



United States
Department of
Agriculture

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Science &
Technology

Monitoring Programs Office
8609 Sudley Rd., Ste. 206
Manassas, VA 20110

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TO: See Distribution List

FROM: Martha N. Lamont, Director
Monitoring Programs Office

THROUGH: Anita Okrend, Chief
Technical Services Branch

SUBJECT: Microbiological Data Program Plan (January – June 2002)

This Program Plan serves as the current Statement of Work for the period January 2002 through June 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 discussed with the Centers for Disease Control and the Food and Drug Administration, and approved by Robert Epstein, Deputy Administrator of the Agricultural Marketing Service (AMS), Science and Technology Program (S&T).

I. ADMINISTRATIVE UPDATES

A. Personnel:

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.

Mr. Robert Whiddon has been hired as a staff microbiologist to work in the Monitoring Programs Office (MPO), Manassas, Virginia. Mr. Whiddon is scheduled to report to Manassas on January 14, 2002.

B. Equipment:

The Florida, New York and Ohio laboratories conducted a study on lettuce and tomatoes to determine equivalency of the BAX-PCR method to the Bacteriological Analytical Method for the detection of *Salmonella*. Results of this side-by-side study were inconclusive. A second side-by-side study on tomatoes, which incorporates an enrichment step, is currently underway. Samples were prepared by the AMS Eastern Laboratory (EL) and will be analyzed concurrently by the Ohio State Laboratory and

EL. Once results are reported and evaluated, a determination regarding equivalency of the BAX-PCR to the cultural method will be made. If results are similar to the first study, MDP laboratories will not use the BAX system to test for Salmonella. If, however, improvement is shown in reducing "false negative" results, further validation will be conducted on all MDP commodities.

C. MDP Public Meeting:

A public meeting is tentatively scheduled for January 10, 2002, USDA Headquarters, Washington, DC to discuss the development and implementation of MDP. USDA will announce the details of the meeting in a Notice in the *Federal Register*.

D. Quality Assurance (QA):

MDP's 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.

E. 2001 Proficiency Testing Program:

All laboratories will be required to participate in MDP's Proficiency Testing Program. Check samples will be issued by the EL to all participating laboratories performing microbiological analysis. Periodically, prepared commodities containing known microorganisms will be sent to all participating laboratories and tested under the same conditions as routine samples. The resulting data are used to determine performance equivalency among the testing laboratories.

The AMS, Technical Services Branch (TSB) is investigating procedures to prepare proficiency samples for produce but no selection has been made yet. There are a number of technical problems with the indicator microorganism that need to be resolved. The EL will provide a plan for distribution of proficiency samples when viable procedures for preparation are selected by TSB.

E. Standard Operating Procedures (SOPs):

SOPs will be reviewed annually and, if necessary, revised to accommodate changes in the Program. The SOPs to test cantaloupe and the procedures for the long-term storage of records are under development. All other laboratory and sampling procedures have been finalized.

SAMPLING

MDP-SAMP-PROC-1	Sampling Plans and Documentation for MDP (Original, 04/01/01)
MDP-SAMP-PROC-2	MDP Sampling Procedures on Site (Original, 04/01/01)
MDP-SAMP-PROC-3	Packing and Shipment of MDP Samples (Original, 04/01/01)
MDP-SAMP-PROC-4	Chain of Custody for MDP Samples (Original, 04/01/01)
MDP-SAMP-PROC-5	Infrared (IR) Thermometer Use (Original, 09/01/01)

LABORATORY

Laboratory Operations

MDP-LABOP-01	Infrared (IR) Thermometer Use (Original, 09/01/01)
MDP-LABOP-02	Sample Wash Procedures (Original, 09/01/01)
MDP-LABOP-03	Microbiological Media (Original, 04/01/01)
MDP-LABOP-04	Shipping Microbiological Cultures (Original, 10/01/01)
MDP-LABOP-05	Sample Receipt and Wash Procedure for Celery (Original, 10/01/01)

