United States Department of Agriculture
Agricultural Marketing Service
Science & Technology
Monitoring Programs Office
8609 Sudley Rd., Ste. 206
Manassas, VA 20110

June 13, 2002

TO: See Distribution List

FROM: Martha N. Lamont, Director
Monitoring Programs Office

SUBJECT: Microbiological Data Program Plan (July - December 2002)

This Program Plan serves as the current Statement of Work for the period July through December 2002 for each State participating in the Microbiological Data Program (MDP). This document also stipulates work assignments for the Federal facility participating in MDP. The contents of the plan have been approved by Robert Epstein, Deputy Administrator of the Agricultural Marketing Service (AMS), Science and Technology Program (S&T), and concurred on by Anita Okrend, Chief of the Technical Services Branch.

I. ADMINISTRATIVE UPDATES

Program participants are reminded to keep MDP management informed of any critical equipment purchases, staffing issues, or expected increases in rent (due to laboratory or office renovation/relocation, etc.). This information is required under the terms of the MDP Cooperative Agreements (Section II, Responsibilities) between USDA and participating States.

A. Personnel

The Monitoring Program Office (MPO) has lost two valuable members of its staff. Paula Todd has retired, and Kenny Payne has accepted a promotion to a new job in USDA. They will be missed. Both Paula and Kenny worked in the Sampling Program. Patricia Moe, Chris Pappas, and Dawn Fay will assume the Sampling Program duties while new personnel are recruited.

B. Equipment

Testing of cantaloupe will begin in July 2002. MDP laboratories must have equipment ready for washing/shaking samples. The SOP for washing/shaking cantaloupe has been developed by Dan Mills of the MDP California laboratory. The procedure was discussed at the June 4-5, 2002, MDP Federal/State Meeting and will be completed this month. The number of samples will determine the size of the washing/shaking equipment needed. A single five-quart pail braced on a platform shaker may be used by MDP laboratories testing fewer samples. Laboratories testing more samples can use the directions developed by Dan Mills to construct a larger platform with multiple buckets.

Lance Bolton of the Dupont Qualicon Company, the BAX-PCR equipment manufacturer, participated in the June 2002 Federal/State Meeting. Dr. Bolton offered updated training on the BAX-PCR equipment.

C. Financial/Cooperative Agreements

All MDP amended Cooperative Agreements have been signed and are complete.

D. MDP Program Meetings

An MDP public meeting likely will be held in the Fall at USDA Headquarters in Washington, D.C., to discuss program status, revisions, and expectations. MDP laboratories will be kept informed of scheduling and planning.

Technical Committee

An MDP Technical Advisory Committee was established at the June 2002 MDP Federal/State Meeting. This committee will be comprised of one representative from each laboratory and will be responsible for addressing program technical and quality assurance issues, including the development and revision of program Standard Operating Procedures. Robert Whiddon, MPO Microbiologist, will serve as the technical liaison. The first committee meeting is being planned for August 2002 in Michigan.

E. Quality Assurance

The MDP QA program covers all aspects of data gathering – from sample collection to data reporting. QA protocols for sampling are designed to protect sample integrity from the time of collection to the time of delivery at the testing facilities. QA protocols for testing comprise all laboratory operations from the time of sample receipt to the time data are reported to MDP's central database which is located in Manassas, Virginia. MDP laboratories guarantee reported results by adherence to strict QA requirements. The QA program is comprised of five elements: 1) Standard Operating Procedures (SOPs); 2) On-Site Reviews; 3) Proficiency Testing; 4) Quality Control Procedures (QC); and 5) Method Performance and Verification Procedures.

