United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Microbiological Data Program

SOP No.: MDP-SHIP-03		Page 1 of 9
Title: Procedures for Packaging, Shipping, and Archiving Microbiological Cultures		
Revision: 05	Replaces: 9/25/2009	Effective: 09/01/2011

1. Purpose

To provide standard procedures to ensure that all shipments of microbial cultures isolated by USDA, AMS Microbiological Data Program (MDP) laboratories are properly prepared and documented in accordance with applicable U.S. Department of Transportation (DOT), U.S. Public Health Service, the Centers for Disease Control and Prevention (CDC), and the International Air Transport Association (IATA) regulations. To provide destination addresses and contacts as well as shipment schedules. To communicate MDP minimum requirements and/or standard procedures regarding the shipment and archival of microbiological isolates.

2. Scope

This standard operating procedure (SOP) shall be followed by all laboratories conducting microbiological studies for MDP, including support laboratories conducting non-routine activities that may impact the program.

3. Outline of Procedures

4. References

- 2011 Dangerous Goods Regulations. International Air Transport Association publication, 52nd edition, Montreal, Quebec, Canada.
- Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). US Department of Transportation, Pipeline and Hazardous Materials Safety Administration. http://phmsa.dot.gov/portal/site/PHMSA (last accessed 3/11)
- Introduction to Commerce Department Export Controls. Bureau of Industry & Security, US Department of Commerce. http://www.bis.doc.gov/licensing/exportingbasics.htm (last accessed 3/11)
- Application for Permit to Import or Transport Etiologic Agents, Hosts, or Vectors of Human Disease. US Department of Health and Human Services, Public Health,

Centers for Disease Control and Prevention.
http://www.cdc.gov/od/eaipp/forms/Permit_to_Import_or_Transport_Etiologic_Agents_Hosts_or_Vectors_of_Human_Diseases_fillable1-17.pdf

- Pro-Lab Diagnostic (Microbank™) Storage System, Instructions for Use, Revision 2005 06.
- SOP MDP-DATA-01, Data Entry, Record Keeping and Results Reporting

5. Procedures

This SOP represents minimum MDP requirements and is presented as a general guideline. Each laboratory shall have written operating procedures that provide specific details concerning the manner in which the procedures have been implemented in that laboratory.

5.1 Shipments by MDP Participating Laboratories

5.1.1 Addresses of destinations are listed in Attachment 01. Addresses for MDP participating laboratories are listed in Attachment 02.

5.1.2. Laboratories may be requested to send samples to additional facilities for testing. Details regarding the type of sample, the shipping address, and the facility point of contact will be provided in writing by the Monitoring Programs Office.

5.1.3 **Prior** to shipping isolates to the MDP Repository, provide notification via email to: achen@agri.ohio.gov and jbalogh@agri.ohio.gov. Attach the Results Notification Form, MDP-DATA-01 Attachment 1, Isolate Information Form, MDP-DATA-01 Attachment 4 (Form 001) and Isolate Shipment Form, MDP-SHIP-03, Atch 4, to the notification email.

5.1.4 For **ALL** organisms (including *E. coli* O157:H7), prepare and package three Potato-Sucrose agar slants or three Nutrient Agar slants or three Tryptic Soy Agar slants per isolate, labeled with the following information:

- Organism type (*Salmonella*, etc.)
- Remote Data Entry (RDE) unique number
- Isolation date (date isolate put onto slants for shipping)
- SIF code

The three slants and completed Isolate Shipment Form, Attachment 04 of this SOP, shall be shipped to the MDP Repository at the following address within five (5) business days after isolation:

Ohio Department of Agriculture Consumer Analytical Laboratory
Building 3, 8995 East Main Street
Reynoldsburg, OH 43068

Clearly annotate on the Isolate Shipment form, Atch 4, that accompanies the slants, whether PFGE and serotyping have been completed or if it still needs to be done.

NOTE: Laboratories are encouraged to archive a vial of the isolates in their laboratories in case further analysis is required by their State.

5.2 **Packaging Requirements -** Each laboratory must comply with all applicable federal, state, and international regulations pertinent to the shipment of microorganisms.

5.2.1 Laboratories shall follow the IATA regulatory requirements for classification, documentation, packaging, and labeling of the materials to be shipped. Laboratories shall follow the IATA regulatory requirements for emergency response procedures and contacts for notification as well as training requirements for personnel involved in the preparation of shipments.

