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

FSIS DIRECTIVE

5610.1
Rev. 2

11/12/20

MANAGEMENT OF CONSUMER COMPLAINTS IN THE 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 version reflects recent updates to CCMS integrated with the FSIS Public Health Information System (PHIS) and complaint management processes. FSIS is reissuing this directive to provide instructions on how to access the new system within PHIS, update links and information related to the online complaint reporting at Report a Problem with Food, update system field names, provide clarification on the complaint referral processes, and update the roles and expectations of FSIS personnel responding to complaint investigation activities.

II. CANCELLATION

FSIS Directive 5610.1, Rev. 1, *Procedures to Implement the Consumer Complaint Monitoring System (CCMS)*, 6/29/18

III. BACKGROUND

A. A consumer complaint is initiated by a consumer or their representative and can involve reports of allergic reaction, economic adulteration, foreign object contamination, illness, injury, misbranding, and off-quality pertaining to an FSIS-regulated food (meat, poultry, or egg products).

B. 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. HOW TO ACCESS CCMS

A. CCMS is a component of the Surveillance, Complaints, and Outbreak Response Enterprise (SCORE) module in PHIS. PHIS is accessible from the following link, https://phis.fsis.usda.gov. Employees can also access PHIS on any FSIS-issued standard loaded computer by selecting PHIS from the Start menu under FSIS Applications.

B. CCMS access is role-based. Users must have access to PHIS in order to access CCMS. Permissions and restrictions are granted dependent upon the user's office location, work assignment, and duties. For example, a user with the Field Personnel role can only view complaints in which either the consumer or the producing establishment is in a State within the user's district or region. CCMS user access roles are created and assigned by a SCORE Administrator in OPHS AES, and some users may have more than one CCMS role.

V. RECEIVING CONSUMER COMPLAINTS

A. FSIS receives consumer complaints through one 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 directly into CCMS or into the Hotline database, enabling it to then be transmitted into CCMS;

2. Consumers contact the following FSIS program area offices that are authorized to enter complaints directly into CCMS:

    a. Office of Field Operations (OFO) Enforcement, Investigations and Analysis Officers (EIAO) and District Office personnel;

    b. Office of Investigation, Enforcement, and Audit (OIEA) Compliance and Investigations Division (CID); or

    c. OPHS AES.

3. FSIS employees are to be aware that consumers can enter a complaint and upload accompanying documentation, such as pictures, online using the Electronic Consumer Complaint Form (eCCF) available at: Report a Problem with Food.

4. Non-FSIS government entities may receive consumer complaints regarding FSIS-regulated products but will not have direct access to CCMS. When this occurs, FSIS employees are to be aware that the person receiving the complaint may send the information to OPHS AES, OFO, or OIEA CID staff via e-mail for entry into CCMS. The referring entity can also enter the complaint online using the eCCF. OPHS AES does not communicate the outcome of a complaint to a referring entity unless specifically requested. Non-FSIS government entities that regularly forward complaints to FSIS include, but not limited to:

    a. USDA Food and Nutrition Service (USDA FNS);

    b. State or local public health offices or departments of agriculture; and

    c. Food and Drug Administration (FDA).

VI. CONSUMER COMPLAINTS FOR CCMS AND CONSIDERATIONS FOR REFERRAL

A. All applicable consumer complaints reported to FSIS are to be entered into CCMS by an FSIS employee who is authorized to do so. If a complaint is entered into CCMS for a product that is not regulated by FSIS (in error) or OPHS AES determines that the complaint requires investigation by another FSIS program area, OPHS AES is to refer the complaint to the appropriate authority. The determination to refer a consumer complaint to another authority for response may not be identified as such until evaluated or investigated by OPHS AES.

B. Consumer complaints can provide information useful for detecting foodborne outbreaks or other public health events, such as intentional contamination, regardless of whether FSIS-regulated product is involved. If an FSIS employee receiving a complaint is unsure whether the complaint is to be entered into CCMS or referred, they are to contact OPHS AES via email or phone for guidance.

C. When a complaint is entered into CCMS and referred internally or externally, the complaint information is still maintained in the CCMS database. OPHS AES and the respective FSIS program area or non-FSIS government entity leading any subsequent investigation will determine if access to the complaint is to be

restricted to specific FSIS users on a need-to-know basis. For example, a complaint involving a criminal violation will be restricted to FSIS users assisting in the investigation.

