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**MEMORANDUM OF UNDERSTANDING**

**BETWEEN THE**

**UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE (FSIS)**

**AND THE**

**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)  
NATIONAL CENTER FOR EMERGING AND ZOO NOTIC INFECTIOUS DISEASES  
(NCEZID)**

**NATIONAL CENTER FOR ENVIRONMENTAL HEALTH (NCEH) AND  
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)**

**REGARDING**

**FOODBORNE HEALTH HAZARDS ASSESSMENTS ASSOCIATED  
WITH FSIS-REGULATED PRODUCT**

**ARTICLE 1 – PURPOSE AND BACKGROUND**

The purpose of this memorandum of understanding is to define expectations related to interagency assessments of foodborne health hazards potentially associated with FSIS-regulated products, meat, poultry, and egg products. This memorandum of understanding will expand FSIS and CDC/ATSDR collaborative One Health efforts by providing a more comprehensive and multidisciplinary approach to health hazard assessments, including assessments of FSIS-regulated establishments associated with or potentially associated with foodborne illness.

CDC/ATSDR and FSIS currently collaborate on assessments of health hazards associated with FSIS-regulated products. The agencies more commonly collaborate on foodborne illness cluster and outbreak investigations which can include food tracebacks, assessments of FSIS-regulated establishments, and food recalls and associated alerts to consumers about food products that may be the source of infections. In response to the identification of an illness cluster or outbreak, or an environmental hazard, CDC, ATSDR, state, and local health departments collect exposure histories from case-patients, generate hypotheses regarding the source of the illnesses, and perform epidemiological studies to test hypotheses and identify statistical association of illness with a food vehicle or other source. FSIS supports hypothesis-generation by reviewing current and historical compliance and food testing data. FSIS ensures case-patient interview questions are designed to capture data and information that will aid in traceback investigations and support regulatory actions. FSIS and state and local agencies lead on food tracebacks, collections of

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investigative food and environmental samples for testing, and on-site environmental assessments at food establishments. The various investigative activities often are performed as soon as possible and in parallel. Epidemiological, laboratory, traceback, and other data along with findings from on-site assessments provide evidence to support a conclusion of that product is implicated in causing illnesses. This memorandum of understanding does not modify existing interagency collaborative work described above, but instead focuses on the engagement of CDC/ATSDR personnel in select regulatory, environmental, and health hazard assessments, including those undertaken at FSIS-regulated establishments as part of foodborne illness investigations. Over the last two decades, CDC participated in a small number of the FSIS-led establishment assessments. The intent of this memorandum of understanding is to enhance opportunities for CDC/ATSDR to participate in FSIS-led in-plant assessments of FSIS-regulated establishments and in other health hazard assessments. As part of the assessment team, CDC/ATSDR epidemiologists, environmental health scientists, and other subject matter experts will be able to leverage their expertise. CDC/ATSDR personnel can aid in the interpretation of data and findings in light of epidemiological and other data and help in the identification of environmental antecedents and a root cause of the contamination event. It is expected that CDC/ATSDR would not participate in all FSIS assessments, but rather a smaller number of assessments where CDC/ATSDR expertise would enhance the assessment. This memorandum of understanding outlines FSIS, CDC, and ATSDR mutual roles and responsibilities for the training of personnel and the planning for and conduct of interagency assessments at FSIS-regulated establishments as part of foodborne illness investigations and other health hazard assessments.

## ARTICLE 2 – DEFINITIONS

**FSIS-regulated establishment** – An establishment producing a meat, poultry, or egg product under FSIS inspection. A federal grant of inspection is issued by FSIS to an establishment provided they have a suitable facility and, for meat and poultry establishments, operate under a Hazard Analysis and Critical Control Point (HACCP) food safety plan and sanitation standard operating procedures. The slaughter of food animals and processing of food products that are amenable to the Federal Meat Inspection Act, Poultry Products Inspection Act, or Egg Products Inspection Act and applicable FSIS regulations must be performed under FSIS inspection or under an equivalent state inspection program.

