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

FSIS DIRECTIVE

5610.1
Revision 1

6/29/18

CONSUMER COMPLAINT MONITORING SYSTEM

I. PURPOSE

This directive provides instructions on how to input, manage, and investigate complaints entered into the Consumer Complaint Monitoring System (CCMS). This directive is being revised to update and clarify the consumer complaint evaluation and investigation processes. This reissuance also includes new sections describing how a case is archived in CCMS, how the data can support other FSIS activities, and that analyses of the data will be made available to the public.

II. CANCELLATION

FSIS Directive 5610.1, *Procedures to Implement the Consumer Complaint Monitoring System (CCMS)*, 8/8/05

III. BACKGROUND

CCMS is an electronic database used by FSIS to document, analyze, and coordinate responses to consumer complaints. CCMS provides FSIS with a surveillance tool that facilitates identification of food safety risks to human health that require an Agency response. It is designed to support the Agency's mission of protecting consumers by ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled. The FSIS Office of Public Health Science (OPHS), Applied Epidemiology Staff (AES), is responsible for the overall management of CCMS and all complaints contained therein.

IV. TYPES OF CONSUMER COMPLAINTS

A. A consumer complaint is initiated by a consumer or his or her representative and can involve reports of illness, foreign objects, an allergic reaction injury, mislabeling, off-quality, and economic adulteration pertaining to an FSIS-regulated food (meat, poultry, or processed egg products.) This includes consumer complaints reported to FSIS by State or local health departments or another Federal agency, such as the Food and Nutrition Service (FNS) or the Food and Drug Administration (FDA).

B. Except as identified below, all applicable consumer complaints reported to FSIS are to be entered into CCMS regardless of which program area office initially receives the complaint. If a complaint is entered into CCMS for a product that is not regulated by FSIS (in error), OPHS AES is to forward the complaint to the appropriate non-FSIS regulatory authority. The need to forward a consumer complaint to another authority for response may not be identified as such until evaluated or investigated by OPHS AES.

C. The following are examples of complaints that are not to be entered into CCMS:

1. Complaints that involve products regulated by FDA;

2. Complaints involving foods not regulated by FSIS that are purchased by USDA and administered through the FNS (i.e. USDA Schools/Child Nutrition Program Foods); such complaints are to be referred to the USDA Food and Nutrition Service (FNS) USDA Foods Programs;

3. Retail-prepared meat, poultry and processed egg products. These complaints involve products that have lost their Federal identity due to further processing or packaging at a retail establishment, such as a grocery store or restaurant and should be referred to the appropriate State or local public health office or department of agriculture for initial evaluation and investigation. Investigation at the State or local levels may conclude that the source of the incident occurred at an FSIS-inspected establishment. Consequently, the complaint may be referred back to FSIS for additional investigation;

NOTE: Consumer complaints, including those involving retail-prepared foods, can provide useful information for detecting foodborne outbreaks. If the complaint involves illness and there are indications that the illness may be associated with an outbreak (e.g., lab-confirmed illness or other similar complaints matching temporally/time or geographically), the complaint will be entered into CCMS and AES is to work with other OPHS staffs, as well as with the respective State or local public health office or department of agriculture to monitor and investigate the outbreak per FSS Directive 8080.3*, Foodborne Illness Investigations*;

4. Complaints regarding FSIS-regulated products that involve potential criminal violations, misconduct, or fraud and/or abuse reported by a whistleblower. These complaints are to be forwarded to the appropriate Regional Director in the Office of Investigation, Enforcement and Audit (OIEA) Compliance and Investigations Division (CID) per FSIS Directive 8010.1, *Methodology for Conducting In-Commerce Surveillance Activities*;

5. Complaints regarding FSIS-regulated products that may involve potential intentional product contamination/tampering. These complaints are to also be initially referred to the appropriate OIEA CID Regional Director. If review by OPHS AES and OIEA CID determines that the complaint involves an intentional product contamination/tampering, an Incident Report (IR) is to be opened in the FSIS Incident Management System (FIMS) by one of the two program areas. For guidance or instruction on the incident, OPHS AES or OIEA CID is to seek activation of the FSIS Emergency Management Committee (EMC) as per procedures in FSIS Directive 5500.2*, Significant Incident Response*; and

6. Complaints regarding FSIS-regulated products reported by an industry competitor. These complaints are to be referred to the appropriate FSIS Office of Field Operations (OFO) District Manager (DM), except when a criminal violation is alleged. If a criminal violation is alleged, the complaint is to be forwarded to the appropriate OIEA CID Regional Director.

