

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

FSIS DIRECTIVE

5500.2
Revision 2

4/9/08

NON-ROUTINE INCIDENT RESPONSE

I. PURPOSE

This directive outlines the procedures that the Emergency Management Committee (EMC) is to follow while managing a non-routine incident.

Key Points:

- *incorporates information on utilizing the new Non-Routine Incident Management System (NRIMS) to track and manage non-routine incidents*
- *provides instructions for completing, and information on accessing, FSIS Form 5500-4, Non-Routine Incident Report (NRIR)*
- *provides instructions for FSIS Form 5500-8, Impact of Non-Routine Incidents on Establishments, Warehouses and Import Houses*

II. CANCELLATION

FSIS Directive 5500.2, Revision 1, Non-Routine Incident Response, 7/16/07

III. REASON FOR REISSUANCE

This directive is being reissued in its entirety to remove the statement that the NRIMS system sends out a second e-mail that provides the NRIR for review, (it only sends out one), to clarify what a non-routine incident is, and to provide available information concerning the EMC.

IV. REFERENCES

9 CFR Part 300 to end

V. BACKGROUND

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

1. life-threatening, human illnesses potentially implicating FSIS-regulated product;
2. Class I recalls resulting from one or more illnesses involving FSIS-regulated product or if a Recall Committee is unable to reach consensus on whether the Agency should request that a company conduct a recall;
3. deliberate contamination of FSIS-regulated product;
4. threat condition Orange or Red with a specific threat to the food and agricultural sector;
5. animal disease with potentially significant public health implications for FSIS-regulated product;
6. ineligible foreign product in the United States (U.S.) where there is a reasonable probability that the consumption of the product will pose a serious health hazard,
7. high risk products in the U.S. as identified by Customs and Border Protection; and
8. suspicious activities observed by program personnel while performing their normal duties.

B. Additional situations that FSIS may consider as non-routine incidents include:

1. natural disasters (e.g., hurricanes, tornadoes, earthquakes);
2. terrorist attacks on the nation's critical infrastructures;
3. other incidents requiring a national coordinated response that result in the activation of the Emergency Support Function -11 (ESF-11), which is described in the Agriculture and Natural Resources Annex to the National Response Framework; and
4. incidents involving FSIS-regulated products and law enforcement authorities, e.g. stolen trucks.

NOTE: This directive does not address routine incidents. Routine incidents include most recalls not involving human illness, consumer complaints not related to life-threatening illnesses potentially implicating FSIS-regulated products, and reports of non-life threatening and isolated cases of human illnesses caused by FSIS-regulated product.

VI. AGENCY PERSONNEL RESPONSIBILITIES FOR REPORTING A NON-ROUTINE INCIDENT

A. Agency personnel are to immediately report any potential non-routine incident through supervisory channels. The information reported, at a minimum, is to include:

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

B. Designated personnel with access to NRIMS will review the incident information and if appropriate, develop the NRIR and enter the report into NRIMS.

C. For Class I recalls resulting in one or more illnesses (Section V, 2 of this directive), OPAEO will initiate the NRIR report into NRIMS and post the recall release.

1. The electronic NRIR form can be accessed through NRIMS via the following internet link: <http://nrims.fsis.usda.gov>

2. The electronic NRIR in the NRIMS automatically saves the NRIR as its case number. The case number is derived using the following: year, month, day-number of NRIR entered that day, e.g. 20070130-01.

3. All NRIRs in NRIMS are automatically forwarded to the Office of Food Defense and Emergency Response (OFDER) and the program area Assistant Administrator (AA), or their designees, for review following the automated process outlined in Attachment 1.

4. Program offices are to update the NRIR as often as necessary through NRIMS. The most recent information will appear first on the NRIR.

VII. NRIMS AND E-MAIL SYSTEM OUTAGE

A. In the event that the NRIMS system is non-operational, the person that generates the NRIR should send the information to the OFDER AA and their respective area AA as an attachment to an e-mail or via fax.

B. In the event that the e-mail system is non-operational, the person that generates the NRIR should send a pin, via personal digital assistant (e.g., Blackberry, Palm Pilot), to the OFDER AA and their respective area AA. The two AAs will review the information and make a determination regarding the NRIR in accordance with this directive.