**Assessment** - a systematic evaluation of the nature, quality, or ability of someone or something, including a review of available data and information. The assessment may follow established methodologies, such as FSIS incident investigation team or health hazard evaluation board methodologies, and includes the efficient organization, collection, analysis, and reporting of data and information. A food safety assessment is more detailed than a routine inspection and focuses on conditions in the establishment, including use of a hazardous substance potentially or known to be in a food item or at a site, and may include an evaluation as to whether exposure to the substance might cause any harm to people. A food safety assessment aims to fill data and information gaps and identify environmental antecedents and a root cause of the contamination event. Multi-disciplinary assessment teams have expertise in ensuring evidence chain-of-custody, analysis of records and data, interviewing, selecting and collecting samples for laboratory analysis. They maintain contact and coordinate activities with agency officials who

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are not a part of the assessment team. The teams review microbial testing and other data to assess probable causes of food safety failures and where it would be most useful to take samples. They also communicate findings and make recommendations to industry and agency officials.

**Environmental antecedents** - significant events in the food facility environment that preceded the contamination event.

**Illness cluster** - a noted group of illnesses often detected through laboratory-based surveillance, such as PulseNet, or through a consumer complaint, which are defined by time and/or place and not yet determined to be associated with a common exposure.

**Outbreak** - two or more cases of similar illness associated with a common exposure.

**Hazard** - A dangerous phenomenon, substance, human activity, or condition that may cause loss of life, injury or other health impacts, property damage, loss of livelihoods and services, social and economic disruption, or environmental damage. A health hazard is a hazard that may impact human health. A food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. Biological hazards are infectious agents (including living organisms and prion proteins) that can make food unsafe to eat. Chemical hazards can be either naturally-occurring or added. Physical hazards are extraneous materials that are not expected in a food and may cause illness or injury.

**Investigation** - a formal or systematic examination or inquiry into an event or incident. The term "incident investigation" refers to the investigation into any type of incident, whereas the term "foodborne illness cluster" or "outbreak" defines a type of incident. Traceback investigation and environmental investigation are often activities that support or are components of the overall foodborne illness investigation. FSIS defines an investigation as a fact-gathering and analytical activity conducted to develop and document facts relevant to apparent violations, food safety incidents, or other allegations to support FSIS decisions, investigative findings, and enforcement or legal actions.

### ARTICLE 3 - FSIS ROLES AND RESPONSIBILITIES

The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for verifying that the nation's commercial supply of meat, poultry, and egg products is safe, secure, wholesome, and correctly labeled and packaged. As part of the FSIS role in protecting public health, FSIS may invite CDC/ATSDR to participate in FSIS-led assessments of FSIS-regulated establishments.

#### Training

I. FSIS agrees to train CDC/ATSDR personnel on:

- statutes that FSIS operates under,
- regulations that the meat, poultry, and egg products industries must comply with,
- what defines industry proprietary and commercial confidential information,

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- current FSIS establishment assessment approaches, such as assessments by FSIS incident investigation teams,
  - current FSIS Health Hazard Evaluation Board procedures, and
  - how CDC/ATSDR personnel would operate on FSIS-led establishment assessment teams.
- II. FSIS agrees to train CDC/ATSDR identified personnel within 30 days from when the names are provided to FSIS. The training will be provided in a classroom style setting in Atlanta, Georgia.
- III. FSIS recommends that CDC /ATSDR identify personnel for training who are seasoned professionals and are not in temporary or training positions, such as the Epidemic Intelligence Service program.
- IV. FSIS agrees to provide the trained CDC/ATSDR personnel with an orientation session on regulatory and personal safety considerations at FSIS-regulated establishments in the Atlanta, Georgia commuting area within 60 days of training completion.
- V. The training and orientation will not exceed 5 days in length.
- VI. FSIS will only invite trained and oriented CDC/ATSDR personnel to participate on FSIS-led establishment assessment teams. FSIS may invite CDC/ATSDR to participate in or contribute to other assessments, such as those performed by convened FSIS Health Hazard Evaluation Boards.
- VII. FSIS agrees to provide the training and orientation of CDC/ATSDR personnel at no cost to CDC/ATSDR. FSIS will not fund CDC/ATSDR travel for training, orientation, or participation in FSIS on-site establishment or other assessments.

