

November 19, 2010

TO: See Distribution List

FROM: Martha Lamont

Director

SUBJECT: 2011 Semi-annual Program Plan (January through June) – Microbiological Data

Program

This Program Plan serves as the current Statement of Work for the period 1 January through 30 June 2011 for each State participating in the Microbiological Data Program (MDP).

I. ADMINISTRATIVE UPDATES

A. Program Status: MDP has been funded through December 3, 2010 under a Continuing Resolution. This means that MDP's budget will remain at the same level as in FY2010 and FY2009. Consequently, MDP will adjust program operations to offset potential budget shortfalls. In addition, in FY2011 the state of Arizona will be joining MDP in a sampling capacity only. MDP is also planning to add the state of North Carolina, but their participation in the program is contingent on securing funding through other federal programs.

The farmgate survey, which was funded by AMS, ended in late October due to lack of trained sampling personnel. For this project, 308 samples of lettuce and spinach were collected with the support of Growers Marketing, LLC/Green Giant Fresh. Only one spinach sample gave a preliminary positive for a target pathogen, but isolation wasn't achieved. Samples were tested by the Colorado and Ohio laboratories following specific protocols which require reporting of results within 48 hours of sample arrival. All samples were tested for *Salmonella* and *E. coli* O157:H7.

B. Personnel: State Program participants are required to inform the Monitoring Programs Office (MPO) of any critical personnel vacancies, staffing issues, expected increase in rent (e.g., due to laboratory or office renovation/relocation, etc.) or delays in sample turn-around-time (e.g., due to staffing issues, equipment repairs, etc.) and sampling or technical issues. These requirements are listed under the terms of MDP Cooperative Agreements (Section II, Responsibilities) between USDA and participating States, as well as Program Standard Operating Procedures (SOPs).

C. Data Reporting: Laboratories must contact MPO as soon as possible with **preliminary** positives (within 48 hours) or immediately (same day) for **final** (VITEK® confirmed) positive results for pathogens. A reporting form for positive pathogen detections is included as Attachment 1 to Standard Operating Procedure (SOP) MDP-DATA-01 and can be faxed or included as part of an email notification.

For reporting **final** (confirmed) positives, MDP requires the laboratories provide PCR data (melting curves, Ct values etc.), and results from VIDAS®, cultural and VITEK®. MDP also requires results of poly O/H agglutination tests for *Salmonella* and O157/H7 agglutination tests for *E. coli* O157:H7. MPO requests that Laboratories FIRST report to MDP on all positive isolations (*Salmonella*, *E. coli* O157:H7 and non-O157 STECs). MDP will review the results and will then forward results to the FDA, along with a cover sheet that contains additional sample and pathogen information. Once FDA acknowledges receipt of the positive results, MDP will inform the laboratory on releasing the detection information to their State agencies. A statement of non-disclosure will be included in the FY2011 cooperative agreement.

State Program participants must transmit **routine batch data results**, (this does NOT refer to pathogen detection results, which are subject to quicker reporting time limits) including any in-house confirmations, within 60 days of receipt of the last sample of each batch to RDE. This requirement is specified in SOP MDP DATA-01, subsection 5.1.5.2.

Changes to PFGE and PulseNet reporting: MDP plans to streamline upload of PFGE data by having only one MDP laboratory upload all MDP isolates' PFGE information. MDP is in discussion with the Centers for Disease Control and Prevention (CDC) PulseNet Laboratory and the New York Department of Agriculture and Markets Food Laboratory to create databases exclusively for MDP use. This PFGE upload change is also being done to ensure uniformity in information collection and data entry and will allow concurrent comparison/matchup with prior MDP isolates as well as isolates from PulseNet database sources, including environmental, human, animal, and outbreaks. This information will be reported via quarterly reports and the MDP annual summary to the USDA, AMS Administrators and collaborating federal agencies, such as the FDA and CDC.

- **D. Financial/Cooperative Agreements:** The Federal Government is under a continuing resolution (CR) until December 3, 2010. FY11 Partial Cooperative Agreements will be prepared and sent to the states in late December.
- **E. MDP Meetings:** A MDP Sampling Meeting and Technical/Quality Assurance Meeting are planned for 2011. Meeting details will be provided in future Program conference calls. Meeting topics of discussion can include MDP operations, planning and sampling, new analytical methods, and MDP SOPs.

F. Advisory Committees:

Sampling Advisory Group: Current members of the Sampling Advisory Group (SAG) are: Brian Regan (Michigan), Nathan Lubliner (Washington) and Tim Parker (New York) serving as the SAG Chairperson. At the next Sampling Meeting, a motion for a volunteer to fill an open position in the SAG will be initiated.

Technical Advisory Group: Members of the MDP Technical Advisory Group (TAG) are: Kristina McCallum (Colorado), Patricia Hanson (Florida), Frances Mohnke (Michigan), Barton Olson (Minnesota), Cynthia Mangione (New York), Crystal Verellen (Washington), Dora Rodgers (Wisconsin) and Maya Achen (Ohio) serving as TAG Chairperson. A new TAG chairperson is due to be nominated and elected at the 2011 MDP Technical/Quality Assurance meeting.

G. Electronic Transfer of Data: The current version (Build 14) of the web-based Remote Data Entry (RDE) system was activated on July 12, 2010. A re-start of development for a major Build 15 version upgrade and RDE eSIF v4.0 upgrade is planned for early 2011. Some planned enhancements include increasing the size of some text fields, adding new data fields for sample identity, increasing the size of the RDE eSIF data entry screens, adding a flag field to indicate if the eSIF has already been exported for transmittal to MPO, fixing the sample receipt location in the LIMS-to-RDE Import database and other modifications based on State and laboratory suggestions, where feasible. MPO maintains a Change Request Database to capture all problems identified and suggestions made regarding the RDE system.

