United States Department of Agriculture

Research, Education, and Economics
Agricultural Research Service

August 30, 2007

Carol Maczka
Assistant Administrator for Food Defense
USDA – Food Safety and Inspection Service
South Building – Room 3130
Washington, DC 20250

Re: Non-Funded Cooperative Agreement No. 58-0101-7N-131 between USDA/Agricultural Research Service (ARS) and USDA/Food Safety and Inspection Servie (FSIS) on Data Sharing

Dear Dr. Maczka:

Enclosed please find a fully executed copy of the referenced agreement, signed by Dr. Antoinette Betschart for Dr. Edward Knipling, Administrator, Agricultural Research Service.

The ARS Information Staff, Office of Director, has requested that they have an opportunity to review any announcement to be made to the public before it is released. This should be sent to the attention of Sandy Miller Hays. Her phone number is (301) 504-1638 and email address is sandy.millerhays@ars.usda.gov.

If you should have any questions, please feel free to contact me.

Sincerely,

Bernadette E. Gregor

BERNADETTE E. GREGOR
Authorized Departmental Officer

cc:
P. Cray, ADODR
J. Lindsay, NPS

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COOPERATIVE AGREEMENT

BETWEEN THE

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE (ARS)

AND THE

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

ON

DATA SHARING

Agreement No. 58-0101-7N-131

ARTICLE 1 – PURPOSE

The purpose of this agreement is to specify expectations and requirements related to the submission of *Salmonella* isolates and carcass rinses from the FSIS Pathogen Reduction/ HACCP Verification, Baseline, and other programs to ARS for Pulsed Field Gel Electrophoresis (PFGE), antimicrobial susceptibility testing and any other laboratory subtyping procedures that may be used for inter-laboratory comparisons in the future.

ARTICLE 2 – BACKGROUND

PulseNet was established in 1998 as a national network of public health and food regulatory agencies including state and local health departments and federal agencies (Centers for Disease Control and Prevention, CDC; US Department of Agriculture/Food Safety and Inspection Service, USDA/FSIS; and the Food and Drug Administration, FDA). PulseNet participants perform standardized molecular subtyping (or "fingerprinting") of foodborne disease-causing bacteria by PFGE to distinguish strains of *Escherichia coli* O157:H7, *Salmonella*, or *Listeria* at the DNA level. DNA "fingerprints," or patterns, are submitted electronically to a dynamic database to allow for rapid comparison of patterns to detect foodborne disease clusters, facilitate early identification of outbreaks, and assist in investigating outbreaks through case finding and investigation of potential sources of illness. In these ways, PulseNet has become a rapid and effective means of communication between public health and food safety regulatory laboratories. As an adjunct to PulseNet, the US Department of Agriculture (USDA) ARS established VetNet in 2004. Results of the analyses from *Salmonella* and *Campylobacter* isolates submitted to ARS by Animal and Plant Health Inspection Service (APHIS) and FSIS,

and ARS Research isolates, are captured in the ARS VetNet database for PFGE.

The National Antimicrobial Resistance Monitoring System (NARMS) was established in 1996 by the FDA, CDC, and USDA (APHIS, ARS, and FSIS) to maintain surveillance of antimicrobial resistance patterns in foodborne pathogens including *Salmonella*, generic *E. coli* (*E. coli* O157:H7 when available), and *Campylobacter*. NARMS is a critical component of an international strategy to maintain the efficacy of antimicrobial drugs used in human and veterinary medicine.

ARTICLE 3 – OBJECTIVES

By statute, FSIS is responsible for regulating the safety of meat, poultry, and egg products. This includes controlling strains of foodborne pathogens in these products that are known to cause human illness. The PFGE and antimicrobial resistance patterns of isolates obtained from inspected products that FSIS receives from ARS provide useful subtype data for evaluating foodborne disease hazards. ARS undertakes research in characterizing the development and extent of the zoonotic spread of antimicrobial resistant pathogens as part of their Food Safety National Research Program for the purpose of exploring and developing mitigation strategies.

I. FSIS Objectives: FSIS has various responsibilities that depend on timely PFGE and antimicrobial susceptibility data:

A. Allocation of Inspection Resources: Spatial and temporal patterns within and between establishments provide a critical basis for Risk-Based Inspection. These patterns provide insight on those establishments to target, and to allocate additional inspection resources.
B. Foodborne Disease Investigation and Attribution: Linking susceptibility patterns and subtyping data on inspected product with strains associated with human illness greatly enhances attribution efforts and outbreak investigation and management.
C. Surveillance and Prevention: Timely integration of surveillance data with data from other public health partners assists in efforts to reduce the number of illnesses and deaths due to outbreaks of foodborne disease.
D. Risk Management: Each of the above objectives is part of an interrelated strategy to strengthen FSIS Risk-Based Inspection.