#### Planning for Assessments

- I. FSIS will consider the inclusion of trained CDC/ATSDR personnel in FSIS meetings convened to plan establishment assessments undertaken in response to foodborne illness clusters and outbreaks.
- II. FSIS may include CDC/ATSDR personnel in assessment planning meetings regardless of whether CDC/ATSDR personnel will join the establishment assessment team or have undergone the FSIS training and orientation sessions. FSIS can also consider including CDC/ATSDR Epidemic Intelligence Service Officers in planning meetings.
- III. FSIS will consider having CDC/ATSDR personnel join the establishment assessment team when the epidemiologic data is key evidence in support of product implication, and public health subject matter experts can aid in the identification of a root cause of and environmental antecedents to the adulteration event. The determination of whether epidemiologic data is key evidence may be made during a call between the two agencies.

#### Assessments of FSIS-Regulated Establishments

- I. FSIS agrees to consider the inclusion of trained and oriented CDC/ATSDR personnel on FSIS-regulated establishment assessment teams. FSIS acknowledges that these CDC/ATSDR personnel will only be utilized on select assessment teams and with the consent of the establishment.
- II. FSIS will secure permission from CDC/ATSDR to share CDC/ATSDR-provided data, information, and interpretation before sharing with establishment management. When such permission has been obtained, it is preferable a CDC/ATSDR team member provide the data to establishment management.
- III. The FSIS assessment team leader will include the CDC/ATSDR team members in all team meetings and communiqués, to ensure that CDC/ATSDR team member perspectives and

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suggestions are given full consideration and to leverage CDC/ATSDR expertise during the assessment. The FSIS assessment team leader will try to include all team members in all meetings; however, the team leader has the discretion to assign team members to disparate tasks to assure the timely completion of the team's work.

IV. FSIS will collaborate with CDC/ATSDR personnel on the development of an assessment report to be submitted to the National Voluntary Environmental Assessment Information System (NVEAIS) for establishment assessments which CDC/ATSDR participated in.

#### ARTICLE 4 – CDC, NATIONAL CENTER FOR EMERGING AND ZOOBOTIC INFECTIOUS DISEASES (NCEZID) ROLES AND RESPONSIBILITIES

CDC is the nation's premier public health agency— working to ensure healthy people in a healthy world. The CDC National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) works to prevent and control a broad range of infectious diseases through public leadership, partnerships, science, and systems. In carrying out these activities, NCEZID works collaboratively across CDC and with external partners to conduct, coordinate, support, and evaluate public health efforts to prevent and minimize morbidity and mortality due to infectious diseases, promoting a One Health approach involving the interface of animal, human, and environmental factors.

##### Training

- I. CDC NCEZID agrees to identify CDC personnel to be trained and participate as part of FSIS-led assessment teams, recognizing the FSIS suggestion for seasoned professionals who are not in temporary or training positions. These personnel will be selected to represent specific skills and expertise that would be of most use to support the FSIS-led assessment team.
- II. CDC NCEZID will identify two individuals for training within 30 days of the start of this MOU and no more than 30 days after trained and oriented personnel are no longer available.
- III. CDC NCEZID will only send trained and oriented personnel to participate on FSIS-led assessment teams as non-regulatory team members.

##### Planning for Assessments

- I. CDC NCEZID, upon invitation from FSIS management, will participate in FSIS meetings convened to plan assessments undertaken in response to foodborne health hazards, including those that result in illness clusters and outbreaks
- II. CDC staff can participate in assessment planning meetings regardless of whether CDC personnel will join the establishment assessment team in the field.
- III. CDC staff will participate in discussions with FSIS staff to make determinations of whether epidemiologic data is key evidence for an assessment.

##### Assessments

- I. CDC NCEZID personnel who are deployed as part of FSIS-led assessment teams will work as an integral part of the team and as such will serve under the direction of the FSIS team leader for the duration of the deployment. Participation as part of the team may be virtual (via telephone or webinar) both prior to and after the deployment.

