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Revision: 4 Replaces: 4/29/09 Effective: 8/31/09		

1. Purpose:

To standardize the sampling procedures for all States participating in the USDA/AMS Microbiological Data Program (MDP).

2. Scope:

This Standard Operating Procedure (SOP) shall be followed by the sample collectors during the sample collection process as required by MDP.

3. Outline of Procedure:

- 5.1 Training and Evaluation of Sample Collectors
- 5.2 Assignment of Sample Collectors
- 5.3 Sample Designation and Amount
- 5.4 Sampling Procedures for Fresh Commodities
- 5.5 Purchasing Samples

Attachment 1 – Template for SF-135 Form

Attachment 2 – Example of SF-135 Form for Federal Records Center Supporting Data Packages for MDP

Attachment 3 – Federal Records Center Addresses for SF-135 Form

4. <u>References:</u>

- Sample Advisory Committee Meeting, December 2-4, 2008
- Sample Advisory Committee and Sampling Manager communications (email and telephone), January, February, and April 2008
- PDP/MDP Technical Meeting, Richmond, VA, March 27-31, 2006
- Sampling Managers' Conference Call, March 13, 2006
- PDP/MDP Federal/State Meeting, Denver, CO, September 27-29, 2005

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- Sampling Managers' Meeting, Kansas City, MO, October 21, 2003
- Program Plan, July-December 2002
- MDP Public Meeting, Washington, DC, April 15, 2002
- Program Plan, January-June, 2002
- MDP Public Meeting, Washington, DC, January 10, 2002
- Program Plan, April-September 2001
- MDP Federal/State Meeting, Tallahassee, Florida, January 10-11, 2001
- PDP SOPs, SAMP PROC-2, Sampling Procedures on Site, June 1, 2000
- Work plan for MDP Pilot Study, August 25, 1999

5. Specific Procedures:

5.1 Training and Evaluation of Sample Collectors

5.1.1 MDP-based training and evaluations serve as tools from which to teach and judge the sample collector's level of knowledge and skills for MDP sampling operations.

5.1.2 Training

- **5.1.2.1** Training shall be conducted at least once a year to ensure that sample collectors have an acceptable level and working knowledge of MDP SOPs, the Monitoring Programs Office (MPO) Remote Data Entry system, and current program updates. Although it is preferable that collectors meet personally with their State Sampling Manager for their training needs, it is acceptable for Sampling Managers to deliver training via electronic means.
- **5.1.2.2** At least once a year, sample collectors shall be provided with a list of objectives and responsibilities that are set by their respective State Sampling Manager.
- **5.1.2.3** Sample collectors shall be expected to view a sampling procedure training presentation offered by MPO or their State Sampling Manager at least once a year.
- **5.1.2.4** Sample collectors shall be updated on MDP program changes at the time State Sampling Managers are notified of such changes by MPO.

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- **5.1.2.5** Sample collectors shall be provided with reference documents listed in Section 5.4.1.1.
- **5.1.2.6** New sample collectors shall become familiar with MDP SOPs, view applicable training presentations, and spend ample time in the field collecting, packaging, and shipping MDP commodities with their respective State Sampling Manager, or designee, prior to initiating their own collections.
- **5.1.2.7** Sample collectors shall be provided and become familiar with all collection, packaging, and shipping supplies that are approved for use by their State Sampling Manager, or designee.
- **5.1.2.8** State Sampling Managers shall keep on file a record of the training each sample collector receives and shall have such records available for viewing by MPO when requested. (Refer to SAMP ADMIN-02).

5.1.3 Evaluation

- **5.1.3.1** Sample collector evaluations shall be conducted once a year or more frequently as necessary.
- **5.1.3.2** As part of the sample collector's routine evaluation, the State Sampling Manager, or designee, shall accompany the collector into the field to observe his/her sample collection techniques and their knowledge of MDP SOPs.
- **5.1.3.3** Evaluations shall include a review of electronic sample information forms (e-SIFs) with the collector to ensure sample information is being obtained and recorded in an acceptable manner.
- **5.1.3.4** Collection problems shall be corrected as they occur and shall include collector retraining as necessary.