Analytical Methods

MDP-MTH-01	<i>Escherichia coli</i> MPN Method (Original, 09/01/01)
MDP-MTH-02	<i>Salmonella</i> VIDAS® Method (Original, 09/01/01)
MDP-MTH-03	<i>Salmonella</i> Cultural Method (Original, 09/01/01)

Data Handling and Reporting

MDP-DATA-01	Microbiological Data and Results Reporting (Original, 09/01/01)
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Quality Assurance

MDP-QA-01	Laboratory Practices and Equipment Preventive Maintenance (Original, 09/01/01)
MDP-QA-02	Proficiency Test Samples (Original, 09/01/01)

G. Electronic Transfer of Data

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 1.1) will be delivered December 2001. The upgrade is required to provide new data entry fields for the sample temperature at collection, the time the sample was packaged for shipping, and the person who received the sample at the laboratory. These field additions require changes to the RDE database structure. 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) has been contracted 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. Joint Application Development (JAD) working group meetings were held in Manassas during July and August 2001 to facilitate the systems analysis phase of the RDE reengineering project. Participants in the JAD sessions included the CNSI project team, MPO staff, and RDE stakeholders from MDP/PDP laboratories. The proposed system architecture for the reengineered RDE system is a hybrid 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. It is considered a hybrid system because there will be a small amount of system code and database files at the laboratory so that work can be done when the Internet is down. This architecture will eliminate the need for modems, dedicated phone lines, and long distance calls for data transmittal. This architecture will also relieve laboratory personnel from the arduous software administration duties required by the legacy RDE system. The estimated completion date for the project is May 2002

II. PROGRAM SAMPLING AND TESTING UPDATES

A. Sampling Changes and Rotations: *(See attached 1st and Draft 2nd Quarter 2002 Shipping Charts)*

Sampling Deletions

None

Sampling Additions

Cantaloupe (CN) is scheduled to begin April 1, 2002. With the exception of samples from Maryland and Texas, each State will collect and analyze their samples. For example, New York will collect and ship samples to the Albany, New York MDP laboratory for analysis. Maryland will ship their samples to the Reynoldsburg, Ohio MDP laboratory and Texas will ship their samples to the EL. Sample collection will be performed aseptically. Samplers will collect three (3) individual cantaloupe and place each sample in a separate sterilized bag. A commodity fact sheet will be distributed to State Sampling Managers and MDP Technical Program Managers to ensure that sample collection, packaging, and shipping are performed in a uniform manner.

Sample Temperature Control: Infrared thermometers were purchased for sample collectors to measure the surface temperature of a randomly selected sub-sample. The temperature is recorded on the MDP Sample Information Form (SIF). Sample

collectors will continue to place a freeze indicator in the shipping container so that laboratory sample receipt personnel can determine if the sample was exposed to temperatures below 32 degrees Fahrenheit. Furthermore, the sample collector will continue to record the time the sample was officially packaged for shipping on the SIF. All temperature and packaging information will be captured in the database to enhance sampling and handling protocol.

B. Testing

The microorganisms to be tested for on all MDP commodities will be enumeration of generic *Escherichia coli* (*E. coli*) and the presence or absence of *Salmonella*. Testing will begin for the presence of *Shigella* on commodities when a method has been developed and validated in each laboratory.

Testing Deletions

None

Testing Additions

Cantaloupe: After review and acceptance of a valid SOP for a wash preparation, participating laboratories will perform analysis for *E. coli* (generic) and *Salmonella*. California will provide information on various wash procedures for cantaloupe and the EL will perform tests to determine the optimum procedure to wash cantaloupe before the SOP is written.

Temperature Control: Infrared thermometers were purchased for all laboratories to measure the surface temperature of each sub-sample upon arrival. These data are used to enhance sample shipping and handling procedures. Laboratory personnel must check the freeze indicator located inside the shipping container to ensure that the sub-samples were not exposed to freezing (below 32 degrees Fahrenheit) temperatures. Results utilizing the infrared thermometer have been favorable. Temperatures are being taken at the sampling site as well as in the laboratory, and this information will be captured in the database.

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