Standard Operating Procedures (SOPs)

Standard Operating Procedures (SOPs) that are being completed or revised include:

1. *Escherichia coli* MPN Method, MDP-MTH-01 (revision)
2. Shipping Microbiological Cultures, MDP-LABOP-04 (revision)
3. Sample Receipt and Wash Procedures for Cantaloupe, MDP-LABOP-06 (original)
4. Records Retention, MDP-DATA-02 (original)

Proficiency Testing Program

An MDP Proficiency Testing Program will be initiated in July 2002. AOAC will ship one Standard Microbiological Program (M09) check sample set to each MDP laboratory on July 8, 2002. Four qualitative samples for *Salmonella* determination and four quantitative samples for *E. coli* enumeration will be included in each set. The AOAC report form will list other organisms that are not required by MDP as part of this proficiency test. Laboratories should note on the report form that these organisms were not tested. However, laboratories may choose to perform and report any of the additional analyses.

Laboratories should send reports of results to both AOAC and to Robert Whiddon, MPO. Additional AOAC proficiency testing may be scheduled for FY2003 with likely AOAC shipping dates of October, January, and April.

Anita Okrend, Chief of the AMS Technical Services Branch, is working with RTech to develop proficiency test samples that better represent MDP samples.

A decision about future proficiency testing will be made later this Summer.

F. Electronic Transfer of Data

Interim RDE System in Use: All MDP laboratory facilities are using the MDP Remote Data Entry (RDE) software to perform data entry and/or generate transmit files for sampling, analysis, and quality assurance data. The MDP data is transmitted electronically to the MDP Staff Office using Internet E-mail facilities. An RDE system upgrade (to Version 1.2) will be delivered July 2002. The upgrade is required to remove data entry fields for sample origin information that is no longer captured and to provide fields to document shipment of samples to reference laboratories. These field additions require changes to the RDE database structure. MDP laboratories also asked for software capabilities to produce sample shipping lists and labels for samples. These features will be included in the new software. Additionally, the database will display a labeling change indicating the unit of count for the MPN results as MPN per ml of wash buffer instead of MPN per gram of food commodity. This change was discussed and agreed upon at the June 4-5 MDP Federal/State Meeting. See additional information in II,B, Modified Testing Procedures for *E. coli*.

The RDE software is an interim system developed in MS-Access that will be used until the reengineered joint MDP/PDP RDE software is implemented.

RDE Reengineering Project: Client Network Services, Inc. (CNSI) was contracted in 2001 to reengineer the RDE system in order to ensure compatibility with new operating systems, to include provisions for shared resources with MDP and PDP, and to employ new technology wherever feasible for capturing and transferring electronic data. The proposed system architecture for the reengineered RDE system is a centralized solution, where all RDE database files and support software will reside in Washington, D.C. and laboratory users will require only an Internet web browser on the front-end. The new RDE software being developed under contract with CNSI is available for testing at the CNSI website. The

site address is http://www.cnsinorth.com/rde. MDP laboratories are asked to review the new software and provide feedback. Use *amsrde* as the user name and *rdeuser* as the password. System testing is planned for November and delivery in December 2002.

II. PROGRAM SAMPLING AND TESTING UPDATES

A. Sampling Changes and Rotations: See the attached 3rd and 4th Quarter 2002 Shipping Charts.

Sampling Deletions: None

Sampling Additions

Cantaloupe sampling is scheduled to begin July 1, 2002. A cantaloupe commodity fact sheet will be distributed to MDP State Sampling Managers and Technical Program Managers at the June 18-19, 2002, Sampling Managers Meeting. The procedures in this fact sheet will ensure that sample collection, packaging, and shipping are performed uniformly.

With the exception of Texas and Maryland, all samples will be collected and shipped to each State's respective laboratory. Texas samples will be shipped to the AMS Eastern Laboratory in Gastonia, North Carolina, and Maryland samples will be shipped to the Ohio Laboratory in Reynoldsburg, Ohio.

Sampling Continuations

Celery, leaf lettuce, romaine lettuce, and **tomatoes** will continue. On April 1, 2002, tomato sampling was switched from two-commodity sampling (imported **and** domestic) to one-commodity sampling (**either** imported **or** domestic). Tomatoes will continue to be sampled as one commodity.