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5.1.3.5 Sampling Managers shall keep a record on file of the evaluations each sample collector receives and shall have such records available for viewing by MPO when requested. (Refer to SAMP ADMIN-02.)

5.2 Assignment of Sample Collectors

- **5.2.1** Each State shall designate individuals to serve as their sample collectors and maintain a list of such personnel (refer to MDP SAMP PROC-01, Section 5.3). Changes to this list shall be provided to the MPO Sampling Manager, or designee, as they occur.
- **5.2.2** States shall designate the number of commodity samples, with corresponding dates and sites, to be collected by each sample collector per month.
- **5.2.3** If a sample(s) will not be collected due to personal emergency, plant closure, weather conditions, etc., the sample collector shall report it to the State Sampling Manager for reassignment to a different collector, alternate site, or sampling date.
- **5.2.4** If it is found that a sample collector cannot sample a product on the scheduled day, he/she shall immediately notify the State Sampling Manager of such scheduled change. The State Sampling Manager (or designee) shall in turn notify MPO and contact the receiving laboratory to arrange for a resampling date.
- **5.2.5** It is permissible to collect a sample on the month following the scheduled sample collection date **only** under one of the following circumstances: (1) carrier delays result in the sample(s) not arriving in acceptable condition on their scheduled date near the end of a month and it is not possible to resample before the month's end, (2) the sample(s) has arrived at the laboratory in unacceptable condition and it is not possible to resample before the month's end, (3) general unavailability of commodity, or (4) special circumstances arise where consultation is made between the State and MPO and it is determined that resampling the following month is deemed necessary. In any of these instances, MPO *and* the receiving laboratory must be notified for approval to "make up" the lost sample(s) on a specified day the following month. Frequent make-ups are strongly discouraged because, over time, these actions may introduce undesirable bias in the MDP results. Make-up

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sampling may not occur at the end of a calendar year because the results would represent sampling efforts from two different years.

5.3 Sample Designation and Amount

- **5.3.1** MPO provides "Fact Sheets" and "Quick Reference Guides" that include collection information for each commodity. Fact Sheets contain statements regarding the size, variety, list of acceptable and unacceptable products for collection, ethylene sensitivity, and special packing/shipping instructions. Fact Sheets are not comprehensive, but serve as a reference to be used in conjunction with MDP SOPs. Quick Reference Guides summarize commodity types that are unacceptable to collect (for all commodities) and also provide details on specially requested e-SIF information.
- **5.3.2** A commodity sample consists of 3 sub-samples taken from an individual box/carton at a given site. All three sub-samples shall have the same lot number.
- **5.3.3** Besides collecting one set of commodity samples from separate collection sites in a State, it is also acceptable to collect one commodity sample from each of two different boxes at a single site to reduce the number of collection sites. It is preferred that each box represent a different grower, packer, or distributor. However, if the collection site does not carry multiple growers, packers, or distributors of the product, it is acceptable to collect the second commodity sample from another box of products with a different lot number.
- **5.3.4** The amount per sample, as designated by MPO, shall be collected for each commodity. Information regarding the amount (number of units or weight) of sample collected will be provided in the Shipping Assignment Chart by the MPO Sampling Manager, or designee, prior to the beginning of each new quarter [refer to MDP SAMP PROC-01, Section 5.7]. The targeted sample size will also be noted on each commodity's Fact Sheet.
- **5.3.5** For some commodities, one entire unit per sub-sample is required, regardless of its size (for example, cantaloupe). For other commodities, the collection of a specific weight (for example, lettuce) is required. In the instances where a collection weight is specified, the sample collector must collect within $\pm 20\%$ of the specified weight if the specified weight is greater than 100 grams (3.5)

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ounces) and within $\pm 10\%$ of the specified weight if the specified weight is less than 100 grams (3.5 ounces).