V. RECEIVING CONSUMER COMPLAINTS

A. FSIS receives consumer complaints through any of the following reporting options:

1. Consumers contact the Meat and Poultry Hotline (1-888-MPHotline) staff - Hotline hereafter - in the Office of Public Affairs and Consumer Education (OPACE), who are to enter the complaint into the Hotline database, enabling it to then be imported into CCMS; or

2. Consumers contact an FSIS program area office that is authorized to enter complaints directly into CCMS including:

    a. OFO;

b. OIEA CID; or

c. OPHS AES.

3. FSIS staff are to be aware that consumers can enter a complaint online using the electronic consumer complaint form (eCCF) available at: https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/report-a-problem-with-food or https://www.ccms.fsis.usda.gov.

4. Non-FSIS government entities may receive consumer complaints regarding FSIS regulated products and they will not have direct access to CCMS. When this occurs, the person receiving the complaint is to send the information to OPHS AES, OFO or OIEA CID staff via email for entry into CCMS. Non-FSIS government entities that regularly forward complaints to FSIS include:

   a. USDA FNS;

   b. State or local public health office or department of agriculture; and

   c. Department of Health and Human Services, FDA.

VI. ENTERING COMPLAINTS INTO CCMS

A. The first step in responding to a consumer complaint is to determine whether the issue meets the definition of a "consumer complaint" appropriate for management in CCMS as provided in Section IV, *Types of Consumer Complaints,* of this directive. The FSIS employee receiving the complaint is to speak with the consumer or his or her representative to document complaint details and determine if the complaint is appropriate for entry into CCMS.

B. If the complaint does not meet the definition of a consumer complaint, then the information provided by the consumer will not be entered in CCMS. The FSIS employee receiving the complaint is to forward the information on behalf of the consumer to the appropriate person in FSIS to handle or refer the consumer to another Federal, State or local public health office or department of agriculture as appropriate.

C. If a complaint meets the definition of a consumer complaint, the FSIS employee is to enter the complaint into the Hotline or CCMS directly. Contact information for the consumer, product and packaging details, and the nature of the complaint are to be entered by the prompts provided in CCMS.

D. Once entry of the complaint is complete and it is submitted to CCMS or Hotline and subsequently imported into CCMS, a unique case number will be generated and viewable to the FSIS employee entering the complaint. The FSIS employee is to provide the case number to the consumer for reference when following-up with FSIS on the status of his or her complaint.

E. For eCCF-reported complaints, OPHS AES is to first review the complaint to determine if it meets the definition of a consumer complaint appropriate for entry into CCMS. If deemed appropriate, OPHS AES is to import the complaint into CCMS and a unique case number will be assigned.

F. In regard to consumer complaint investigations, the "consumer district" in CCMS is the OFO District Office (DO) responsible for activities in the location where the consumer resides. The "establishment district" in CCMS is the OFO DO responsible for activities within the official establishment identified in CCMS. The appropriate OFO DOs are automatically assigned by CCMS when the FSIS employee enters the consumer's State or the establishment number into CCMS.

VII. CONSIDERATIONS FOR COMPLAINT INTAKE

A. If the consumer wants to make a complaint but does not have the original packaging or a record of the packaging information, other available information about the complaint such as the complaint description, product brand, type of product, and point-of-purchase location can still be entered into CCMS. If necessary, OPHS AES is to communicate with the consumer to gather the missing information. If efforts to locate more information are unsuccessful and there is too little information to coordinate an investigation, the information that is received can be used to assist in surveillance and may benefit future investigation efforts should FSIS receive similar complaints about the same product. For example, in addition to packaging information, the description of the complaint, the product brand and type of product and point of purchase location, are to be recorded in CCMS. All pieces of information can contribute to active surveillance.