D. The following are examples of complaints that are to be considered for referral to an outside organization in lieu of entry into CCMS:

1. Complaints that involve products regulated by FDA are to be referred to FDA;

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

3. Complaints involving retail-prepared meat, poultry, and egg products that have lost their Federal identity due to further processing or packaging at a retail establishment, such as a grocery store or restaurant, are to be referred to the appropriate State or local public health office or department of agriculture. Investigation at the State or local levels may conclude that the source of the incident occurred at an FSIS-inspected establishment or that violations at the retail location severely impact FSIS-regulated product, such as temperature abuse and cross contamination. Consequently, the complaint may be referred back to FSIS for additional investigation;

4. Complaints involving FSIS-regulated products that indicate potential misconduct, fraud, or abuse reported by a whistleblower or an industry competitor are to be referred to the appropriate FSIS OFO District Manager (DM). The OFO DM will determine if the complaint is to be further referred for evaluation by the respective OIEA CID Regional Director; and

5. Complaints involving FSIS-regulated products that indicate potential criminal violation, intentional product contamination, or tampering are to be referred to the respective OIEA CID Regional Director for further disposition or referral to Office of the Inspector General (OIG).

VII. 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 entry into CCMS as provided in Section VI, *Consumer Complaints for CCMS and Considerations for Referral,* of this directive. The FSIS employee receiving the complaint is to make this determination after obtaining complaint details from the consumer or their representative. If the FSIS employee receiving a complaint is unsure whether the complaint is to be entered into CCMS, they are to contact OPHS AES via email or phone for guidance.

B. If the complaint does not meet the definition of a consumer complaint appropriate for entry into CCMS, the information provided by the consumer will not be entered in CCMS. The FSIS employee receiving the complaint is to send the information on behalf of the consumer to the appropriate program area in FSIS or refer the consumer to the appropriate Federal, State, or local public health office or department of agriculture.

C. If a complaint meets the definition of a consumer complaint appropriate for entry into CCMS, the FSIS employee is to enter the complaint into CCMS by following the complaint entry wizard in the system. If the employee receiving the complaint is an OPACE employee with access to the Hotline, they are to enter the complaint into the Hotline system. Employees are to avoid using special characters in free-text fields during complaint entry in CCMS or the Hotline.

D. Once entry of the complaint is completed in CCMS, or the Hotline and then transmitted to 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 their complaint.

E. For eCCF-reported complaints, OPHS AES is to first review the complaint in the eCCF dashboard of CCMS 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. At that time, a unique case number will be generated and viewable. If a complaint reported online does not meet the definition of a consumer complaint appropriate for entry into CCMS, OPHS AES is to use the eCCF dashboard to refer the complaint to the appropriate authority. If the information provided is not enough to determine whether the complaint should be referred or to whom it should be referred or to determine whether FSIS-regulated product is involved, OPHS AES is to mark the complaint invalid in the eCCF dashboard and archive the complaint.

VIII. CONSIDERATIONS FOR COMPLAINT INTAKE

A. If the consumer wants to file 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. When necessary, OPHS AES is to follow-up with the consumer to gather the missing information. If efforts to locate more information are unsuccessful, the information collected can be used for surveillance and may benefit future investigation efforts should FSIS receive similar complaints. The system will prompt the user during complaint entry if information is missing from mandatory fields.

B. A consumer has the right to remain anonymous. If the consumer does provide contact information, the FSIS employee conducting the initial interview and complaint entry is to inform the consumer that their complaint and contact information may be shared with other USDA program area offices, FDA, or a State or local public health office or department of agriculture, for investigative purposes. The consumer's name and contact information are not to be shared with the manufacturer.

C. The Incident Date 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 documented as the date that the person became ill, not the date the food was consumed. This date may differ from the Reported Date or Purchase Date, which are also captured in CCMS. The FSIS employee is to manually enter the incident date in the designated field in CCMS.

D. The Reported Date field in CCMS is automatically captured in the system when the FSIS employee enters the complaint and cannot be changed manually.

E. CCMS will allow more than one type of consumer complaint to be recorded in a case. When this occurs, one complaint must be assigned as the primary complaint. In general, the primary complaint type is the issue directly associated with the product. The additional complaint type, the effect or consumer's response to the primary complaint, becomes the secondary complaint. The secondary or additional complaint type(s) 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 the secondary or additional complaint type. The CCMS system will automatically designate the first complaint type entered as primary. The FSIS employee entering the case can manually change the auto-assigned primary complaint type within CCMS, if necessary.