C. In the event that both systems are non-operational, the person that generates the NRIR should verbally notify their respective EMC representative. The EMC representative will provide further communication instructions at that time.

D. When the NRIMS system becomes operational, the person that generated the information during the outage is to enter the information into NRIMS.

VIII. REVIEW OF THE NRIR

A. The OFDER AA and the AA responsible for the NRIR, or their designees, will review the submitted NRIR and, as appropriate, decide:

1. that no action is required at this time,
2. to pre-alert the EMC, or
3. to activate the EMC.

B. If the OFDER AA and the AA responsible for the NRIR determine that no further action is necessary at that time, the NRIR will either remain open, be closed, or be archived in NRIMS. An NRIR is closed when the incident that caused the report is resolved. An NRIR is archived when it is determined that the incident will take an extended period of time to resolve such as a criminal investigation is pending. NRIRs can also be classified as restricted when it contains sensitive information that is not to be shared with all NRIMS users.

C. If the OFDER AA and the AA responsible for the NRIR determine that the incident may warrant further discussion by the EMC, NRIMS will send a notification (pre-alert) to the EMC representatives. This notification pre-alerts the EMC representatives that there is a non-routine incident that may warrant the EMC activation. The pre-alert notification will include information on how and when the discussion will take place.

D. If the OFDER AA and the AA responsible for the NRIR determine that the EMC

needs to be activated, NRIMS will send an e-mail, a phone message, or both to the on-call EMC representatives for each program area that instructs them 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 Homeland Security Office will be provided a copy of the notification.

IX. EMERGENCY MANAGEMENT COMMITTEE (EMC)

A. The EMC is comprised of senior management personnel (AA or designee) from each of the FSIS program offices. Each program office EMC representative has 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 NRIMS and is also issued via email weekly to all program areas. The list contains on-call members and contact information for each program area.

B. The EMC may be pre-alerted or activated at any time, on any day of the year, to address and manage the Agency's response to a non-routine incident involving potentially adulterated or adulterated FSIS-regulated product. In the event the incident does not result in FSIS-regulated product adulteration, the purpose of the EMC activation would be to determine how to work with other involved agencies to assign responsibilities for any additional information gathering, and how to best provide the public with information about the safety of the product.

C. The AA or the EMC representative from OFDER serves as the Incident Commander (IC). The IC coordinates the work of the EMC in response to a particular non-routine 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. OFDER maintains an up-to-date roster of on-call EMC members, including home, work, and cell phone numbers and e-mail addresses. OFDER develops emergency incident reports (e.g., NRIRs, Situation Reports when the ESF-11 is activated) and monitors related intelligence. OFDER maintains the FSIS Situation Room and Agency preparedness plans in conjunction with the Department's Continuity of Operations Plans (COOP). In conjunction with the Department's Homeland Security Office, OFDER is FSIS' emergency incident liaison with other Federal agencies.

X. THE WORK OF THE EMC

A. Upon activation, the EMC evaluates the information provided on the NRIR and determines what further information is needed to complete the assessment of the non-routine incident. The EMC also develops and implements an incident action plan, whose execution is monitored by the IC through NRIMS.

B. The EMC coordinates the development of responses to questions about the incident, including responses to standard 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). All program areas are to routinely provide updates through NRIMS 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, will deactivate the EMC and advise the Administrator and FSIS Management Council. All EMC representatives and other parties will be notified through NRIMS, and the NRIR will be closed.

XI. COMPLETING FSIS FORM 5500-8 IMPACT OF NON-ROUTINE INCIDENTS ON ESTABLISHMENTS, WAREHOUSES, AND IMPORT ESTABLISHMENTS

A. Agency personnel complete FSIS Form 5500-8 to collect and submit information about the operational status of official establishments, facilities that handle FSIS-regulated products (e.g. warehouses), and import facilities affected by a non-routine incident such as an earthquake or hurricane.

NOTE: The form can be accessed through NRIMS at <http://nrims.fsis.usda.gov>, and it is also available in Outlook Public Folders\All Public Folders\Agency Issuances\Forms\5000 Series.

B. OFDER will notify the appropriate EMC representatives to collect information about the operational status of establishments or facilities within their jurisdiction.