B. A consumer has the right to remain anonymous. If the consumer does provide contact information, the FSIS employee conducting the initial interview is to inform the consumer that his or her complaint and contact information may be shared with other USDA program area offices, FDA, and a State or local public health office or department of agriculture, for investigative purposes.

C. The Report Date in CCMS of the complaint is automatically captured in the system when the FSIS employee enters the complaint and cannot be changed manually.

D. The Incident Date in CCMS is the date that the consumer first experienced the adverse event mentioned in the complaint. For example, if a consumer eats a food product and becomes ill three days later, the Incident Date is the date that the person became ill, not the day the food was consumed. This date may differ from the Report Date or the Purchase Date, which are also both captured in CCMS. The FSIS employee is to manually enter the Incident Date in the designated field when entering the complaint into CCMS.

E. CCMS will allow more than one type of consumer complaint to be recorded in a case. In general, the primary complaint type in CCMS is the issue directly associated with the product, and the secondary complaint type is the consumer's response to the primary complaint type. For example, if a consumer finds a foreign object that caused injury, then "foreign object" is the primary complaint type and "injury" is secondary.

F. If there is more than one complaint type directly associated with the product and the primary complaint type is not readily distinguishable, such as when product is mislabeled and also contains a foreign object, the FSIS employee is to document the primary complaint type as the complaint first observed by the consumer.

G. The CCMS system will automatically designate the first complaint entered as the primary complaint type. The FSIS employee entering the case can change the designated primary complaint type within CCMS. However, it is the responsibility of OPHS AES to review the case and make any necessary edits to ensure that the proper complaint type is designated as the primary complaint type.

H. The FSIS employee is to record more than one product type in a single case in CCMS when appropriate. For example, an illness complaint in which a consumer ate hot dogs with chili involves one complaint type with two food products.

I. In the event that a consumer is reporting multiple complaints or incidents with different food products, such as one complaint of illness associated with hamburgers and one complaint of foreign objects in chicken, the FSIS employee entering the complaint is to record each complaint and its associated food product as a separate case in CCMS.

J. The FSIS employee receiving the complaint is to determine the appropriate way to capture the complaints using the information provided by the consumer.

K. At the close of the interview, the FSIS employee is to advise the consumer to keep the complaint evidence, including remaining food products and packaging, in the freezer for a minimum of two weeks. The FSIS employee is to explain to the consumer that this allows FSIS time to evaluate the case and determine the appropriate response, which may result in an investigation requiring that the evidence, product, and packaging be sent to an FSIS laboratory for further analysis.

VIII. COMPLAINT EVALUATION

A. After a complaint has been entered into CCMS, OPHS AES is to evaluate the complaint and accompanying information to identify any trends and similar cases. To evaluate the complaints, OPHS AES is to:

1. Review complaint details and assess severity (i.e., lab-confirmed illness, death, or injury);

2. Conduct a historical case search in CCMS for similar complaints at least one year prior to the current complaint report date. At a minimum, the search is to evaluate against the known product brand, complaint type and establishment number; and

3. If an establishment number has been identified, review data in the Public Health Information System (PHIS) to determine if there is a history of in-plant incidents that may have contributed to the reported complaint. Data and information contained in various PHIS reports, such as noncompliance records (NRs), and memorandums of interview (MOI), are to be evaluated for issues documented within at least the six months prior to the current complaint report date.

B. OPHS AES is to be aware that additional information provided by the consumer in CCMS may indicate that the respective CCMS and PHIS evaluations should be narrowed or expanded to include other search variables or timeframes.