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. If a consumer is reporting one incident with more than one food product, such as an illness in which the consumer ate hot dogs (product 1) with chili (product 2), the FSIS employee entering the complaint is

to record one complaint type with two food products in a single case.

H. If a consumer is reporting multiple 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.

I. At the close of the initial interview, the FSIS employee is to advise the consumer to keep the complaint evidence, including remaining food product(s) 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 that requires the evidence be presented for visual examination or sent to an FSIS laboratory for analysis.

J. OPHS AES is to review the submitted complaint and make edits, if needed, to ensure that the complaint and product information is documented correctly in the case.

IX. COMPLAINT EVALUATION

A. After a complaint has been entered into CCMS, OPHS AES is to review the complaint and accompanying documentation. The evaluation process helps OPHS AES to look for complaint trends and gather the information needed to determine the appropriate response. To evaluate the complaints, OPHS AES is to:

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

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, if known; and

3. If an establishment number is identified, review reports in PHIS, such as noncompliance records (NRs) and memorandums of interview (MOI), at least six months prior to the current complaint report date. This review is to determine if there is a history of in-plant incidents that may have contributed to the reported complaint.

B. OPHS AES is to be aware that 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.

X. 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, such as a medical diagnosis, that is needed to fully assess the severity of the complaint;

2. The complaint involves special risk populations, such as young children or the elderly;

3. There is evidence that the complaint may involve a widespread, non-isolated problem evidenced by laboratory confirmed illnesses, multiple similar complaints, or a recent voluntary product recall associated with the establishment named in the complaint;

4. There is evidence that the complaint may be related to an active outbreak investigation; or

5. Allergic reaction, injury, hospitalization, or death is reported.

XI. POSSIBLE OUTCOMES AFTER EVALUATION

A. Close Case: OPHS AES will close a case without additional follow-up if they or FSIS determines that the complaint is isolated and/or there is no apparent public health concern that requires further action by FSIS. OPHS AES is the only program area office permitted to close a case in CCMS. When a case is closed without additional follow-up, OPHS AES isto:

1. Select a closing reason from the prepopulated list and document why additional action was not warranted;

2. Generate a letter in CCMS that provides information on the outcome of the complaint along with USDA FSIS Freedom of Information Act (FOIA) contact information and send the letter to the consumer's e-mail or physical address, if provided; and

3. If the establishment number is known, send a letter documenting a summary of the complaint via email to the OFO District Office (DO) where the establishment is located to be forwarded to the FSIS inspector-in-charge (IIC). Personal identifiable information of the consumer, such as name and address, are not to be included in the letter and are not to be communicated to the establishment.

B. Refer Case: OPHS AES is to refer a complaint if the evaluation (Section IX) results indicate that the complaint involves a food product regulated by another authority, such as FDA, or the complaint requires review by another FSIS program area office. 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 by sending an email to: FOImports@usda.gov. See Section VI. of this directive for other considerations for referral. After the complaint is referred and OPHS AES has completed their evaluation, OPHS AES is to notify the consumer via email or letter to a physical address that their case was referred, to whom the case was referred, and that they may be contacted for additional information by the respective entity. Once the referral is complete, OPHS AES is to close the case in CCMS and not conduct additional follow-up.

C. Request Follow-Up Activities with OIEA CID or OFO: OPHS AES is to request follow-up activities if OPHS AES determines that the complaint is not isolated or there is a potential public health concern requiring further action by FSIS.

XII. CCMS COMPLAINT FOLLOW-UP ACTIVITIES WITH OIEA CID AND OFO

A. OPHS AES is to use CCMS to coordinate and request tasks or follow-up activities with the consumer through the respective OIEA CID region and at the establishment through the respective OFO DO.

B. When a CCMS task request is entered into the case, an e-mail containing the request is automatically generated and sent to the respective OIEA Regional Director and Deputy Regional Director where the consumer is located or designated OFO DO contact where the establishment is located. OPHS AES determines whom to send the request based on the type of task requested and if follow-up is requested with the consumer or the establishment. If the OIEA Regional Director, Deputy Regional Director, or OFO DO contact receiving the task request will not be the FSIS employee to complete the CCMS task request, they are to use the Update Task Assignee function in CCMS to reassign the task request and is to consult with supervisors to determine the new task assignee as needed.