II. ARS Objectives: ARS has the following objectives:

A. Continued receipt of isolates: Receive and characterize zoonotic and commensal (where appropriate) isolates from FSIS federally inspected slaughter and processing establishments for use in the NARMS and VetNet programs to assess relatedness between isolates through antimicrobial susceptibility profile and PFGE typing. FSIS isolates may be

part of their PR:HACCP, baseline or special projects programs. Study the development and movement of resistant isolates throughout the slaughter/processing continuum and assess relationships to data generated at the farm level.

B. Continued receipt of rinsates: Receive and isolate zoonotic and commensal bacteria from spent rinsates collected by FSIS for use as described in (1) above. Currently FSIS only recovers Salmonella as part of their HACCP program. Using spent rinsates, ARS recovers enterococci, generic *E. coli* and *Campylobacter*.

C. Surveillance, Prevention, and Reporting: Identify trends and disseminate information to: public health partners to predict and/or avert outbreaks; industry in order to institute mitigation strategies; and guide future research.

ARTICLE 4 – MUTUAL RESPONSIBILITIES

FSIS and ARS jointly agree to develop and timely disseminate data on PFGE, antimicrobial susceptibility testing and any other laboratory subtyping procedures that may be used for inter-laboratory comparisons. These data will be used to fulfill each Agency's responsibilities and needs.

FSIS and ARS agree to each designate specific work units that will be responsible for interagency interactions. In ARS, the Bacterial Epidemiology and Antimicrobial Resistance (BEAR) Research Unit, Athens, GA is responsible for generating NARMS and VetNet data, and will be the work unit designated. In FSIS, the Office of Public Health Science (OPHS) in Washington, DC will be the work unit designated, and OPHS will work with an FSIS liaison who will be located in Athens, GA.

ARTICLE 5 – FSIS RESPONSIBILITIES

It is expected that the FSIS will provide ARS, upon isolation or receipt, isolates and/or rinsates collected from its PR:HACCP testing program, baseline studies, and other programs (if deemed appropriate) by FSIS. Isolate identifiers, such as date, product type, and location will be submitted by FSIS to BEAR in order to allow subtype data to be merged back into FSIS databases. In this way FSIS will have a seamless system that includes subtype data, Sample-ID, form number, product class, source, collection date, region, establishment, PR/HACCP set, and serotype – to assist FSIS in tracing isolates at the plant. These identifier data will be provided from FSIS back to ARS as a routine request. If a technical difficulty is encountered that does not allow this routine transmission, ARS-BEAR will be immediately notified, and the submission will be made as soon as possible. Current needs are for timely receipt of *Salmonella* data.

ARS anticipates routine/regular requests for PFGE and antimicrobial susceptibility

patterns from various offices within FSIS, including OPHS, Human Health Sciences Division (for outbreak investigations and disease attribution), the Microbiological Analysis and Data Branch, Microbiology Division, OPHS (for surveillance and baseline studies); the Data Analysis and Integration Group of the Office of Food Defense and Emergency Response (OFDER, for data analysis needs), and the Technical Service Center and Headquarters staff in the Office of Policy, Program and Employee Development (OPPED; for risk management decisions). ARS requires that such requests, including requests for publication, be coordinated through the designated FSIS unit for interagency interactions. Requests will be sent from FSIS-OPHS through the FSIS liaison located in Athens, GA to the ARS-BEAR. In this way requests can be prioritized and coordinated, thus eliminating duplication of effort, time, and resources.

ARTICLE 6 – ARS RESPONSIBILITIES

It is expected that ARS-BEAR Unit will provide where possible (unless otherwise notified) on a routine basis (at least every 30 days following receipt of isolates or 40 days following receipt of rinsates) PFGE and antimicrobial susceptibility patterns to FSIS. Likewise ARS will require a code for masking so that the isolate can be seamlessly merged and stored with other FSIS isolates by establishment, sample set and sample identification code. If a technical difficulty is encountered that does not allow this routine transmission, FSIS-OPHS will be immediately notified, and the submission will be made as soon as possible. Current needs are for timely receipt of *Salmonella* data.

ARS agrees to catalogue and store isolates received from FSIS in a secure repository. ARS anticipates that requests for isolates from FSIS may occur. ARS-BEAR will make available isolates from the repository to FSIS or a third laboratory; however, fulfillment of any request will be based on isolate number requested, time involved, anticipated use of isolates (so as not to be in conflict of ARS research) and requesting source. ARS-BEAR is not to be considered as a Culture Collection resource since it has neither the fiscal or personnel capacity. ARS will not release any isolate without prior and written consent/approval of FSIS-OPHS. When and where appropriate, ARS may send isolate DNA to collaborators working on projects with ARS scientists. A Materials Transfer Agreement (MTA) originating from ARS-BEAR, will be submitted and approved by ARS Office of Technology Transfer prior to shipment of the isolate. The MTA must state specifically the research objectives for isolate use, and how isolates will be disposed of after use. FSIS will be provided a copy of the MTA. Use of any FSIS isolate by the collaborator is limited to the scope of the MTA. ARS will not release any information concerning the isolate that may lead to its source unless deemed appropriate and approved in writing by FSIS. In accordance with ARS and FSIS requirements, the receiving laboratory must meet at least Biosafety Level 2 status.