IX. FOLLOW-UP INTERVIEWS

After the initial complaint information has been evaluated, OPHS AES may conduct follow-up interviews with the consumer, representatives of the consumer or a representative at the point-of-purchase if:

1. The case is missing pertinent information and more specific details, such as medical diagnosis, are required to fully assess the severity of the complaint;

2. Special risk populations such as young children, elderly or prisoners, are involved;

3. There is an indication that the complaint may involve a potential widespread, non-isolated problem evidenced by laboratory confirmed illnesses or multiple similar complaints;

4. There is an indication that the complaint is related to a recent recall or outbreak investigation; or

5. A death has been reported.

X. POSSIBLE OUTCOMES AFTER EVALUATION

A. OPHS AES will close a case without additional follow-up if they determine that the complaint is isolated and there is no public health concern that warrants an investigation or further action by FSIS. OPHS AES is the only program area office permitted to close a case in CCMS. When a case is closed <u>without</u> additional follow-up by FSIS, OPHS AES is to:

1. Document in CCMS the reason that additional action was not necessary;

2. Send a letter to the consumer's e-mail or physical address informing the consumer of the final outcome of the complaint;

3. If known, send a letter documenting a summary of the complaint to FSIS inspector-in-charge (IIC) via the DO where the product was produced. Personal identifying information of the consumer is not included in the letter and is not to be communicated to the establishment without consent from the consumer; and

4. Upload electronic copies of the letters in the Documents section of the respective case file**.**

B. OPHS AES is to refer a complaint to another FSIS program area office when the evaluation results indicate that another office needs to be made aware of the complaint or that another regulating authority, such as FDA, should respond. For example, if a complaint involves imported product, OPHS AES is to notify the OFO Recall Management and Technical Analysis Division (RMTAD), Import Operations Branch. If OPHS AES has completed their evaluation and investigation into the case, the case will be closed in CCMS after referral.

C. OPHS AES primarily coordinates consumer complaint investigation activities with OFO. The respective OIEA CID Regional Office may be requested by OPHS AES to assist in the investigation in certain situations such as when the complaint is linked to an outbreak requiring traceback. For the purposes of this directive, unless circumstances provide reason, task requests for additional follow-up are primarily directed to OFO from OPHS AES.

XI. OPHS AES COORDINATION WITH OFO

A. OPHS AES is to enter all task requests listed below into CCMS. Once OPHS AES submits the task request in CCMS, an e-mail containing the task details is automatically generated and sent to the employees noted by OPHS AES and the DO to be responsive to the task. OPHS AES is to update the OFO DO contacts in task requests every six months through e-mail communication with OFO DOs. The contacts can be viewed in Contacts located in the Reference Materials tab in the system.

B. If OPHS AES identifies similar complaints from the same establishment involving non-identical products in CCMS or potentially related NRs or MOIs in PHIS, OPHS AES is to submit an inspector in charge (IIC) review task through CCMS. This task will request that the respective contacts in the OFO DO for the establishment forward the complaint information through the appropriate channels to the IIC at the establishment for review and situational awareness.

C. On a case-by-case basis, OPHS AES is to seek additional information from OFO regarding in-plant practices or conditions that may identify the need for additional review or investigation without requesting a formal investigative report. For example, in addition to a review of the complaint, OPHS AES is to ask the respective contacts in the OFO DO for the establishment to request that the IIC report back if the establishment has received similar complaints not previously reported to CCMS.

D. The respective contacts in the OFO DO for the establishment are to mark the task "Complete" in the Task Notes in CCMS after it has been confirmed that the IIC has received the information and all information requests from OPHS AES have been addressed. OPHS AES is to close the case in CCMS after review of the response and if no additional information is needed for assessment. In the event that the IIC provides new, significant information related to the complaint, such as evidence of similar complaints reported to the establishment, OPHS AES is to reevaluate the case and recommend additional follow-up if necessary.

E. If OPHS AES determines that the complaint warrants a formal investigation, OPHS AES is to submit an investigation task request in CCMS to the respective contacts in the OFO DOs for the consumer and establishment.

F. OPHS AES is to request an investigation if one or more of the following public health concerns are indicated after evaluation of the complaint:

1. There is evidence of laboratory confirmed illness, allergic reaction or foreign material with the potential to cause serious injury;

2. There are multiple similar complaints reported within a short time period, indicating a potentially widespread problem. For example, two or more complaints within 30 days as the current complaint, involving the same product and establishment;

3. There is evidence of multiple in-plant failures from PHIS that appear to be related to the reported complaint; or

4. There is evidence of a rare or unusual food safety incident or the potential health risk of the food safety hazard is unknown.

