MEMORANDUM OF UNDERSTANDING

BETWEEN THE

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE (FSIS) OFFICE OF DATA INTEGRATION AND FOOD PROTECTION (ODIFP)

AND THE

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

ON

DATA SHARING

Article 1 - PURPOSE

The purpose of this Agreement is to define expectations and requirements related to the daily sharing of data for the functioning of the FSIS Public Health Information System (PHIS) and for the use in investigations of foodborne illness clusters and outbreaks and tracebacks and recalls of potentially contaminated food products. FSIS will provide data from the Pathogen Reduction/HACCP verification program, nationwide microbiological baseline surveys, and other FSIS microbiological testing programs. FSIS will contribute data associated with isolates obtained from microbiological sampling of FSIS products, including subtyping information. CDC will provide data obtained from surveillance for infections with pathogens transmitted commonly through food in the U.S. This agreement will provide for the use of automated methods for the routine transfer and processing of food safety and public health information and data to support the new FSIS PHIS. This agreement will also expedite information and data sharing with CDC, NCEZID and PulseNet and OutbreakNet partners to prevent foodborne illness and to facilitate foodborne illness cluster and outbreak investigations.

Article 2 – BACKGROUND

CDC specializes in the critically important public health activities of surveillance, epidemiologic response, and investigation of illness clusters and outbreaks. Routine disease surveillance systems coordinated by CDC's National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) provide an essential early-information network to detect potential threats to the public from the food supply. These systems can be used to identify new or changing patterns of foodborne illness.

The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, secure, wholesome, and correctly labeled and packaged.

CDC, NCEZID and FSIS have partnered together on numerous projects, including PulseNet, FoodNet, OutbreakNet, NARMS, and FSIS risk management uses of human surveillance data to prevent and reduce human exposure to foodborne pathogens via FSIS-regulated products, and collaborative projects aimed at increasing the understanding of the burden and trends in foodborne diseases and the attribution of illnesses to sources. CDC, NCEZID and FSIS recently collaborated on a Predictive Analytics demonstration project which served as a preliminary and foundational step toward this MOU. The parties are now agreeing to enter into a long term agreement.

ARTICLE 3 - NEW USES OF DATA BY FSIS

As part of its ongoing effort to improve food safety and food defense, FSIS has been actively strengthening its public health data infrastructure. FSIS is proactively building an integrated system and infrastructure to support a comprehensive, timely, and reliable data-driven food public health system. FSIS is using an integrated strategic approach to build a reliable infrastructure that can evolve as the agency's needs change. The FSIS strategic plan emphasizes the importance of the agency's work to continue to build its infrastructure over the next five years. A key element to building a quality public health infrastructure is readily accessible data for FSIS decision-makers and front-line personnel. By using tools that regularly mine and aggregate the data, the agency will be able to better use its resources to interpret and act on indicators to better protect public health. The infrastructure supporting data system for FSIS is called the Public Health Information System (PHIS). Embedded within PHIS is a component called Predictive Analytics. Predictive Analytics provides enhanced reporting tools with geospatial and real-time and historical data mapping of pathogen isolation and subtyping information. Predictive Analytics may aggregate data by establishment over time to determine establishments of higher risk, cluster associations with human illness by product type, establishment, geographic distribution and parent corporation. Predictive Analytics, for example, can also provide information on trends in antimicrobial resistance patterns by food or animal category, food producer/processor, and geographic distributions. The Predictive Analytics algorithms will regularly review streams of data and automatically flag areas of potential interest for the public health workforce. This agreement will allow nightly uploading and processing of food safety and public health information to support the new FSIS regulatory inspection through PHIS and will expedite sharing of information and data with CDC, NCEZID and PulseNet and OutbreakNet partners to facilitate foodborne illness cluster and outbreak investigations.

ARTICLE 4-OBJECTIVES AND DELIVERABLES

By statute, FSIS is responsible for regulating the safety of meat, poultry, and egg products. This includes oversight of the regulated industries to ensure that they prevent and control foodborne pathogens in these products. FSIS has a wealth of information regarding contamination of meat, poultry, and egg products at slaughter and processing facility environments where these foods are produced. Pathogen isolates, characterized by pulsotype, serotype, phagetype, and/or antibiotic resistance patterns, can be linked to an associated product, product type, establishment, establishment type and size, geo-location, time, and /or corporation information.

