MEMORANDUM OF UNDERSTANDING

BETWEEN THE

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

AND THE

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

NATIONAL CENTER FOR EMERGING AND ZOONOTIC INFECTIOUS DISEASES (NCEZID)

ON

DATA SHARING

Article 1 – PURPOSE

To enhance collaboration between the Department of Agriculture, Food Safety and Inspection Service (FSIS), and U.S. Department of Health and Human Services Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), specifically, to:

- a. Facilitate information-sharing and collaboration between FSIS and NCEZID;
- b. Promote efficient use of interagency expertise, technologies, and tools to improve identification of contaminated products;
- c. Strengthen interagency infrastructure and processes to investigate and prevent foodborne illness and protect public health;
- d. Expedite the transfer and interpretation of data with industry entities to protect public health; and
- e. Facilitate public reporting of allele code or other microbiological characterization data derived from FSIS isolates.

Article 2 - BACKGROUND

FSIS and NCEZID specialize in critically important public health activities, including surveillance, epidemiologic evaluation, investigation of illness, traceback, and food sampling. Both NCEZID and FSIS utilize surveillance systems that provide essential information used to detect potential threats to the public from the food supply. Both agencies conduct analyses to estimate and report, among other things, the relative importance of each food category as a potential source of illness caused by key pathogens. Both parties in this agreement have data-sharing-limitations.

Regarding microbiological data, FSIS publicly shares all data derived from isolates obtained from regulatory activities. NCEZID shares microbiological data to the extent possible, while protecting patient confidentiality.

ARTICLE 3 -USES OF DATA

By sharing data, the agencies will improve the independent and collaborative use of their resources to benefit public health. Data sharing between FSIS and NCEZID will allow routine review of data for accuracy and could flag areas of potential public health interest. This agreement supports expedited sharing of information and data between FSIS and NCEZID, which will improve routine surveillance and reporting of foodborne pathogens and strengthen detection and investigation of foodborne illnesses, clusters, and outbreaks. It will also help foster analytic projects that are maintained and developed in collaborative interagency workgroups. Lastly, data sharing will enhance the availability and use of pathogen data by food production facilities, researchers, and the public.

ARTICLE 4 – RESPONSIBILITIES

The agreements listed below are key to achieve the objectives of this MOU.

Jointly, FSIS and NCEZID agree to the following:

- a. Hold collaborative meetings, as needed, to further refine the data-sharing process including interagency workgroups to foster analytic projects.
- b. Develop and follow collaboration and clearance guidelines.
- c. Facilitate notification, communication, and data sharing with third parties, subject to the parameters outlined in Article 5, such as (but not limited to) government agencies, academic institutions, industry and consumer associations, and the public.
- d. Coordinate with the other agency in a timely manner about planned activities that will involve the other's use and interpretation of each agency's data and about plans to produce a report or publication including the other agency's data, allowing for collaboration and input as appropriate.
- e. Notify and coordinate with the other agency before contacting industry or public health entities to request or provide data, to prevent duplication of efforts.

FSIS agrees to the following:

- a. Upload isolate characterization data generated by FSIS to PulseNet in a timely manner.
- b. Provide metadata requested by NCEZID in a timely manner as appropriate for such purposes as (but not limited to) surveillance, epidemiologic analysis, and foodborne illness investigations.
- c. Communicate with NCEZID before sharing non-FSIS data with academic and other entities, including the public, and follow guidelines for limited metadata release described in the PulseNet Terms of Reference and Data Collection and Integration for Public Health Event Response (DCIPHER) rules of behavior and non-disclosure agreement.

NCEZID agrees to the following:

- a. Share isolate microbiological characterization and analysis data with FSIS on a timely basis.
- b. Provide data requested by FSIS in a timely manner for such purposes as (but not limited to) surveillance, epidemiologic analysis, and foodborne illness cluster investigations.

c. Include and collaborate with FSIS for outreach to external entities, especially industries and firms subject to FSIS regulation.

ARTICLE 5 - COLLABORATION AND CLEARANCE

To the extent consistent with U.S. Federal law, FSIS and NCEZID will not disclose information or data without having followed the procedures set forth ensuring consent of the individual, institution, or organization that submitted or prepared the information or data.

All parties are expected to seek clearance(s), cross-clearance(s), or courtesy review as applicable (e.g., abstracts, presentations, web postings, and manuscripts) when documents include data from the other agency, including publicly available data. Clearance is in accordance with each agency's standing policies. Items for clearance must be submitted and processed in a timely manner. It is agreed to keep each other informed of related data analyses and interpretations to ensure consistent messaging.

Both parties agree to use the other party's data and information in public communications only if that data and any conclusion or explanatory statements have been cleared by the agency owning/ generating the data. If the data is shared in documents or reports that follow the same format or template and are shared with regular frequency, clearance is only required one time to approve the template and data planned for sharing. Both parties agree that the clearance process will be repeated if there are changes to the format or type of data shared in a previously cleared document or report.

Public communications include (but are not limited to) information postings on the agencies' websites, publications in journals, and verbal or written communications to the media, industry or consumer groups, and conferences.

Both parties agree to update public communications during an ongoing outbreak investigation with the other party's data, as needed, to ensure accurate and timely reporting of public health data.

Both parties agree to provide a courtesy review of public communication involving shared data and information to the extent possible, providing the review process does not interfere with agency mission obligations. Both parties agree to provide a good faith effort and timely review and agree the agency may publish the communication if the reviewing agency does not respond within the courtesy review by the requested, appropriate deadline.

It is mutually agreed that both parties will collaborate to communicate shared data and information to individual entities external to each agency. The agency responsible for the data will be the lead agency in communicating with the external entity. For example, FSIS will facilitate investigation information discussions between NCEZID and inspected establishments or inspected establishment industry groups. For multistate outbreaks, NCEZID will facilitate information sharing between FSIS and state public health entities. For single state outbreaks, FSIS will facilitate information sharing with state public health entities and will keep NCEZID apprised of these communications. Discussions with external entities will be initiated at the request of either agency and may include both sharing and solicitation of data necessary to facilitate investigations.

ARTICLE - 6 PROTECTION OF DATA

The agencies agree to not disclose sensitive information, including personally identifiable information, trade secret information, and confidential business or financial information to the extent consistent with U.S. Federal law, without the prior written consent of the individual, institution, or organization.

ARTICLE 7 – 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 needed.

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

Paul Kiecker, Administrator	Date
Food Safety and Inspection Service	
United States Department of Agriculture	
	
Rima Khabbaz, Director	Date

National Center for Emerging and Zoonotic Infectious Diseases Centers for Disease Control and Prevention United States Department of Health and Human Services