G. During an investigation, the respective OFO DO, or as indicated, the OIEA CID regional office, are to manage the daily field activities with OPHS AES providing coordination and subject matter expertise.

XII. RESPONSIBILITIES OF THE OFO DISTRICT DURING AN INVESTIGATION

A. The first step in the investigation process is to obtain and examine available evidence. To initiate an investigation, OPHS AES is to send a task request from CCMS to the respective OFO DO where the consumer resides. The task will request that an Enforcement Investigations and Analysis Officer (EIAO) be designated to verify the complaint per instructions in FSIS Directive 8010.3, *Procedures for Evidence Collection, Safeguarding and Disposal*. To complete the complaint verification process, the designated EIAO is to:

1. Arrange to meet with the consumer to collect relevant information and evidence needed to adequately identify and further document the alleged problem;

2. Visually inspect and photograph the product and product packaging that is the subject of the complaint to verify that the correct information was entered into CCMS; and

3. To ensure that the personal safety of FSIS personnel is maintained when meeting with the consumer, the EIAO is to alert his or her supervisor to any safety concerns. As necessary, the EIAO is to discuss methods and strategies with OPHS AES. In the event that there are significant risks or concerns to personal safety, OPHS AES is to document the issue in the CCMS case Task Notes and is to cancel the evidence collection task.

B. If requested by OPHS AES and if the consumer is willing to relinquish the product for analysis, the designated EIAO is to collect the product and submit it to an FSIS laboratory. If requested, the EIAO is also to collect identically-coded companion samples from the consumer or the point-of-purchase for analysis when available.

C. OFO and OPHS AES are to be aware that an evidence collection task requiring an in-person visit with the consumer is not always required to initiate an investigation. For instance, when a consumer provides pictures of an easily identifiable foreign object in a product, and no sampling is needed, the pictures may be sufficient evidence to continue the investigation at the establishment. The decision to move forward in

the investigation without in-person evidence collection is to be made on a case-by-case basis by OPHS AES and the respective OFO DO.

D. OFO concerns about the decision to request an investigation or questions about how to complete the verification should be directed via email or phone to the OPHS AES employee who requested the task.

XIII. PROCEDURES FOR SUBMITTING PRODUCT SAMPLES TO AN FSIS LABORATORY FOR ANALYSIS

A. If OPHS AES determines that product samples are to be analyzed at an FSIS laboratory, they are to consult with OFO, the OPHS Science Staff, and the appropriate OPHS laboratory subject matter expert to determine what type of analysis is to be conducted and which laboratory is to conduct the analysis.

B. Once the type of analysis and laboratory location has been determined, OPHS AES is to create a task request in CCMS for OFO to collect samples and submit them to the designated FSIS laboratory. This task is often requested at the same time as the evidence collection task.

C. OPHS AES is to describe in the task request the type of samples to be collected, the laboratory analysis to be performed, to which FSIS laboratory the samples should be submitted, and instructions for collecting and shipping the product samples.

D. OFO EIAOs are to maintain the integrity of the samples and not cause contamination during sampling. If microbiological analyses are requested, EIAOs are to use aseptic techniques as outlined in FSIS Directive 10,230.2, *Procedures for Collecting and Submitting Domestic Samples for Microbiological Analysis*, when collecting samples from non-intact (opened) packages, and to the extent necessary when collecting samples from intact (unopened) packages. Refer to FSIS Directive 13,000.2, *Performing Sampling Tasks in Official Establishments Using the Public Health Information System*, for directions on ordering sampling supplies.

E. To complete the request, the EIAOs are to use the PHIS Sampling Dashboard to enter sample collection data and information on the requested analysis prior to submitting samples to the respective FSIS laboratory.