5.2.2 The CDC and Department of Transportation **do not currently require** any permit to transport *Salmonella, E. coli,* or *E. coli* O157:H7 **within the U.S.**

5.2.3 **If shipping to international destinations, export** permits **MAY** be required. The shipper shall notify the intended recipient that their government agencies should be contacted regarding needed permits. *E. coli* O157:H7 has been placed on the Department of Commerce's Control List, requiring a CDC permit for international shipments but not domestic shipments.

5.2.4 MDP cultures shall be considered infectious bacteria.

5.2.5 MDP laboratories will ship only microorganisms which are classified as Biosafety Level (BSL) 2 or lower.

5.3 **Shipping Requirements**

5.3.1 All shipments shall be handled by a traceable overnight delivery service.

5.3.2 The Isolate Shipment Form, Attachment 04, shall be completed and accompany each shipment.

5.3.3 Slants shall be shipped with adequate packing (bubble wrap, etc.) and/or appropriate refrigerant (coldpack or ice) to ensure their integrity during transport.

5.3.4 Other materials (cultures, wash eluate, samples, etc.) shall be shipped as specified in section 5.1.2.

5.4 Documentation Requirements

5.4.1 RDE documentation requirements reside in SOP MDP-DATA-01.

5.4.2 An internal record shall document the transport for each vial by containing the following information:

- Identity of bacterium shipped
- Isolation date (date isolate was put on slants for shipping)
- Quantity shipped in each package, i.e., total volume (ml) or total mass size (g) of material in all test tubes and number of such primary containers
- Laboratory reference number for the individual culture and sample identifier (RDE unique number)
- Date shipped and commercial shipping company used
- Identity of produce from which each bacterium was isolated, and the State of origin in the United States, if available
- Shipping conditions used shall be described as ambient temperature, ice packs, etc. (specify net weight)
- Printed name of person performing the packaging
- Printed name of person shipping cultures
- The identity of the facility to which each package is shipped and the date the receiving laboratory was notified of shipment
- Confirmation of sample receipt

5.5 Requirements of the Culture Repository

5.5.1 Unless specifically requested by the Monitoring Programs Division (MP), the laboratory acting as the culture repository shall not perform analytical examinations or verification analyses on the materials sent for archival.

5.5.2 All isolates shall be archived in Microbank™ vials and held at -70ºC or lower, for an indeterminate period of time.

5.5.3 Labeling of vials: Microbank™ vials of target organisms shall be identified by accessing the Tools section of the RDE system and entering the future

shipment date to the destination(s). (An identification number was automatically provided to the originating laboratory by RDE for use in labeling the vials prior to shipment to the Repository.) The number generated will consist of the last two digits of the calendar year, followed by a dash and the next available number consisting of five digits. (i.e. 11-00001) The Repository will insure transfer of the RDE number from the slant/shipment documentation to the cryovial prior to storage.

5.5.4 Subculturing Repository Organisms - The laboratory responsible for maintaining the repository shall develop and implement internal procedure(s) for the recovery and subculturing of organisms.

5.6. **Shipments by Culture Repository** (Ohio Department of Agriculture (ODA) Consumer Analytical Laboratory)

5.6.1 ***Salmonella* spp**: Within five business days after *Salmonella* sp. culture isolation, one slant of of each isolate received from participating and reference laboratories shall be labeled as "MDP-yy-xxxxx", no spaces (this will become the PulseNet key number - Please refer to MDP-DATA-01 SOP, Atch 3, QRG) and transfer to the Ohio Department of Health (ODH) for *Salmonella* serotyping and PFGE. Once PFGE and serotyping are completed, ODH/ODA will relay results to MP and CDC. Data upload to PulseNet shall be completed within three business days of PFGE completion.

5.6.2 ***E.coli* O157: H7**: Within five business days after *E.coli* O157:H7 culture isolation, one slant of each isolate received from participating and reference laboratories shall be labeled as "MDP-yy-xxxxx", no spaces (this will become the PulseNet key number - Please refer to MDP-DATA-01 SOP, Atch 3, QRG) and transfer to the ODH for PFGE. Once PFGE is completed, ODH/ODA will relay results to MP and CDC. Upload to PulseNet for *E.coli* O157:H7 isolates shall be completed within three business days after completion of PFGE. The MDP Repository will also ship an *E.coli* O157: H7 isolate slant to Pennsylvania State University (PSU) for further characterization. PSU will report its test results to the MDP Repository and MP. The information from PSU shall also be uploaded to PulseNet.