C. The EMC representative will then notify the appropriate personnel within his or her program, for example, the District Manager (DM), Import Inspection Division's (IID) Deputy Director for Operations (DDO), or the Compliance Investigation Division (CID) Regional Manager (RM), to collect the information and complete FSIS Form 5500-8, available through NRIMS.

D. To complete the 5500-8, the DM, DDO, RM, or their designees may need to contact other personnel such as Front-line Supervisors, Consumer Safety Officers, Enforcement Investigative and Analysis Officers, Investigators, Regional Import Field Officers, Import Surveillance and Liaison Officers (ISLO), or Import Inspectors. The following information is needed to complete the 5500-8:

1. the official identification numbers for non-operational establishments or facilities in OFO's or OIA's areas of responsibility;

2. the addresses of non-operational high volume distribution points (e.g.,

wholesale grocery suppliers or transportation centers) in OPEER's area of responsibility; and

3. 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).

E. The DM, DDO, RM, or their designees will complete FSIS Form 5500-8 in NRIMS.

F. After the initial submission of a completed FSIS Form 5500-8, the DM, DDO, RM, or their designees will notify OFDER through NRIMS each time there is a change in a facility's operational status. This notification should be provided no later than at the close of business each day. Daily updates are not needed if there is no change in status.

XII. ANALYSIS OF INFORMATION

The information collected about non-routine incidents in NRIMS including operational status of establishments will be evaluated and analyzed by OFDER. Results of the analysis will be used to inform new or existing data initiatives and the development of further enhancements of the capabilities of NRIMS towards the effective management on non-routine incidents.



Assistant Administrator
Office of Policy and Program Development

NRIR Process Via the NRIMS Based on Incident Information

| Program Area | Incident Information Sources | FSIS Personnel with Access to the NRIMS for NRIR Development | FSIS Personnel Responsible for NRIR Review | FSIS Personnel Responsible for Approving NRIR | NRIMS Dissemination of NRIR |
|---------------------|--|---|---|---|------------------------------------|
| OA | External Federal Agencies | OFDER - Recorder | OFDER – AA or designee | OFDER – AA or designee | OFDER AA/EMC reps |
| OFDER | OA External Agencies Other Program Offices | OFDER - Recorder | AA or designee | AA or designee | AA/EMC Rep |
| 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 OFDER AA |
| | Foreign Governments | Deputy Director Import (IID) Operations | Directors: IES, IEPS, IAS, IID | Directors: IES, IEPS, IAS * *cc: DAA, Directors: IES, IEP, IID, IAS | OIA AA OFDER AA |
| | External - (Others) Field ISLOs | Deputy Director Policy Deputy Director Operations | Director IID | Director- IID* *cc: DAA, Directors: IES, IEPS, IID, IAS | OIA AA OFDER AA |

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|---------------------|-------------------------------------|---|---|--|------------------------------------|
| OPEER | External Agencies or CID | Deputy Director, Compliance Specialist, Regional Manager, Supervisory Compliance Investigator, Sr. Compliance Investigator, Compliance Investigator | Regional Manager | Regional Manager* *cc: CID Director | OPEER AA OFDER AA |
| | ICAD Federal State Programs | Director ICS | Director ICAD | Director ICAD | OPEER AA OFDER AA |
| OPAEO | Hot Line Information | Hot Line Specialist and Manager | FSES Director | OPHS/HHSD Director | OPHS AA OFDER AA |
| | External Sources | Director: ECIMS, CPAO, WSS, FSES, SIPO | Director: ECIMS, CPAO, WSS, FSES, SIPO | OPAEO AA | OPAEO AA OFDER AA |
| OFO | External Agencies IICs FLS | District Manager or designee, DDM, Case Specialist, District Analyst, Director RMD or designee | District Manager or designee | District Manager or designee | OFO AA OFDER AA |
| OPPD | IICs Industry FLS | Director: PDD, PAD, LPDD | OFO District Manager | OFO District Manager | OFO AA OFDER AA |

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|---------------------|--|---|---|--|------------------------------------|
| OPHS | External Agencies, State and Local Partners, PHELS, CCMS | HHSD Director Or designee CCMS staff | HHSD Director Or designee | HHSD Director Or designee | OPHS AA OFDER AA |
| | Laboratories, CDC Liaison | OPHS AA Lab Directors | OPHS AA | OPHS AA | OPHS AA OFDER AA |