F. If PHIS is not accessible at the time of sample collection, EIAOs are to complete FSIS Form 10,000-2, *Domestic Laboratory Report*. Contact OPHS AES if a hardcopy of this form is needed. The following blocks are to be filled out on FSIS Form 10,000-2:

1. Block 2 – enter 42;

2. Block 7 – enter the establishment number of the collected product (if the establishment number is not known leave blank and in Block 16 enter the abbreviation of the State where the sample was collected);

3. Block 10 – enter CCMS;

4. Block 11 – enter the CCMS case number;

5. Blocks 13 and 14 – enter the date sample was taken and the date mailed to the laboratory, respectively;

6. Block 15 – check off the laboratory to which the sample is being shipped;

7. Block 24 – enter the product information, any relevant information related to the sample, the requested analyses, and the OPHS AES contact name, phone number and email for sending

results;

8. Block 25 – collector's name (printed and signed); and

9. Block 27 – collector's phone number

NOTE: Any blocks not listed above can be left blank.

G. The OFO EIAO is to complete FSIS Form 8000-17, *Evidence Receipt and Chain of Custody*, to submit with the samples. The form is located at: https://inside.fsis.usda.gov/fsis/emp/static/global/forms/forms.jsp. (Level 2 e-Authentication log-in is required to access the site.)

H. Sample seal set packets (FSIS Forms 7355-2A and 2B) are available in the sample box. See FSIS Directive 7355.1, *Use of Sample Seals for Laboratory Samples and Other Applications*, for guidance on sample seals and procedures.

I. The OFO EIAO submitting the sample is to upload a copy of the forms in the Documents section of the respective case file.

J. Once the laboratory analysis is complete, the FSIS laboratory that analyzed the sample is to send the form to the submitter and the OPHS AES contact for uploading to the Documents section of the respective case.

K. After the OFO EIAO in the DO where the consumer resides has completed the evidence collection tasks, he or she is to document the findings in an EIAO verification report template previously uploaded to the Documents section of the case by OPHS AES. This document is also available by accessing the Reference Materials tab in CCMS.

L. The EIAO verification report is to be completed before laboratory results are available and should be uploaded to CCMS even if laboratory results are pending. When the EIAO verification report has been completed, the EIAO is to send the report to his or her DM for review and approval. Once approved, the DM, or his or her designee, is to upload the report, pictures, and supporting documentation to the Documents section of the respective case.

M. Except where circumstances prevent it, every attempt is to be made by the OFO DO where the consumer resides to complete the EIAO verification task and report within seven business days from receipt of the task request. The OFO EIAO is to notate completion of the task in the Task Notes and mark the task "Complete."

N. If during the investigation the EIAO finds that any information originally entered into CCMS is inaccurate, he or she is to confirm the correct information with the appropriate sources and enter the updates into the case file. The EIAO is to also document in the Notes section of the case file which changes or updates were made to the case.

O. After the evidence collection task has been completed and documents have been uploaded to CCMS, OPHS AES is to review the information submitted. If there are questions or additional information is needed to make a thorough assessment and decision on the next steps, OPHS AES is to consult with the respective OFO DO.

P. If OPHS AES determines that the incident does not constitute a public health hazard and additional action is not necessary by FSIS, OPHS AES is to document the reason additional actions were not required in CCMS and close the case.

Q. On occasion, the OFO DO where the consumer resides may request that OPHS AES arrange for the evidence collected to be sent to the respective OFO DO where the establishment is located for visual examination. When requested, OPHS AES is to coordinate the task request through CCMS with the appropriate instructions to the contacts in the OFO DO where the consumer resides.

XIV. RESPONSIBILITIES OF THE OFO ESTABLISHMENT DISTRICT DURING INVESTIGATION

A. If during or after verification, OPHS AES determines that review and response from the establishment is necessary, OPHS AES is to send a task from CCMS to the respective OFO DO where the establishment is located and request that the IIC be notified of the complaint.

The task from OPHS AES will request that the IIC complete a report documenting if there were failures observed in the establishment's Hazard Analysis and Critical Control Point (HACCP) system or production processes which are believed to have contributed to the current consumer complaint. The task will also request that the report document if similar complaints have been received by the establishment, the establishment's response to the current complaint, and any other relevant information related to the complaint which triggered the investigation.

C. The IIC is to document the findings in an IIC Report template previously uploaded to the Documents section of the case in CCMS by OPHS AES. This document is also available by accessing the Reference Materials tab in CCMS.