C. Common CCMS task requests from OPHS AES:

1. Seek Clarifying Information Task: OPHS AES may request that OFO or OIEA seek clarifying information if important complaint information from the consumer or establishment is incomplete or OPHS AES determines that additional information or clarification of documented information is necessary to make a thorough evaluation of the complaint. For example, OPHS AES may request that the OFO DO for the establishment contact the IIC to determine if similar complaints not previously reported to CCMS have been reported to the establishment.

2. IIC Review Task: OPHS AES may request an IIC review task if similar complaints from the same establishment involving non-identical products are identified in CCMS or potentially related NRs or MOIs are identified in PHIS and the issue does not present a public health hazard. The goal of this task or activity is to provide the IIC situational awareness of complaints where OPHS AES has concerns about a potentially ongoing issue that does not immediately warrant a formal CCMS investigation.

   The IIC review task is sent to the respective contacts in the OFO DO for the establishment and requests that they forward the IIC Review file generated by the OPHS AES case manager through the appropriate channels to the IIC at the establishment. The IIC Review file contains details of the complaint, product, and photos, if available. Case tasks, contacts, and personal identifying information of the consumer are not included in the IIC Review file.

   Except on rare occasions, OPHS AES does not request a response from the IIC. However, OPHS AES is to be notified and may request additional follow-up if after review of the complaint, the IIC identifies new, significant information or in-plant issues related to the respective CCMS complaint not already known to OPHS AES; and

3. CCMS Investigation Tasks: OPHS AES may request an investigation if one or more of the following public health concerns are indicated after evaluation of the complaint:

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

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

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

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

XIII. CCMS INVESTIGATION TASK REQUESTS AT THE CONSUMER LEVEL

A. OPHS AES primarily coordinates consumer-level investigation tasks and submission of samples to an FSIS laboratory with OIEA CID. On occasion, OPHS AES may request the respective OFO DO where the consumer is located to assist with these activities.

B. The first step in the CCMS investigation process is to verify the complaint and examine available evidence from the consumer. This can be performed in-person with a CID investigator or OFO employee, or via email communication with OPHS AES. To initiate in-person verification and examination of evidence, OPHS AES is to send a task request from CCMS to the OIEA Regional Director and Deputy Regional Director or to the OFO DO contacts for the state where the consumer resides. The task will request that a CID investigator or an OFO employee be designated to verify the complaint and collect evidence as set out in FSIS Directive 8010.3, *Procedures for Evidence Collection, Safeguarding,*

and Disposal. The CID investigator or OFO employee is to:

1. Arrange to meet with the consumer at their home or other safe place where the product and accompanying evidence are located;

2. Visually observe and photograph the product, packaging, and other evidence; and

3. If requested by OPHS AES and if the consumer is willing to relinquish the product for analysis, the CID investigator or OFO employee is to collect the product and submit it to an FSIS laboratory (See Section XIV). OPHS AES may also request to collect identically coded companion samples from the consumer or the point-of-purchase. The consumer is to be provided a property receipt, FSIS Form 8200-1, or payment for fair market value when collecting evidence for sampling. The form is located at: https://inside.fsis.usda.gov/fsis/DocumentViewerServlet?filename=FSISIntranet/Forms/Forms/stelprdb6006384.pdf. (Level 2 e-Authentication log-in is required to access the site.)

NOTE: To ensure that the personal safety of FSIS personnel is maintained when meeting with the consumer, the CID investigator or OFO employee is to alert their supervisor and OPHS AES of potential safety concerns. If there are significant risks or concerns to personal safety, OPHS AES is to document the issue in the CCMS case Task Notes and cancel the evidence collection task in CCMS.

C. After the verification and evidence evaluation tasks are complete, the CID investigator or OFO employee is to document the findings in a CCMS Verification Report template that has been developed by OPHS AES. The report template is to be uploaded to the case documents by OPHS AES and is also available in the reference materials tab within CCMS.

D. FSIS employees are to be aware that an in-person verification and evidence collection task is not always required for a CCMS investigation. For example, 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 CCMS investigation at the establishment. The decision to move forward in the investigation without in-person verification and evidence collection is to be made on a case-by-case basis by OPHS AES.