ARTICLE 7 – COLLABORATION AND CLEARANCE

Pulsed Field Gel Electrophoresis and antimicrobial susceptibility patterns that ARS provides to FSIS will not be released publicly until these data are published, unless legally obligated to do so, with the exception of distributing PFGE patterns and antimicrobial susceptibility patterns to an FSIS-regulated establishment as part of their *Salmonella* set results. ARS and FSIS data published and in the public domain may be used without permission. Collaborative projects between FSIS and ARS are encouraged and should be pursued in accordance with standard scientific and ethical principals of collaboration governing the pursuit of public health and scientific advances. The use of Appendix 1 is required for both Agencies' participation in collaborative projects. Both ARS and FSIS are required to request clearance for abstracts and manuscripts. Clearance must be submitted 45 days in advance of submission of abstract/manuscript and each agency agrees to clear the request within the 45 day limit at which time the requesting agency may submit the abstract/paper.

Data derived solely by FSIS (without ARS participation) or vice versa may be used as necessary. Use of data for internal reports (FSIS and ARS) and routine (quarterly and yearly) NARMS and VetNet reports (ARS-BEAR) may be generated as needed. Each agency agrees to immediately notify each other when these reports are generated and provide copies as soon as available. It should be noted that FSIS-OPHS routinely participates with ARS-BEAR in generating the NARMS and VetNet reports. FSIS is not required to obtain ARS clearance prior to release of individual plant-specific data for regulatory purposes. ARS and FSIS agree to keep each other informed of specific data analyses and interpretations in order to prevent conflicting statements from occurring.

ARTICLE 8 – EFFECTIVE DATE

This agreement will be in effect upon final signature and will continue for a period of five years. At such time, the agreement will be reviewed for programmatic relevancy and, as mutually agreed, extended for an additional five years. This agreement may be modified or discontinued at the request of either party. Each party shall provide in writing a 60-day notice in advance of the effective date desired for termination of this agreement or any major modification.

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

for 8/28/07

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

Date

8/29/07

Edward B. Knipling
Administrator
Agricultural Research Service
United States Department of Agriculture

Date

APPENDIX 1

ARS-FSIS
ABSTRACT, PROCEEDINGS, AND MANUSCRIPT PROPOSAL

NOTE: Clearance by both agencies will occur within **45 days** of receipt of this document.

PART I. Both agencies

PROPOSED TITLE OF ABSTRACT/PROCEEDINGS/MANUSCRIPT (circle on):

TARGETED JOURNAL OR MEETING:

PROPOSED ORDER AND JUSTIFICATION FOR AUTHORSHIP (please indicate corresponding author with *):

	NAME	JUSTIFICATION/CONTRIBUTION[a,b]
1.		
2.		
3.		
4.		

Add additional names if required.

[a] Based upon ARS P&P 152.2 requirements for authorship which includes:
1. Conception or design ***or*** analysis and interpretation of data, ***or*** both; ***and***
2. Drafting the article ***or*** revising it for critically important intellectual content; ***and***
3. Final approval of the version to be published.

[b] ***All*** elements of an article critical to the main conclusions must be attributable to at least one author. The order of names on a multi-authored article will be decided by the group ***responsible for the research***. Participation ***solely*** in the collection, supply or summarization of data does not justify authorship.

PART II. ARS Only

JUSTIFICATION FOR NON-SCIENTIFIC YEAR (SY) AUTHOR (CAT 3-SUPPORT SCIENTIST; CAT 7-TECHNICIAN):

Author No.:
Author Name:

Xxxx (name)_____ has met the criteria for authorship on this publication as outlined in P&P 152.2 by (circle all that apply):

1. Conception or design ***or*** analysis and interpretation of data, ***or*** both; ***and***
2. Drafting the article ***or*** revising it for critically important intellectual content; ***and***
3. Final approval of the version to be published.

Certification by supervisor of non-SY author _____

Certification and approval by RL _____

Certification and approval* by Area Director:_____

*of ARS non-SY author

PART III. Both agencies

We are in agreement with the proposal as outlined, including inclusion of the non-SY author. (Note: Non-SY author must also sign.)

AUTHOR 1:_____ DATE:_____

AUTHOR 2:_____ DATE:_____

AUTHOR 3:_____ DATE:_____

AUTHOR 4:_____ DATE:_____

Add additional authors if necessary.

PART IV. Attach abstract

PART V. Clearance signatures

ARS certifies that this has cleared ARS established clearance procedures:

ARS-BEAR RL signature and date:_____

FSIS certifies that this has cleared FSIS established clearance procedures:

FSIS-OPHS representative signature and date:_____