5.3.6 Sample collectors may not "sub-sample" a commodity that is already pre-packaged in an individual bag or plastic container. Explicitly, sample collectors may not open a processed or pre-packaged "ready-to-serve" bag or plastic container to remove a portion of the commodity to create a sub-sample. An example would be for the commodity alfalfa sprouts: a 3-lb bag or container of alfalfa sprouts may not be opened to obtain one, two, or three individual 3-oz. samples. A sub-sample in this case must consist of one unopened bag or plastic container. For large, institutional-sized bags, the collector may be requested to collect and ship a single bag as a commodity sample from which laboratory personnel will select and remove three sub-samples. When in doubt, collectors should refer to Fact Sheets and Shipping Assignment Charts for details on each commodity sample.

5.4 Sampling Procedures for Fresh Commodities

Fresh commodities refer to raw, whole produce (i.e., lettuce, tomatoes, celery bunches, etc.). Fresh commodities that are washed, brushed, cut, or bagged as part of normal packing procedures are acceptable as defined in each commodity's Fact Sheet and Shipping Assignment Chart.

- **5.4.1** Procedures for Selecting Fresh Commodity Samples at Collection Sites
 - **5.4.1.1** Sample collectors are responsible for carrying the necessary reference documents with them when sampling:
 - Fact Sheets
 - Quick Reference Guides
 - Access to SOPs
 - Blank paper SIF forms
 - Site List
 - Current Shipping Assignment Chart
 - Current collection schedule
 - Phone numbers of all active sampling sites

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- **5.4.1.2** Samples shall be collected at sites that include chain store distribution centers, warehouses, and terminal markets where each vendor is assigned an individual site code. Refer to MDP SAMP PROC-01, Section 5.1.4 for exceptions.
- **5.4.1.3** When selecting a pallet/group to be sampled at a vendor site, the sample collector shall use an appropriate means of random selection that is outlined in the State's internal Sampling Standard Operating Procedures (SOPs). These SOPs shall be kept on file by the State Sampling Manager. The random selection process used by the sample collectors must be acceptable to both the National Agricultural Statistical Service (NASS) statistician and the State Sampling Manager.
- **5.4.1.4** Personnel at collection sites may randomly select a box or crate of product and have it available for the sample collector to pick-up. The sample collector shall request that the product remain in a refrigerated area of the collection site until sample pick-up if that commodity would normally require refrigeration. Collection site personnel may <u>not</u> collect sub-samples from a box/crate.
- **5.4.1.5** Once a pallet/group has been randomly chosen, sample collectors must collect all three (3) sub-samples from the same box and that have the same lot number. Sample collectors should make every attempt to locate and record brand name; grower, packer, and distributor information; and country of origin.
- **5.4.1.6** Sample collectors shall be careful to select individual fruit or vegetables that are in good condition, without any noticeable bruises, decay, or other visible defects. Additional information regarding sampling of fresh fruit and vegetables is provided on commodity Fact Sheets.
- **5.4.1.7** Sample collectors shall take note of any expiration or use-by date marked on the commodity to be collected and record it on the e-SIF. *Sample collectors may not collect a commodity for which the expiration date has passed.* A "Best Used By" date is not the same as an expiration date and only describes possible quality changes over time. Sample collectors may collect samples after a "Best Used By" date if the quality of the product has not been compromised.

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- **5.4.1.8** If an entire case or carton of product is purchased, samples should, if at all possible, be collected and bagged in the warehouse facility to avoid exposure to inclement weather, high or sub-freezing temperatures, and external contamination possibilities. If necessary, however, the entire case or carton of product may be taken to a more convenient location before selecting the sub-samples, provided that no more than 30 minutes will lapse before removing the samples and sufficient precautions are taken to ensure the samples remain in optimum condition and are not contaminated by external factors. Perishable products must be stored at refrigerated temperatures if the transfer/transit time exceeds 30 minutes before packaging for shipment is initiated.
- **5.4.1.9** Additional information regarding the sampling of specific fresh fruit and vegetables will be provided, as necessary, in writing to State Sampling Managers by the MPO Sampling Manager.
- **5.4.2** Special Sampling Techniques for the Collection of MDP Samples
 - **5.4.2.1** For perishable samples, insulated sample transport containers must be pre-cooled to a refrigerated temperature prior to sample collection. If shipping containers are used to store and transport perishable samples, they too must be pre-cooled to a refrigerated temperature prior to sample collection.
 - **5.4.2.2** All loose and/or perishable produce must be collected aseptically. Aseptic collection means that samples will be collected with the use of sterile gloves in a manner that will avoid contact with any foreign objects which may contaminate the sample.
 - **5.4.2.3** The same sterile gloves may be used for all three (3) subsamples of a given commodity obtained from a single box. New sterile gloves must be worn for each new box and/or lot number of a given commodity.
 - **5.4.2.4** Sample collectors must use a separate sterile plastic bag for each loose and/or perishable sub-sample. For example, sample collectors must use three (3) sterile bags to collect the three (3) sub-samples from a given box or carton.

