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

# FSIS DIRECTIVE	5100.2	10/4/05

ENFORCEMENT, INVESTIGATIONS, AND ANALYSIS OFFICER (EIAO) RESPONSIBILITIES RELATED TO RECALLS AND CONSUMER COMPLAINTS

Part I -- General

I. PURPOSE

This directive provides directions to EIAOs on how to conduct activities other than comprehensive food safety assessments, which are addressed in FSIS Directive 5100.1, Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology. The activities addressed in this directive include assignments related to effectiveness checks for recalls and investigation of complaints entered in the Consumer Complaint Monitoring System (CCMS).

II. RESERVED

III. RESERVED

IV. REFERENCES

21 U.S.C. 451 and 601
9 CFR 300 to end
FSIS Directive 5500.1 5610.1, 8091.1, 8410.1, Revision 2, and 8800.1

V. BACKGROUND

This directive is the second in a series of directives addressing the responsibilities of EIAOs, who are under the direction of District Offices, Office Field Operations. In addition to conducting comprehensive food safety assessments in federally-inspected establishments (see FSIS Directive 5100.1), EIAOs conduct other activities such as recall effectiveness checks and investigation of complaints entered in the CCMS.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC; Import Offices

OPI: OPPED

Part II -- Recall

I. Pre-Recall Committee – Stage One

A. The Agency's activities before a company decides to recall product primarily relate to pathogen results and begin once the determination is made that a presumptive positive laboratory sample result has occurred, and product has not been held by the plant. The District Recall Officer (DRO) is expected to assume overall responsibility for preparing the Agency for a recall and to assign an EIAO to visit the establishment. An EIAO's activities may, as determined by the DRO, be conducted on or off-site. An EIAO is to:

1. Immediately contact establishment's Recall Coordinator to discuss findings that may lead the establishment to conduct a recall (e.g., FSIS presumptive lab results or consumer complaint).

2. Contact in-plant inspection personnel to obtain their perspective on the establishment's operations that may be relevant.

3. Update the DRO regarding the outcome of discussions.

4. Verify that the establishment has the applicable worksheets and that the Recall Coordinator is clear on the needed information.

5. Discuss with establishment management that if the laboratory results are confirmed, and the establishment decides to conduct a recall, the Agency will ask the establishment to provide recall data as outlined in the applicable worksheets and relevant product labels (preferably electronically) as soon as possible.

6. Conduct preliminary assessment of establishment practices (e.g., sanitation, microbiological data, possible cross-contamination potential between the product implicated for the recall action and other products, and production history).

7. Update the DRO on the outcome of these discussions with the establishment and in-plant inspection personnel.

NOTE: When assessing possible cross-contamination potential between the product implicated and other product, the EIAO may need to evaluate the product flow chart and microbiological programs related to food safety. If the EIAO is not familiar with the steps in a process, the Agency's Hazards Control Guide (HCG) can be used as a tool to become familiar with the common steps associated with a particular process (See the FSIS web site at: http://www.fsis.usda.gov/regulations/Compliance_Guides_Index/index.asp.

II. Recall Committee – Stage Two

A. When product confirms positive, or in the case of other (non-pathogen) recall situations, the EIAO serves as a member of the Recall Committee. As a member of the Recall Committee, the EIAO is to:

1. participate in both the FSIS preliminary meeting and the external conference call held with the plant.

2. in the pre-meeting with the Recall Committee, share information that he or she learned during preliminary meetings and conversations with establishment management and in-plant inspection team.

3. share factual information he or she gathered that will assist in the Committee in deciding the classification and the scope (amount and kind of product in question) of the recall.

III. Stage Three – Recall Effectiveness Checks

A. Once an establishment decides to conduct a recall, the Recall Committee decides on the Class of the recall using precedent, and if needed, the Health Hazard Evaluation Board's (HHEB) advice (See FSIS Directives 8080.1, Revision 4, Amendment 2, and 8091.1). When an establishment initiates a voluntary recall, the EIAO will perform recall effectiveness check verifications. This is a process by which FSIS personnel verify that the recalling firm has been diligent and successful in notifying and advising consignees of the need to retrieve and control recalled product and has ensured that the consignees have responded accordingly. The EIAO is to:

1. ensure that the DRO has copies of all distribution and labeling information provided by the establishment.