CDC, NCEZID has tremendous knowledge, experience and data sources regarding surveillance and reporting of foodborne illness in the U.S. By linking these data streams in a real-time fashion, algorithms may be used to analyze data automatically and identify potential risks that may be evaluated by public health scientists. The key objective of this agreement is to allow nightly uploading and processing of food safety and public health information and data to support the new FSIS PHIS and expedite sharing of information with CDC, NCEZID and PulseNet and OutbreakNet partners to facilitate foodborne and illness cluster and outbreak investigations.

ARTICLE 5 – FSIS RESPONSIBILITIES

I.FSIS agrees to hold interactive working group meetings as needed with CDC, NCEZID to further refine the data sharing collaborative process.

II.FSIS agrees to share FSIS data with CDC, NCEZID on a timely basis for purposes of food outbreak illness investigations and potential attribution information. FSIS also agrees to share appropriate FSIS data with CDC PulseNet and OutbreakNet partners in the states.

III.To the extent permitted by law, FSIS agrees to keep CDC data confidential and to follow collaboration and clearance guidelines as delineated in ARTICLES 8 and 9.

ARTICLE 6 – CDC, NCEZID RESPONSIBILITIES

I.CDC, NCEZID agrees to hold interactive working group meetings as needed with FSIS to further refine the data sharing collaborative process.

II.CDC, NCEZID agrees to share select human surveillance data with FSIS on a timely basis for operational support of the FSIS Public Health Information System to conduct food outbreak illness investigations and in support of recall and traceback of contaminated FSIS foods products.

III. To the extent permitted by law, CDC, NCEZID agrees to keep FSIS data confidential and to follow collaboration and clearance guidelines as delineated in ARTICLES 8 and 9.

ARTICLE 7 - ISSUES RELATED TO FOIA REQUESTS

Information entered into the shared database by CDC belongs to and is owned by CDC. Information entered into the shared database by FSIS belongs to and is owned by FSIS. In the event of a request for this information such as a FOIA request, the request will be directed to the agency that entered the information into the shared database or the responsive information will be referred to that agency.

ARTICLE 8 - MUTUAL RESPONSIBILITIES

It is recommended that requests for information be coordinated through the designated liaison for interagency interactions. In this way requests can be prioritized and coordinated, thus eliminating duplication of effort, time, and resources.

ARTICLE 9 -- COLLABORATION AND CLEARANCE

To the extent consistent with U.S. Federal law, FSIS and CDC, NCEZID will not disclose unpublished information or data without the prior written consent of the individual, institution, or organization that submitted and/or prepared the information or data.

To the extent consistent with U.S. Federal law, unpublished data from FSIS food pathogen sampling, including isolates and subtyping information that FSIS provides to CDC or to the states, will not be released publicly without prior approval from FSIS. In addition, since data fields of the USDA Vet-Net molecular subtyping program are also included in the data to be shared in PHIS, collaboration and clearance with USDA, Agricultural Research Service (ARS) scientists must also be adhered to when VetNet data fields are used. To the extent consistent with U.S. Federal law, unpublished VetNet data will not be released publicly without prior approval by ARS.

To the extent consistent with U.S. Federal law, unpublished foodborne disease human surveillance data that NCEZID provides to FSIS will not be released publicly without prior approval by CDC, NCEZID.

Collaborative projects between FSIS and CDC, NCEZID are encouraged and should be pursued in accordance with standard scientific and ethical principles of collaboration governing the pursuit of public health and scientific advances. Both CDC, NCEZID and FSIS are required to seek clearances and cross-clearances for abstracts, presentations, and manuscripts that include previously unpublished data from both agencies. Clearance is in accordance with each agency's standing policies. Abstracts, presentations, and manuscripts must be submitted and processed in a timely manner. FSIS and CDC, NCEZID agree to keep each other informed of related data analyses and interpretations in order to prevent conflicting statements from occurring.

ARTICLE 10- 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. To the extent consistent with U.S. Federal law, confidential information, as defined above, shall 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 11- EFFECTIVE DATE

This Agreement will be in effect upon final signature. The agreement will be reviewed every five years for programmatic relevancy and updated as agreed upon by FSIS and CDC, NCEZID.

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

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Terri Nintemann, Assistant Administrator Office of Data Integration and Food Protection Food Safety and Inspection Service United States Department of Agriculture

3/30/12

Date

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

4/3/12

Date