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- **5.4.2.5** The produce boxes or cartons and sterile sampling bags must be opened before the sample collector puts on sterile gloves. Loose and/or perishable produce being sampled must be handled only when wearing sterile gloves.
- **5.4.2.6** Each sub-sample must carefully be placed into its sterile bag so that the product is not broken, bent, or bruised. *The sample collector must not permit ungloved arms or clothing to enter a sterile bag.*
- **5.4.2.7** If a sterile bag is used that does not have a twist-and-fold closing mechanism, the sample collector should refer to State internal SOP for approved closure procedures. Laboratory personnel must be able to open the sterile bags without tearing the bag to avoid potential product contamination. State Internal SOPs shall dictate any sub-sample labeling requirements.
- **5.4.2.8** After each loose and/or perishable sub-sample has been placed in its separate sterile plastic bag, each <u>set</u> of sub-samples from a particular box shall be placed together in a larger plastic bag. (The outer plastic bag contains the entire box or carton sample.) The outer plastic bag is not required to be sterile. Paper bags are not acceptable for use with any loose and/or perishable MDP samples.
- **5.4.2.9** Products that are hermetically sealed (closed by the packer by means that prevent gas or vapor from entering or escaping the bag, jar, or can) need not be handled with sterile gloves or placed in sterile bags. However, products in sealed bags, sealed clamshells, or other sealed containers that have small holes or other venting apertures in them do not require handling with sterile gloves, but they must be placed in sterile bags. Guidelines for special or unique situations will be placed on each commodity's Fact Sheet. *This paragraph provides minimal requirements; through internal SOPs, States may elect to require sterile gloves and bags for use with all MDP commodities.*
- **5.4.2.10** The outer plastic bag containing the sub-samples shall be sealed in a manner that any attempt to tamper with the contents would easily be noticed. A detailed description of the tamper-proofing method used shall be included as part of the State's internal SOPs for

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sampling. These SOPs must be kept on file by the State Sampling Manager. If the sample is hand delivered to the laboratory, tamper proofing methods are optional, provided chain of custody is maintained. *The tamper proofing mechanism shall be dated and initialed by the sample collector*.

- **5.4.2.11** Each outer bag that contains a set of 3 sub-samples shall be labeled with information that uniquely identifies the commodity sample. The following information must be included on each sample label: 2-digit State of collection, 6-digit date (yy/mm/dd), 4-digit site code number, 2-digit commodity code, 3-digit receiving laboratory code, a "P" for proxy site in the Source ID box if a proxy site is sampled, and name of person who collected and packed the sample.
- **5.4.2.12** All information may be pre-entered on the label except for the site number, date, and whether an alternate and/or proxy site was sampled. If the samples are packed on site, all information for a particular sample shall be unequivocally identified before leaving the site.
- **5.4.2.13** Pin holes for ventilation may NOT be placed in the sterile sample bags or the larger, outer plastic bag.
- **5.4.2.14** After the outer plastic bag containing the loose or perishable commodity sample (set of 3 sub-samples) has been labeled and tamperproofed, it must immediately be placed in a pre-cooled insulated container. If the situation requires that a paper Sample Information Form (SIF) be included with the commodities, the completed form must be placed in the shipping container with the commodities in a separate sealed plastic bag [refer to MDP SAMP PROC-03, Section 5.1.11].
- **5.4.2.15** Sterile bags and gloves shall be purchased from a source(s) approved by the USDA/AMS Sampling Manager after consultation with the State laboratory(ies) to ensure that both products or lots have been certified as sterile. Sterile whirl paks or sterile non-strainer stomacher bags may be used depending on the size of the sample.