B. Testing

Shipping Samples for Further Testing

Shipment of samples to reference labs for further testing has been modified. In summary, samples testing positive for *E. coli* now are shipped simultaneously to the ARS laboratory and to the laboratory at Pennsylvania State University (PSU). Samples testing positive for *Salmonella* are shipped simultaneously to the ARS laboratory and to the AMS Eastern Laboratory in Gastonia, North Carolina. Previously, MDP laboratories shipped samples only to the ARS laboratory, and ARS the was responsible for forwarding samples to either PSU or the Eastern Laboratory.

A summary of the new shipping procedure is attached. MDP SOPs will be formally updated to include these revisions.

Microorganisms

MDP laboratories will continue to test samples for *E. coli* (quantitative testing) and for *Salmonella* (presence or absence). Testing for *Shigella* will begin in 2003 after a method has been developed and validated in each laboratory.

Commodity Deletions: None

Commodity Additions: Cantaloupe testing will begin in July 2002.

Modified Testing Procedures for *E. coli*

The testing procedure is being modified based on MDP research and the discussion at the June 2002 MDP Federal/State Meeting. To complete and document the revised procedure, Robert Whiddon, MPO, will distribute a summary and flow chart of the revised procedure and schedule a June conference call with the MDP laboratories. The final revised procedure should be completed by the end of June. MDP laboratories will begin to use the procedure on July 1, 2002.

Development of Testing Procedures for *Shigella*

MDP laboratories will participate in evaluation of the BAX-PCR equipment to test for the presence of *Shigella*. At the June 2002 Federal/State Meeting, meeting, Keith Lampell of FDA/CFSAN and Yulien Shen of the Florida MDP laboratory reported on their developmental work. The MDP laboratories in California, Florida, North Carolina, and Ohio will be part of the pilot project. Laboratories at the Minnesota Department of Agriculture, FDA, and Canada also will participate in the study. Lance Bolton of the Dupont Qualicon Company, the BAX-PCR equipment manufacturer, is providing quotes for the cost of test materials. Qualicon also volunteered to pay for testing reagents. The testing protocol will be written by Keith Lampel. Yulien Shen is available for consultation and training at the Florida lab.

Development of Testing Procedures for *Salmonella*

MDP laboratories also will participate in the continuing evaluation of the BAX-PCR equipment for *Salmonella* testing. The MDP laboratories in California, Florida, Michigan, New York, North Carolina and Ohio, as well as the Minnesota Department of Agriculture laboratory will evaluate the BAX-PCR equipment in a side-by-side comparison with cultural methods. This side-by-side study will be conducted after the *Shigella* collaborative study has been completed.

Consultation and Training on BAX-PCR

Lance Bolton of the Dupont Qualicon Company is available to the laboratories for consultation and updated training.

Cantaloupe Wash Procedures

Final cantaloupe wash procedures will be based on the research conducted by Dan Mills of the California laboratory and on the discussions at the June 2002 Federal/State Meeting. Dan Mills will complete the SOP to describe the final procedure. The MDP laboratories will be asked to review the final procedure in June and begin using the procedure in July 2002.

Revision to Units for MPN Count for *E. coli*

On-going MDP testing procedures require washing of samples with a volume of wash buffer equal to the weight of the sample. Resulting MPN values are then reported per gram of tested sample. An MPN value could have been reported in MPN per gram of sample or MPN per milliliter of wash buffer; the MPN value would have been the same. However, the MDP practice has been to report MPN per gram of tested sample.

The units for MPN reporting now will change to MPN per milliliter of wash buffer. This change will permit ease of reporting now that cantaloupe, a larger commodity, is included in the program and will be tested by using a volume of wash buffer equal not to the entire weight of the sample (a whole cantaloupe) but to one-fourth the weight of the sample. Use of wash buffer equivalent to the weight of a whole cantaloupe would have been unwieldy in the laboratory. The MDP database is being revised to reflect the change in units (see section F, Remote Transfer of Data, of this Program Plan).

C. Web Site for MDP Information

An Internet Web Site for MDP has been developed to provide SOPs, contact information, program status, and other background information.
http://www.ams.usda.gov/science/mpo/

Attachments