5.6.3 **Non-O157 STEC**: Within five business days of receipt of non-O157 STEC isolates from participating and reference laboratories, the isolates shall be labeled as "MDP-yy-xxxxx", no spaces (this will become the PulseNet key number - Please refer to MDP-DATA-01 SOP, Atch 3, QRG) and one isolate slant shall be

shipped to PSU for further characterization and one isolate slant transferred to ODH for PFGE. PSU will report its test results to the MDP Repository and MP. Within two business days of receipt of the results from PSU, the Repository shall relay PSU results to ODH so that the PulseNet record for the particular isolate shall be updated. Once PFGE and upload is completed, ODH/ODA will notify MP and CDC.

5.6.4 **For all isolates**: ODA/MP will be responsible for populating the repository database with information. (Repository database has been placed on MP Extranet). The repository may ship isolates of appropriate number and type of slants to other facilities as requested in writing by MP.

5.7 **Repository Inventory -** The repository inventory database may be manual, electronic or a combination of both. At a minimum, the inventory control system must document:

- Unique RDE number
- Laboratory ID
- Organism
- MDP lab/commodity
- SIF code
- Isolation Date (date isolate was put on slants for shipping)
- Date received by ODA
- Transfer date to ODH
- Transfer date to PSU
- Date frozen/location
- PFGE result
- Serotyping result
- ETEC/STEC results
- Comments (outbreak related, recall, etc.)

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- Add words "shipment and" to last sentence of Section 1
- Added Outline of Procedures, Section 3
- Updated References, Section 4
- Revised old Section 4.1.3 (new 5.1.3) by adding "Attach the Results Notification Form, MDP-DATA-01 Attachment 1 and the Isolate Information Form, MDP-DATA-01 Attachment 4 (Form 001) to the notification email."
- Revised old Section 4.1.3 (new 5.1.4) by changing (in bold) "For ALL organisms (including *E. coli* O157:H7), **three** Potato-Sucrose agar slants or **three** Nutrient Agar slants or **three Tryptic Soy Agar** slants per organism, labeled with:
    - **Organism type (*Salmonella*, etc.)**
    - **Remote Data Entry (RDE) unique number**
    - **Isolation date (date isolate put onto slants for shipping)**
    - **SIF code**

  The three slants and completed MDP Shipment Form, Attachment 04 of this SOP, shall be shipped to the MDP Repository at the following address within five (5) business days after isolation:

  Ohio Department of Agriculture Consumer Analytical Laboratory
  Building 3, 8995 East Main Street
  Reynoldsburg, OH 43068

  Clearly annotate on the shipment form that accompanies the slants, whether PFGE and serotyping have been completed or if it still needs to be done."
- Replaced the word "import" with "export", Section 5.2.3
- Revised old Section 4.6. (new 5.6) (subsection changes in bold type) to read as: "**5.6.1** ….Once PFGE and **serotyping** are completed, ODH/ODA will relay results to **MP and CDC**…."

  "5.6.2 …. Within five business days after ***E.coli* O157:H7** culture isolation, one slant **of each isolate** received …. Once PFGE is completed, ODH/ODA will relay results to **MP and CDC**. Upload to PulseNet for ***E.coli* O157:H7** isolates shall be completed within three business days after completion of PFGE. **The MDP Repository will also ship an *E.coli* O157: H7 isolate slant to Pennsylvania State University (PSU) for further characterization. PSU will report its test results to the MDP Repository and MP. The information from PSU shall also be uploaded to PulseNet."**
- Added new subsections 5.6.3 and 5.6.4

- Revised Attachment 01, Shipment Destinations
- Revised Attachment 02, Shipment Addresses
- Revised Attachment 03, Shipment Flowchart
- Revised Attachment 04, MDP Isolate Shipment Form

Revision 04 September 2009 Monitoring Programs Office

- Updated References, Section 3
- Revised Sections 4.1 through 4.7
- Revised Attachment 1
- Revised Attachment 2
- Revised Attachment 3

Revision 03 March 2009 Monitoring Programs Office

- Updated Outline of Procedures
- Updated References
- Updated Shipments by MDP Participating Labs
- Updated Requirements of the Culture Repository
- Updated Shipments by Culture Repository
- Updated Attachments

Revision 02 January 2006 Monitoring Programs Office

- Removed shipment of vials for mPCR testing
- Updated addresses and added alternate contact person for shipping destinations.
- Added allowance for specific MP request for additional testing on isolates by archival laboratory

Revision 01 October 2004 Monitoring Programs Office

- Updated references
- Removed revision numbers from attachments
- Corrected Attachment 01