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II. CDC NCEZID acknowledges that trained CDC personnel will only be utilized on select assessment teams.

III. CDC NCEZID will promptly respond to FSIS requests to share the CDC-provided data, information, and interpretation with establishment management. NCEZID will make a CDC team member available to provide epidemiologic data to establishment management, when needed.

## ARTICLE 5 – CDC, NATIONAL CENTER FOR ENVIRONMENTAL HEALTH (NCEH) AND THE AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)

### ROLES AND RESPONSIBILITIES

CDC is the nation's premier public health agency— working to ensure healthy people in a healthy world. The CDC National Center for Environmental Health (NCEH) and the Agency for Toxic Substances and Disease Registry (ATSDR), plan, direct, and coordinate a national program to maintain and improve the health of the American people by promoting a healthy environment and by preventing premature death and avoidable illness and disability caused by environmental toxic exposures. NCEH and ATSDR assist domestic and international agencies and organizations to prepare for, and respond to natural, technologic, humanitarian, and terrorism-related environmental emergencies.

#### Training

I. CDC NCEH agrees to provide training in general environmental assessment techniques for food facilities involved in foodborne outbreaks through on-line e-training modules and possibly in-person training sessions with FSIS, together with an introduction to the National Voluntary Environmental Assessment Information System (NVEAIS). CDC/ATSDR will provide this training at no cost to FSIS but will not fund travel for FSIS personnel attending the training.

II. CDC NCEH and ATSDR agree to receive training and orientation of their staff from FSIS trainers, and for orientation of CDC/ATSDR personnel to FSIS-regulated establishments and outbreak responses.

III. CDC NCEH and ATSDR will each identify two individuals for training within 30 days of the start of this MOU and no more than 30 days after trained and oriented personnel are no longer available, acknowledging the FSIS suggestion to identify seasoned professionals who are not in temporary or training positions

IV. CDC NCEH and ATSDR will only send trained and oriented personnel to participate on FSIS-led assessment teams as non-regulatory team members.

#### Planning for Assessments

I. CDC NCEH and ATSDR will be invited to participate in FSIS meetings convened to plan assessments undertaken in response to foodborne health hazards, including those that result in illness clusters and outbreaks.

II. Should an assessment of an FSIS-regulated establishment be required, CDC NCEH and ATSDR staff can participate in assessment planning meetings regardless of whether they will join establishment assessment teams in the field.

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III. CDC NCEH and ATSDR staff will participate in discussions with FSIS staff to make determinations of whether epidemiologic data is key evidence for an assessment.

IV. CDC NCEH and ATSDR may provide technical support, exposure/risk assessment, and subject matter expertise to FSIS during assessments of foodborne health hazards, adding to existing FSIS expertise in FSIS, in any of the following areas:

- Microbiological, chemical, toxicological, or radiological hazards associated with contaminated or potentially contaminated FSIS-regulated product
- Exposure/Risk Assessments for contaminated FSIS-regulated product to consumers or in-plant personnel

#### Establishment Assessments

I. CDC NCEH and ATSDR agree to consider the inclusion of trained personnel in FSIS establishment assessment teams. FSIS acknowledges that trained CDC/ATSDR personnel will only be utilized on select assessment teams.

In the event of a serious incident involving radioactive contamination of food, the CDC NCEH unit that leads on radiation incidents may call on (a) the interagency Advisory Team for Environment, Food and Health as defined by the Nuclear/Radiological Incident Annex of the National Response Framework (including USDA members); and (b) staff from the Department of Health and the radiation control agency in each state impacted by the incident, as needed.

II. CDC NCEH and ATSDR personnel who are deployed as part of FSIS-led assessment teams will work as an integral part of the team and as such will serve under the direction of the FSIS team leader for the duration of the deployment. Participation as part of the team may be virtual (via telephone or webinar) both prior to and after the deployment.

III. CDC NCEH and ATSDR will promptly respond to FSIS requests to share the CDC/ATSDR-provided data, information, and interpretation with establishment management. Whenever possible, it is preferable that a CDC/ATSDR team member with appropriate training and credentials be present to provide establishment management with the data, information, and interpretation that CDC/ATSDR developed and/or secured, barring the provision of any confidential or other restricted information.