2. conduct effectiveness checks at locations identified by the DRO and as outlined in FSIS Directive 8080.1, Revision 4, Amendment 2, to verify that consignees have received appropriate notification on the recall and are acting on the basis of that notification. As determined by the DRO, effectiveness checks may be conducted on-site or via the telephone.

3. if the recall is ineffective, take further action to mitigate the risk to the public (i.e., a detention, seizure, and other action within the prohibited acts section of the FMIA (21 U.S.C. 610), the PPIA (21 U.S.C. 458), and the EPIA (21 U.S.C. 1037); and FSIS Directive 8410.1, Revision 2).

4. as directed by the DRO, conduct on-site visits at establishments that received the product to verify product disposition by reviewing records or by observing product disposition to determine that recalled product has undergone proper disposition in accordance with regulatory requirements.

5. conduct product disposition verification on a subset of consignees using the same effectiveness checks tables selected for the recall as set out in FSIS Directive 8080.1, Revision 4, Amendment 2, Attachment 3.

6. contact or conduct on-site visits of establishments that received the product.

IV. Documentation

The EIAO should record all recall information obtained on FSIS Form 8400-4. This documentation should include distribution information, information about product being returned to establishment, and product that was destroyed. The EIAO is to fax or e-mail the completed form to the District Office.

Part III – Consumer Complaint Monitoring System (CCMS)

A. All consumers should expect that the products they receive are safe, wholesome and properly labeled. The CCMS is an electronic database used to record, triage, coordinate, and track all consumer complaints reported to the agency. FSIS Directive 5610.1 describes the purpose, activities and maintenance of the CCMS system. The Agency uses consumer complaints to ***help identify*** unsafe meat, poultry, and egg products in commerce that may have to be removed from commerce. Consumer complaints are complaints made by consumers and generally allege illness, injury, foreign material, allergic reaction, under-processing, misbranding, economic adulteration, or inferior quality. Under the direction of the District Office, an EIAO may conduct an investigation of a consumer complaint if there is a potential for health or safety hazards such as:

- One complaint of under-processing of an RTE product
- One laboratory confirmed illness/injury
- One allergen complaint
- One complaint of unusual signs or symptoms that may represent the deliberate introduction of a chemical, biological, or radiological threat agent to the food supply
- Two or more foreign material complaints
- Two or more complaints of quality, economic adulteration, etc.
- Two or more complaints for misbranding

B. In the CCMS case notes field, the Office of Public Health Science (OPHS) will document the reason it was determined that FSIS should investigate a consumer complaint or the reason that it closed the case without requesting an investigation as set out in FSIS Directive 5610.1. The EIAO may be requested by the District Office to follow up with consumers, collect evidence (e.g., product, documents, and photographs), submit samples, and enter information gathered from an investigation into the CCMS database as outlined in FSIS Directive 5610.1. If an EIAO is assigned to investigate a complaint, he or she should:

1. immediately contact the consumer to verify information.

2. visit the consumer to verify that the information provided by the consumer is accurate.

3. collect the relevant information and evidence needed to identify and document the problem. The EIAO may be requested to obtain photos or samples.

4. enter investigation findings in the “case note” section of the CCMS screen.

5. collect and submit laboratory samples to an FSIS laboratory, if requested.

6. contact or visit point of purchase (POP) to determine product origin and associated establishment number.

7. meet with plant officials about the matter and verify that the establishment's Sanitation SOPs, HACCP plan, or other food safety controls are effective.

8. discuss the information with the Deputy District Manager as it may be appropriate to initiate recall proceedings or take a regulatory or enforcement action.

9. contact Office of Program Evaluation, Enforcement and Review (OPEER) and CCMS staff if there are concerns regarding criminal activity and document such in CCMS.

10. immediately contact the Office of Food Defense and Emergency Response and CCMS staff, concerning product tampering or potential food security threats, complete a Non-Routine Incident Report (FSIS Form 6500-5), and update the CCMS.

11. forward complaints to appropriate agency (e.g. state or local department of health or agriculture) if it is deemed that the product in question falls outside FSIS jurisdiction.

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