that include natural disasters, intentional contamination, or significant economic adulteration.

   1. OIEA personnel are to input an Investigative Plan (see FSIS Directive 8010.2, Investigative Methodology) for all IR approved illness outbreak investigations.

   2. OIEA personnel are to input a Response Plan for all IR approved natural disasters or threats of natural disasters. Response plan templates can be found on the Library page in FIMS.

B. OIEA personnel are to ensure that within 12 hours after the IR is approved in FIMS, a timeline (see FSIS Directive 8010.2) is developed and submitted for Investigative and Response Plans. OIEA personnel are to update the timelines daily. Timeline templates can be found on the Library page in FIMS.

XII. DATA ANALYSIS

The information collected about significant incidents in FIMS, including the operational status of establishments, is to 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.
XIII. QUESTIONS

All questions regarding this Directive are to be directed to the Emergency Coordination Staff through email at ERI-Mail@fsis.usda.gov or by telephone at 202-690-6486.

[Signature]

Assistant Administrator
Office of Policy and Program Development
## Incident Report (IR) Process Via FSIS’ Incident Management System (FIMS) Based on Incident Information

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<th>Program Area</th>
<th>Incident Information Sources</th>
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<th>FSIS Personnel Responsible for IR Review</th>
<th>FSIS Personnel Responsible for Approving IR</th>
<th>FIMS, E-mail notification of an Approved IR</th>
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