IV. CDC NCEH and ATSDR will provide the FSIS and CDC-cleared assessment report for inclusion in the National Voluntary Environmental Assessment Information System NVEAIS.

## ARTICLE 6 – MUTUAL RESPONSIBILITIES

### Communication and Collaboration

I. Each agency agrees to promote effective communication and strong collaborations during the assessment planning, establishment assessment, and during post-assessment activities.

II. Each agency agrees to seek out agency subject matter expertise not described in this memorandum of understanding but identified as needed to assure the performance of a comprehensive assessment aimed at protecting public health.

III. Each agency agrees to utilize the FSIS assessment team lead to resolve issues that arise any FSIS establishments.

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IV. Each agency agrees to keep the FSIS Liaison to CDC apprised of significant issues. The FSIS Liaison will pass along to the other agency or agencies that an issue has been raised and will assist in the resolution of such issues, concerns, or challenges.

V. Each agency will strive to use the same slide set for briefings of other entities on the investigation and strive to have mutually agreed upon interpretations of investigative findings, conclusions, recommendations.

Handling of Data, Information, including industry proprietary and commercial  
confidential information, Reports, Requests for Information under FOIA,  
Abstracts, Presentations, Manuscripts, Publications

I. Each agency agrees to maintain as confidential, data and information, as required by law or agency's protocol regarding disclosure of information.

II. Each agency will apprise the other agency when requests for information under a FOIA related to foodborne health assessments associated with FSIS-regulated products have been received

III. Each agency agrees to apprise the other agency in a timely manner regarding the development of abstracts, presentations, and manuscripts on the investigation. Each agency agrees to strive to include a co-author from the other agency.

IV. Each agency will provide drafts of abstracts, presentations, and manuscripts to the other agency for clearance (co-authorship) or courtesy review (no co-authorship) in advance of submission to conference, journal, etc.

ARTICLE 7 - PROTECTION OF DATA

Handling of Confidential Information

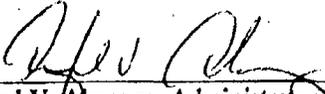
Confidential information, as used in this clause, means unpublished information or data submitted by or pertaining to an organization and FSIS-regulated establishment. FSIS will create unique identifiers that will not include company or corporation name and address to maintain confidentiality of the FSIS-regulated establishment. FSIS and CDC/ATSDR Federal employees will use the unique identifiers in correspondence, presentation, and publications. To the extent consistent with U.S. Federal law, confidential information, as defined above, will not be disclosed without the prior written consent of the individual, institution or organizations. A determination of consent will be made within 45 days of submission of the request.

ARTICLE 8 – EFFECTIVE DATE

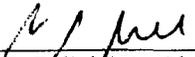
This memorandum of understanding will be in effect upon final signature of all parties. The memorandum of understanding will be reviewed every five years, or per request of FSIS or CDC/ATSDR, for programmatic relevancy and updated as agreed upon by FSIS and CDC NCEZID, CDC NCEH, and ATSDR.

The undersigned approve the terms and conditions of this memorandum of understanding and represent that they have the requisite authority to enter into it.

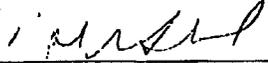
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Alfred V. Almanza, Administrator  
Food Safety and Inspection Service  
United States Department of Agriculture

1/23/14  
Date

  
Beth P. Bell, M.D., Director  
National Center for Emerging and Zoonotic Infectious Diseases  
Centers for Disease Control and Prevention  
United States Department of Health and Human Services

1/24/14  
Date

  
Robin M. Ikeda, MD, MPH, RADM, USPHS  
Deputy Director, Office of Noncommunicable Diseases,  
Injury and Environmental Health, and  
Acting Director, National Center for Environmental Health, and  
Agency for Toxic Substances and Disease Registry  
Centers for Disease Control and Prevention  
United States Department of Health and Human Services

1.22.14  
Date