E. The CID investigator or OFO employee is to upload all documentation, including forms, reports, and photos, to the case Documents section, notate important observations in the respective Task Notes, and mark the task complete. If a CCMS investigation reveals potential criminal violations or intentional product contamination or tampering, the complaint is to be referred to the appropriate OIEA CID Regional Director. OPHS AES will restrict access to the case to OPHS AES, OIEA CID, and other FSIS personnel on a strict, need-to-know basis. Depending on the circumstances, OPHS AES is to understand that certain documentation and evidence may not be uploaded to the case. OPHS AES will not conduct additional CCMS investigation activities after referral. See Section XVI., Considerations for Completing Follow-Up Activities and Task Requests.

F. OPHS AES is to review the documentation submitted. If additional information is needed to make a thorough assessment and decision on the next steps, OPHS AES is to consult with the CID investigator or OFO employee that completed the task.

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

A. If product samples are to be analyzed at an FSIS laboratory, OPHS AES is to:

1. Prior to sending the request to submit samples and shipping, consult with the appropriate OPHS laboratory subject matter expert to determine what type of analysis is to be conducted

and at which FSIS laboratory. If products are to be sampled for foodborne microbial pathogens or residues, OPHS AES is to also consult with the OPHS Science Staff and the designated CID investigator or OFO employee responding to the task request.

2. Create a task request in CCMS that provides the designated CID investigator or OFO employee information on the type of samples to collect, the analysis to be performed, and to which FSIS laboratory the samples are to be submitted. This task is often requested at the same time as the evidence collection task.

B. FSIS personnel are to maintain the integrity of the samples and not cause contamination during sampling as set out in FSIS Directive 8010.3, *Procedures for Evidence Collection, Safeguarding, and Disposal*. If microbiological analyses are requested, the CID investigator or OFO employee is 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.

C. The CID investigator is to use the PHIS Sampling Dashboard to enter sample collection data and requested analysis using the COMPLAIN project code in PHIS.

D. If an OFO EIAO is to complete the verification task or PHIS is unavailable to the CID investigator, the FSIS employee is to complete FSIS Form 10,000-2, *Domestic Laboratory Report*. This form is not available electronically. 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 21 – enter type of analysis;

8. Block 24 – enter the product information, relevant information related to the sample, the requested analyses, and the OPHS AES case manager's name, phone number and email for sending results;

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

10. Block 27 – collector's phone number.

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

E. The designated CID investigator or OFO employee is to also complete FSIS Form 8000-17, *Evidence*

Receipt and Chain of Custody, tosubmit with the samples. The form is located at: https://inside.fsis.usda.gov/fsis/DocumentViewerServlet?filename=FSISIntranet/Forms/Forms/stelprdb6006393.pdf. (Level 2 e-Authentication log-in is required to access the site.)

F. The CID investigator or OFO employee is to seal the sample in accordance with FSIS Directive 7355.1, *Use of Sample Seals for Laboratory Samples and Other Applications*. Sample seal set packets (FSIS Forms 7355-2A and 2B) are available in the sample box.

G. The CID investigator or OFO employee submitting the sample to the laboratory is to upload a copy of all forms in the Documents section of the respective case file in CCMS.

H. The FSIS laboratory that analyzed the sample is to send the results via email to the submitter and the OPHS AES case manager to upload to the Documents section of therespective case. Laboratory personnel will document the sample and results according to established procedures.

XV. INVESTIGATION ACTIVITIES AT THE ESTABLISHMENT LEVEL

A. If OPHS AES requests a review of the complaint and response from the establishment, OPHS AES is to send a task from CCMS to the respective OFO DO where the establishment is located. The task will request that the IIC complete a report documenting if there were deviations or failures observed in the establishment's Hazard Analysis and Critical Control Points (HACCP) system or production processes believed to have contributed to the consumer complaint. The task will also request that the IIC document any similar complaints received by the establishment and the establishment's response to the current complaint.

B. The IIC is to document the findings in an IIC Report template that has been developed by OPHS AES. The report template is to be uploaded to the case Documents section by OPHS AES and is also available in the reference materials tab within CCMS.

C. After the IIC has completed their review and documentation, they are to forward the report to the DM, or their designee, for review. Once approved, the DM or their designee is to upload the report and supporting documentation to the Documents section of the respective case.

D. 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, OPHS AES is to consult with the OFO DO where the establishment is located.

E. The OFO DO where the establishment is located is to upload all documentation to the case Documents section, notate completion of the task in the Task Notes, and mark the task complete.

