

MEMORANDUM OF UNDERSTANDING
BETWEEN THE
FOOD SAFETY AND INSPECTION SERVICE
AND THE
UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

ARTICLE 1 - PURPOSE

This Memorandum of Understanding (MOU) documents the procedures and responsibilities under the collaborative effort between the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS) in assessing root cause in outbreaks of foodborne illness in humans.

ARTICLE 2 - BACKGROUND

Assessments of disease occurrence, regardless of the disease etiology, encompass a range of activities including but not limited to definition of scope, observational study design, questionnaire development, collection of data and samples, and statistical analysis and reporting. FSIS foodborne-related illness investigations are multifaceted, multidisciplinary undertakings that involve collecting and analyzing data from epidemiological, laboratory, and environmental assessments (see FSIS Directive 8080.3).

ARTICLE 3 - MUTUAL RESPONSIBILITIES

FSIS and APHIS mutually understand that:

1. This MOU in no way restricts APHIS or FSIS from participating in similar activities with other public or private agencies, organizations, and individuals.
2. This MOU is neither a fiscal nor a funds obligation document. Any endeavor involving reimbursement or contribution funds between the parties to this instrument will be handled in accordance with applicable laws, regulations, and procedures, including those for government procurement and printing. Such endeavors will be outlined in separate agreements that shall be made in writing by representatives of the parties and independently authorized by appropriate statutory authority. Signing this instrument does not provide or create such authority.
3. Approval of FSIS and VS staff participation on foodborne-related illness root cause assessment teams and of information disclosure practices will be in accordance with existing VS protocols and FSIS Emergency Management Committee guidance.
4. If an outbreak is ongoing when a root cause assessment is initiated, the assessment team may want to provide frequent, descriptive updates on the outbreak, including specific findings and actions being taken. In these situations, information may be disseminated to

VS and FSIS public health partners, including the Centers for Disease Control and Prevention, the Food and Drug Administration, State Departments of Health, or FSIS product consumers.

5. Once the root cause assessment is complete and the outbreak is controlled there may be opportunities to do further detailed root cause and statistical analyses. The analyses could help FSIS and VS better understand factors associated with the outbreak. A better understanding of the root cause processes will help identify options for preventing or controlling future outbreaks. These detailed evaluations will be disseminated to producers and plant owners (as appropriate) and broadly to the industry to effect changes in production. The evaluations would also likely be submitted for peer review in professional journals. VS and FSIS will collaborate in writing the evaluations to provide appropriate perspective. This will also document the methods and procedures for root cause assessment collaborations between the two Agencies.
6. The Agencies mutually agree that if practices that endanger the health of the public are identified during an APHIS investigation, the producer may be informed as expeditiously as possible that cessation of such practices might mitigate the food safety issue. The decision to share such information with the producers in question will be made jointly by the Agencies.
7. The Agencies mutually agree that the information and data obtained, produced, maintained during, or derived from root cause assessments and as a part of foodborne-related illness investigations, criminal investigation, or other authorized regulatory activity, will be protected against unauthorized use, disclosure, or release. This includes implementing proper safeguards and procedures consistent with MOU 225-12-007 to, at a minimum, prevent unauthorized use and disclosure of this information; limit access to this information and data to employees, agents, and officials of the Agencies who require access to such information and data to perform their official duties; and prevent the use, disclosure, or release of any information and data protected by law, including the Trade Secrets Act [18 U.S.C. 1905 et seq.], the Privacy Act of 1974, as amended [5 U.S.C. 552a et seq.], the Freedom of Information Act [5 U.S.C. 552 et seq.], the Food Security Act of 1985 [7 U.S.C. 2276 et seq.], and Section 1619 of the Food, Conservation, and Energy Act of 2008 [7 U.S.C. 8791]. Moreover, the Agencies agree, consistent with MOU 225-12-007, to promptly notify each other of any requests for this information and data and of any actual or suspected unauthorized release, disclosure, or use of this information and data.

ARTICLE 4 - FSIS RESPONSIBILITIES

FSIS agrees to designate the Applied Epidemiology Staff Director as its authorized representative. This individual will be responsible for collaboratively administering the activities conducted under this MOU.

FSIS furthermore agrees to:

1. Submit request to the FSIS Emergency Management Committee (EMC), per Directive 5500.2, for consideration and approval for collaboration with APHIS-VS.
2. Route for review routine requests for coordination in assessing root causes of foodborne-

related illnesses to the VS Chief Epidemiologist in accordance with established VS protocols.

3. Make requests requiring an immediate decision on implementation of the MOU (within 48 hours) to the APHIS VS Deputy Administrator (or his designee).
4. Follow procedures detailed in FSIS Directives (see Table 1).
5. Give VS a summary of the foodborne-related illness cluster or outbreak and a statement of request to include the relative urgency and priority needed for action.

ARTICLE 5 - STATEMENT OF NO FINANCIAL OBLIGATION

Signing this MOU does not place FSIS under any financial obligation. Each signatory party is to use and manage its own funds in carrying out the purpose of this MOU. This MOU does not authorize transfers of funds or items of value.

ARTICLE 6 - APHIS RESPONSIBILITIES

APHIS agrees to designate the VS Chief Epidemiologist as its authorized representative. This individual is responsible for collaboratively administering the activities conducted under this MOU.