II. PROGRAM SAMPLING AND TESTING UPDATES

A. Sampling: Shipping Charts are distributed quarterly to Sampling Managers by MPO. Draft Shipping Charts for the 1st and 2nd quarters of calendar year 2011 are attached to this document. Actual shipping dates and fact sheets will be sent under separate cover with the final version of each Shipping Chart. The draft Shipping Chart, fact sheets, and proposed sampling schedule for the 4th quarter were distributed on November 15, 2010 and the final version will be distributed by December 1, 2010.

Sampling Changes:

Round tomato collection will end on December 31, 2010 and will be replaced by cherry/grape tomatoes beginning January 1, 2011.

Beginning January 1, 2011, all leaf/Romaine lettuce and spinach collected will be **bagged.**

Cantaloupe collection will end on March 30, 2011 and will be replaced by a commodity yet to be determined. MPO is in consultation with FDA on commodity replacement candidates.

<u>Sampling Continuations:</u> Cilantro, hot peppers, **bagged** lettuce (leaf/Romaine), **bagged** spinach, sprouts (alfalfa/clover), and plum/Roma tomatoes.

NOTE: Arizona could start collecting cilantro, hot peppers, plum/Roma tomatoes and cherry/grape tomatoes in early December if an agreement is put into place. If funding is provided, North Carolina could start collecting samples beginning April 1, 2011.

For January to June sample shipping destinations, please refer to the attached 1st and 2^{nd} quarter 2011 draft Shipping Charts.

B. Sample Analysis:

<u>From 1 January to 31 March:</u> Cantaloupe, cilantro, hot peppers, bagged lettuce (leaf/Romaine), bagged spinach, sprouts (alfalfa/clover), and plum/Roma tomatoes will continue. Cherry/grape tomatoes will begin.

From 1 April to 30 June: Cilantro, hot peppers, bagged lettuce (leaf/Romaine), bagged spinach, sprouts (alfalfa/clover), cherry/grape tomatoes and plum/Roma tomatoes will continue. One additional commodity to replace cantaloupe is yet to be determined.

C. Quality Assurance:

<u>Combined MDP/FERN Salmonella PT Round:</u> A combined MDP/FERN Proficiency Test (PT) round was scheduled for the week of 15 November 2010. Bagged shredded lettuce was used as the test source and the target organism was *Salmonella*. PT results are pending.

The next MDP PT round is tentatively planned to occur in the third or fourth quarter of CY2011.

D. Standard Operating Procedures: All SOPs are posted to the MDP website at the time of distribution to Program participants. Refer to: http://www.ams.usda.gov/mdp. All currently in use MDP SOPs are provided on the extranet.

Laboratory SOPs Released September 2010 (Effective October 1 or November 1, 2010)

- MPO-ADMIN: Administrative Procedures for the Microbiological Data Program and Pesticide Data Program, Rev 1, 11/01/2010
 - o Attachment 1. MPO Designated Federal Records Centers
 - o Attachment 2. Standard Form SF-135 Template
 - o Attachment 3. Example SF-135 for Routine Data Packages

- o Attachment 4. Example SF-135 for Method Validation Data Packages
- o Attachment 5. Example SF-135 for Supporting Documentation
- o Attachment 6. Example SF-135 for Sampling Documentation
- o Attachment 7. Instructions for Assembly and Packaging of Record Boxes
- Attachment 8. Form GSA-49, Requisition/Procurement Request for Equipment Supplies or Services
- o Attachment 9. Equipment Inventory
- Attachment 10. Form AD-112, Report of Unserviceable, Lost, Stolen, Damaged or Destroyed Property
- Attachment 11. Form AD-107, Report of Transfer or Other Disposition or Construction of Property
- MDP-DATA-01: Data Entry, Record Keeping and Results Reporting, Rev 10, 10/01/2010
 - o Form 01, MDP Isolate Information
 - o Attachment 01, Fillable Reporting Form
 - o Attachment 02, MPO Contact Information
 - o Attachment 03, PulseNet Quick Reference Guide
- MDP-LABOP-02: Sample Receipt, Elution, Pre-enrichment and DNA Extraction, Rev 17, 10/01/2010
 - o Appendix A, Cantaloupe
 - o Appendix B, Cilantro
 - o Appendix C, Hot Pepper
 - o Appendix D, Lettuce
 - o Appendix E, Spinach
 - o Appendix F, Sprouts
 - o Appendix G, Tomato
- MDP-QA-02: Proficiency Test Samples, Rev 04, 10/01/2010
- MDP-QA-03: Quality Assurance (QA) Controls, Rev 07, 10/01/2010
 - o Attachment 01, Current QA Control Strain Information
 - o Attachment 02, QC Control Failure Reporting Form

Planned 2011 MDP SOP Revisions

- DATA-01
- E. coli O157:H7 Cultural Isolation and Identification SOP
- LABOP-02
- MTH-06
- MTH-10

- qPCR for Salmonella Detection SOP
- SHIP-03
- VIDAS® Easy SLM SOP
- **E. Transfer of Data:** MDP data is uploaded to the FERN eLEXNET system on an annual basis and also transferred to the Centers for Disease Control and Prevention (CDC) and the FDA on an annual basis; pathogenic findings are communicated to the FDA, CDC and applicable State agencies as soon as possible. In addition, MDP data is reported to USDA's Food Safety and Inspection Service (FSIS) and Agricultural Research Service (ARS). Custom MDP data reports are available on request to MPO.