F. On occasion, the OFO DO where the establishment is located may request that OPHS AES arrange for foreign object evidence to be collected and sent to the establishment for visual examination. For example, if OPHS AES determines that the foreign object is no longer required for other investigative activities, OPHS AES is to coordinate the request through CCMS and provide instructions for the OFO DO where the consumer is located to collect the evidence and send to the OFO DO where the establishment is located.

XVI. CONSIDERATIONS FOR COMPLETING FOLLOW-UP ACTIVITIES AND TASK REQUESTS

A. If OIEA CID or OFO has concerns about OPHS AES's decision to request a task or there are questions about how to complete the requested task, those employees are to contact the OPHS AES case manager via e-mail or phone for guidance.

B. If it is discovered that information entered into the CCMS case is inaccurate, OPHS AES is to confirm the correct information with the appropriate sources and update the case.

C. If food safety issues related to the reported complaint are identified at the establishment, at any point in the complaint evaluation and CCMS investigation process, the OFO DO where the establishment is located may recommend additional follow-up, such as a Public Health Risk Evaluation as set out in FSIS Directive 5100.4, *Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology,* or may notify OFO RMTAD to discuss a potential recall as set out in FSIS Directive 8080.1, *Recall of Meat and Poultry Products*.

D. If at any point in the CCMS investigation potential criminal violations or intentional product contamination or tampering are identified, the complaint is to be referred to the appropriate OIEA CID Regional Director for investigation as set out on FSIS Directive 8010.2, *Investigative Methodology*. An Incident Report is to be opened in the FSIS Incident Management System by OPHS AES or OIEA CID. For guidance on the response to the incident, OPHS AES or OIEA CID is to seek activation of the FSIS Emergency Management Committee (EMC) as set out in FSIS Directive 5500.2, *Significant Incident Response*. After referral to OIEA CID, the case will be restricted to OPHS AES, OIEA CID, and other FSIS personnel on a strict need-to-know basis and closed in CCMS. OPHS AES will not conduct additional CCMS investigation activities.

XVII. CLOSING A CASE AFTER FOLLOW-UP ACTIVITIES AND CCMS INVESTIGATION

A. After all task requests and follow-up activities are completed, the CID investigator or designated OFO DO personnel are to mark the respective task(s) “complete” in the Tasks section of the case.

B. If OPHS AES determines that the incident does not constitute a public health hazard or additional action is not necessary by FSIS at any point in the complaint evaluation and CCMS investigation process, OPHS AES is to document the reason additional actions were not required in CCMS and close the case.

C. To close a case after follow-up activities and CCMS investigation, OPHS AES is to:

1. Select a closing reason from the prepopulated list and document which actions were taken in response to the complaint and the outcome of those actions;

2. Generate a letter in CCMS that provides information on the outcome of the complaint along with USDA FSIS FOIA contact information and send the letter to the consumer’s e-mail or physical address, if provided; and

3. Generate an establishment letter in CCMS and send a task request to the respective OFO DO contacts to forward the letter via email to the IIC of the identified establishment. Personally identifiable information of the consumer, such as name and address, are not to be included in the letter and are not to be communicated to the establishment.

XVIII. ARCHIVING A CASE AND COMPLAINT STATUS UPDATES

A. FSIS personnel are to be aware that complaint data is maintained in CCMS and is retrievable by case number or other case details, such as the establishment number. If new information is received after a case is closed that corrects previous statements made by the consumer or could impact the previous outcome, OPHS AES is to reopen the case and enter the new information.

B. FSIS program area offices involved in the intake or investigation of a complaint are to notify OPHS AES if a consumer is requesting a status update. OPHS AES is to contact the consumer via telephone or email to provide an update.

C. If a complaint is reported via the eCCF, consumers are to be directed to go to https://foodcomplaint.fsis.usda.gov to check the status of their complaint online.

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 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.

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

A. OPHS AES is to use CCMS data for surveillance of foodborne hazards. This includes monitoring for potentially related complaints before and after food recalls and illness outbreaks involving product under FSIS jurisdiction. 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 include the establishment or product brand and specific date(s) or date ranges.

B. Before each FSIS recall committee meeting, the OPHS AES recall representative is to review CCMS data to search for complaints similar to the pending potential recall as set out in 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.

XX. 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 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.

XXI. QUESTIONS

Refer questions through supervisory channels.

Assistant Administrator
Office of Policy and Program Development