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5.4.2.16 When collecting and packaging more than one commodity at the same site (or even on the same day), the sample collector shall prevent potential cross-contamination between the samples.

5.5 Purchasing Samples

- **5.5.1** The sample collector shall make payment to the appropriate site/vendor(s) as necessary.
- **5.5.2** Exact method of payment (e.g., cash or State voucher) is determined by the individual States.
- **5.5.3** A receipt must be provided by the vendor and retained by the State for all sample payments for a two year period. After two years, State Sampling Managers may transfer these receipts to a Federal Records Center (FRC) by completing form SF-135 for Supporting Data Packages (refer to template in Attachment 1, example in Attachment 2, and FRC addresses in Attachment 3 in this SOP) and follow directions in MDP DATA-02. MPO should be contacted for any questions concerning the disposition or transfer of records or if a State wishes to transfer records within a timeframe shorter than two years.
- **5.5.4** The sample collector may purchase either the required sample amount or the entire case of product as required by the vendor.
- **5.5.5** If an entire case is purchased, records must be kept and maintained for two years by the States as to the disposal of the unused product (donated, left with vendor, discarded, etc.). After two years, State Sampling Managers may transfer these records to an FRC by completing form SF-135 for Supporting Data Packages (refer to template in Attachment 1, example in Attachment 2, and FRC addresses in Attachment 3 in this SOP) and follow directions in MDP DATA-02. MPO should be contacted for any questions concerning the disposition or transfer of records or if a State wishes to transfer records within a timeframe shorter than two years.
- **5.5.6** Payment for samples should approximate the local retail price, but an additional amount may be added, as appropriate, for the vendor's time and trouble.

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5.5.7 Specific procedures/requirements regarding the purchase of MDP samples shall be explained as part of the State's internal SOPs for sampling.

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8/31/09

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Revision 4

- Changed paragraph 5.4.2.4 to show that the same sterile gloves may be used for all three subsamples in a box.
- In paragraph 5.3.3, clarification was made regarding the collection of samples from two boxes at one site.

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MDP SAMP PROC-02, rv4, Attachment 1

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USDA/AMS Microbiological Data Program Designated Federal Records Centers

State Agency	Region	Send to:			
		Name	Address		
California Department of Pesticide Regulation California Department of Food and Agriculture	Pacific Region	Federal Records Center	1000 Commodore Drive San Bruno, CA 94066-2350		
Colorado Department of Agriculture	Rocky Mountain Region	Federal Records Center	Bldg. 48, Denver Federal Center West 6 th Avenue and Kipling Street Denver, CO 80225-0307		
Florida Department of Agriculture and Consumer Services	Southeast Region	Federal Records Center	4712 Southpark Blvd. Ellenwood, GA 30294		
Maryland Department of Agriculture	Washington National Records Center	Federal Records Center	4205 Suitland Road Suitland, MD 20746-8001		
Michigan Department of Agriculture	Great Lakes Region	Federal Records Center	7358 South Pulaski Road Chicago, IL 60629-5898		
Minnesota Department of Agriculture	Great Lakes Region	Federal Records Center	7358 South Pulaski Road Chicago, IL 60629-5898		
Montana Department of Agriculture	Rocky Mountain Region	Federal Records Center	Bldg. 48, Denver Federal Center West 6 th Avenue and Kipling Street Denver, CO 80225-0307		
New York Department of Agriculture and Markets	Northeast Region	Federal Records Center	National Archives-Central Plains Region 200 Space Center Drive Lee's Summit, MO 64064-1182		
Ohio Department of Agriculture	Great Lakes Region	Federal Records Center	Federal Records Center – Dayton 3150 Springboro Road Dayton, OH 45439-1883		
Texas Department of Agriculture	Southwest Region	Federal Records Center	1400 John Burgess Drive Fort Worth, TX 76140		
Washington State Department of Agriculture	Pacific Alaska Region	Federal Records Center	6125 Sand Point Way NE Seattle, WA 98115-7999		
Wisconsin State Department of Agriculture	Great Lakes Region	Federal Records Center	7358 South Pulaski Road Chicago, IL 60629-5898		