D. After the IIC has completed his or her review and documentation, he or she is to forward the report to the DM, or his or her designee, for review. Once the report has been approved by the OFO DO where the establishment is located, the DM or his or her designee is to upload the report and supporting documentation to the Documents tab of the respective case.

E. Except where circumstances prevent, every attempt is to be made by the OFO DO of the establishment to complete the IIC Report task and report within seven business days from receipt of the task request. The OFO DO where the establishment is located is to notate completion of the task in the Task Notes and mark the task "Complete."

F. OPHS AES is to review the IIC report and supporting documentation to make a final assessment. If there are questions or additional information is needed to complete the final assessment and make a decision on next steps, OPHS AES is to consult with the OFO DO where the establishment is located.

G. If there are concerns by OPHS or OFO after reading the IIC report that there may be bigger food safety issues at the establishment, the OFO DO where the establishment is located may recommend additional follow-up such as an evaluation as set out in FSIS Directive 5100.4, *Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology* (or a recall as set out in FSIS Directive 8080.1*, Recall of Meat and Poultry Products*. The OFO DO where the establishment is located is to make the final decision on whether follow-up after the initial CCMS investigation is necessary to adequately address the hazards reported in the complaint.

XV. ARCHIVING A CASE

A. OPHS AES is responsible for ensuring that all actions taken by the FSIS program area offices responding to a CCMS complaint and investigation are thoroughly documented in the CCMS case file. After all actions have been completed and documented, OPHS AES is to close the case and notify the consumer of the outcome in a letter sent to the e-mail or physical address noted in the case file.

B. FSIS personnel are to be aware that CCMS maintains complaint data and it is retrievable by case number or other case details, such as the establishment number. If new information is received after a case is closed which corrects previous statements made by the consumer or which could impact the

previous outcome, OPHS AES is to reopen the case and enter the new information. In consideration of any new information received, OPHS AES is to consult with the respective OFO DO or OIEA CID Regional Office for follow-up, if needed.

C. FSIS program area offices involved in the intake or investigation of the complaint are to contact OPHS AES directly for status updates. FSIS program area offices are to inform consumers reporting complaints via the Meat and Poultry Hotline or eCCF that they should contact the Hotline to request status updates. The Hotline is to notify OPHS AES that the consumer is requesting a status update and OPHS AES will contact the consumer and provide an update.

D. If a consumer requests case documentation such as copies of the laboratory sampling results, they are to be advised to contact the USDA FSIS Freedom of Information Act (FOIA) Office in writing at:

Freedom of Information Act Officer
USDA, Food Safety and Inspection Service
Room 2168 South Building
1400 Independence Ave., SW
Washington, DC 20250

XVI. USE OF CCMS DATA FOR SURVEILLANCE, OUTBREAK MONITORING, AND RECALLS

A. OPHS AES is to use the data in CCMS as a surveillance tool for detecting foodborne hazards and illness outbreaks and to monitor for potentially related complaints during illness outbreaks and recalls. Requests from other FSIS program area offices to review CCMS data or conduct ongoing surveillance during outbreaks or other foodborne events of interest should be directed to OPHS AES. At a minimum, the request is to identify the establishment or product brand and timeframe for which the review or surveillance should be conducted.

B. Before each recall committee, the OPHS AES recall representative is to review CCMS data to search for complaints similar to the pending recall using the product and recall issue information provided in the recall committee notification according to FSIS Directive 8080.1. The result of a CCMS complaint search is to be considered in the determination of the scope of the recall, public health risk, and recall classification.

XVII. COMPLAINT DATA ANALYSIS AND REPORTING

The complaint data maintained in CCMS is analyzed annually for the previous year by OPHS AES. This descriptive analysis will allow OPHS AES to assess potential trends and identify areas for system and process improvement. The results of the analysis will be shared internally through the FSIS Data Coordination Committee (DCC) as set out in FSIS Directive 5800.1, *FSIS Data Coordination Committee*, and with other FSIS personnel, as required. The results will also be made available to the public.

XVIII. QUESTIONS

Refer questions through supervisory channels.

Assistant Administrator
Office of Policy and Program Development