APHIS furthermore agrees to:

1. Review FSIS requests for coordination in assessing root causes of foodborne-related illnesses (by conducting an epidemiological investigation) with reference to making findings that allow decision makers and producers to make science-based decisions on intervention or mitigation strategies.
2. Review FSIS requests for coordination in assessing root causes of foodborne-related illnesses in light of FSIS and VS authorities, potential costs and benefits, and resource availability to conduct root cause assessments.
3. Provide details of the request to senior VS leadership. The urgency of a needed decision will determine the appropriate level of VS review.
 - A. Make requests requiring an immediate decision to implement the MOU (within 48 hours) to the Assistant Administrator for the Office of Public Health Science, FSIS.
 - B. Requests not requiring an immediate decision will be sent to the VS Leadership Team for assessment within 5 business days.
4. Communicate the VS senior leadership decision to trigger an assessment or the rationale behind not proceeding with the assessment to FSIS before any assessment activity occurs.
5. Determine the size and required expertise of the team to conduct the APHIS investigation depending on the specific situation and scope of the assessment requested. VS, in consultation with FSIS, will also determine specific skills required to meet the assessment objectives. Assessments conducted at the field level will use local personnel whenever possible. Teams may also include FSIS staff as collaborators.
6. Determine the deployment of team members based on the assessment objectives. In many cases local staff selected as team members may be able to conduct the on-the-ground

assessment with help from other team members occurring remotely. Some assessments may rely solely on remote assistance. In some cases a full assessment team consisting of epidemiologists, laboratory personnel, field veterinary medical officers, and others may be deployed to conduct an assessment. Funding of assessment team deployment will be determined at the time of team assembly.

7. Acquire voluntary participation and collaboration in its epidemiological investigation with individual producers or companies associated with the outbreak in question to identify on-farm risk factors for disease occurrence or spread that could be controlled or mitigated by some intervention in current or future situations. The size, scope, and complexity of the assessment will affect the timing, format, and venue for communicating results.
8. Summarize and disseminate the results of the assessment in ways that provide flexibility in communicating among investigators, decision makers, and producers participating in the assessment.

ARTICLE 7 - STATEMENT OF NO FINANCIAL OBLIGATION

Signing this MOU does not place APHIS under any financial obligation. Each signatory party is to use and manage its own funds in carrying out the purpose of this MOU. This MOU does not authorize transfers of funds or items of value.

ARTICLE 8 - LIMITATIONS OF COMMITMENT

This MOU and any continuation thereof shall be contingent on the availability of funds appropriated by the Congress of the United States. The parties understand and agree that any monies allocated for purposes covered by this MOU shall be expended in accordance with its terms and the manner prescribed by the fiscal regulations and/or administrative policies of the party making the funds available. Transfer of fiscal resources will require a separate agreement by the parties.

ARTICLE 9 - CONGRESSIONAL RESTRICTION

Under 41 USC 22, no member of, or delegate to, Congress shall be admitted to any share or part of the MOU or to any benefit to arise therefrom.

ARTICLE 10 - AMENDMENTS

This MOU may be amended at any time by mutual agreement of the parties in writing.

ARTICLE 11 - TERMINATION

This MOU may be terminated by either party on 60 days written notice to the other party.

ARTICLE 12 - EFFECTIVE DATE AND DURATION

This MOU shall become effective upon the date of signature by both parties and shall continue indefinitely. It may be modified or discontinued at the request of either party on 60 days written notice to the other party.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

4/17/14 
Date Administrator

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

4/21/14 
Date Administrator

Table 1: FSIS and APHIS Roles and Responsibilities

FSIS Foodborne-Related Illness Investigation Roles and Responsibilities	Outbreak Assessment Stage	APHIS Epidemiological Investigation Roles and Responsibilities
<p>Applied Epidemiology Staff of the Office of Public Health Science coordinates investigation of foodborne-related illness in accordance with FSIS Directive 8080.3.</p> <p>Compliance Investigation Division of the Office of Program Evaluation, Enforcement, and Review manages investigations in accordance with FSIS Directive 8010.2.</p>	Detection of foodborne-related illness outbreak resulting in traceback to FSIS-regulated product	None.
Recall Management and Technical Analysis Staff coordinates recall of adulterated and mislabeled product in accordance with FSIS Directive 8080.1.	Product recall.	None.
<p>FSIS will conduct Incident Investigation Team Reviews in accordance with FSIS Directive 6500.2.</p> <p>The Office of Field Operations will conduct Food Safety Assessments in accordance with FSIS Directive 5100.1.</p> <p>The Applied Epidemiology Staff (AES) of the Office of Public Health Science identifies triggers to share data and request APHIS assistance.</p>	Plant and product specific data analysis.	<p>Participation on investigation working group teleconferences as appropriate for situational awareness when potential preharvest link is suspected.</p> <p>Consultation.</p> <p>Collaboration on questionnaires and collection of data.</p>
<p>OPHS submits the request to the FSIS Emergency Management Council (EMC) per FSIS Directive 5500.2 for consideration.</p> <p>Upon FSIS approval request for collaboration is forwarded to APHIS-VS.</p>	Identification of potential production-level link for source of contamination.	<p>Participation on investigation working group teleconferences as appropriate for situational awareness when potential preharvest link is suspected.</p> <p>Consultation.</p> <p>Review of request and decision to commit resources</p>
<p>Independent FSIS investigation.</p> <p>The EMC pursues independent investigation per FSIS Directive 5500.2.</p> <p>Upon EMC conclusion, decision for independent FSIS investigation is forwarded to APHIS-VS.</p>	On-farm/production level assessment.	<p>Solicits industry/producer participation.</p> <p>Leads data acquisition and analysis.</p>
Joint for public statements and press releases.	Reporting.	Joint for public statements and press releases.