

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

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Title: Sampling Plans and Documentation for MDP		
Revision: 3	Replaces: 4/24/06	Effective: 4/29/09

1. Purpose:

To standardize the development of quarterly sampling plans and sampling documentation for all States participating in the USDA/AMS Microbiological Data Program (MDP).

2. Scope:

This Standard Operating Procedure (SOP) shall be followed by all State personnel involved in the management of sample collection for MDP.

3. Outline of Procedure:

- 5.1 Sample Availability
- 5.2 State Sample Allocation
- 5.3 State Sample Collectors List
- 5.4 Master List of Sampling Sites
- 5.5 Relative Volume Information for Sampling Sites
- 5.6 Quarterly Selection of Sampling Sites and Dates
- 5.7 MDP Quarterly Sampling Schedules, Shipping Assignment Charts, and State Sampling Schedules

4. References:

- Sample Advisory Committee Meeting, December 2-4, 2008
- Sample Advisory Committee and Sampling Manager communications (email and telephone), January, February, and April 2008
- Sampling Managers' Conference Call, March 13, 2006
- PDP/MDP Federal/State Meeting, Denver, CO, September 27-29, 2005
- Program Plan, July-December, 2005
- Program Plan, January-June, 2005
- MDP Federal/State Meeting, Fairfax, VA, June 22-24, 2004
- Sampling Managers' Meeting, Kansas City, MO, October 21, 2003

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- MDP Public Meeting, Washington, DC, April 15, 2002
- Public Meeting, Washington, DC, January 10, 2002
- Program Plan, July-December 2002
- Program Plan, January-June, 2002
- Program Plan, April-September 2001
- MDP Federal/State Meeting, Tallahassee, Florida, January 10-11, 2001
- Pesticide Data Program (PDP) Semi-Annual Program Plan, January-June 2001
- PDP Federal/State Meeting, Dulles, Virginia, October 31-November 2, 2000
- PDP SOP, SAMP PROC-1, Sampling Plans and Documentation, June 1, 2000
- Workplan for MDP Pilot Study, August 25, 1999

5. Specific Procedures:

Designated samples shall represent a given number of units, volume, or weight of a specific commodity collected at an assigned site on an assigned date. Each commodity sample is unique in that its label and associated Sample Information Form (SIF) contain information indicating it is different from other samples of the same commodity in at least one of the following areas: collection State; collection date; collection site; lot number; and origin of grower, packer, or distributor.

5.1 Sample Availability

5.1.1 Sample collectors should make every effort to collect samples at the scheduled primary site. If it is determined that the commodity(ies) will not be available at the primary site, sample collectors should then choose an alternate site that is of similar size measurement as the primary site, if feasible. If it is determined that the commodity(ies) will not be available at the selected alternate site, the sample collector should notify the State Sampling Manager who will then make arrangements with the laboratory for a future make-up collection [Refer to MDP SAMP PROC-02, Section 5.2.5]. Proxy sites MAY occasionally be selected for those commodities approved in writing by the Monitoring Programs Office (MPO) – [Refer to Sections 5.1.4 through 5.1.6]

5.1.2 If the sample is collected at an alternate site, it is the sample collector's responsibility to include the primary (scheduled) site code on the sample identification label that is affixed to each individual sample. The sample collector is also responsible for entering this information on the electronic or paper Sample Information Form (SIF).

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5.1.3 It is desirable for States to call ahead to the scheduled sampling site up to one business day in advance of the assigned sampling date to inquire about the availability of the commodity(ies) to be sampled.

5.1.4 “Proxy sites” (retail stores or alternate sites that receive the product directly, in the distribution chain, from the primary or alternate site) may NOT be used for the collection of MDP samples. Exceptions include only those commodities that have been specially approved for proxy-site collection by MPO (examples: pre-bagged items such as spinach, lettuce, or lettuce mixes; alfalfa sprouts in clamshells). In these instances, the specified commodity may be collected at a proxy site (retail store or commodity grower facility) only under one of the following circumstances: (1) the sample is not available at any of the selected primary or alternate sites, (2) an emergency situation arises in which a commodity needs to quickly be resampled (it arrived at the laboratory in unacceptable condition or the sample was missing), or (3) as permitted on commodity Fact Sheets or through special notification by MPO.

5.1.5 Samples that have approval to be collected at proxy sites must be in their original carton/container and collected in the facility’s storage room. Loose samples shall not be collected from retail shelves because of the increased risk of contamination by the consumer. However, in cases where the commodity is in a sealed bag or container (one that the consumer cannot open without breaking a seal, label, or tape), the collector may make a selection from the store’s front shelf *if all necessary sample information can be verified*. Sample collectors shall ensure that all necessary tracking information on the sample is available and that it is correctly recorded on the SIF.

5.1.6 If a proxy site is used for the collection of samples, the sample collector must note the following information on the SIF: (1) the primary site code number and a “P”, shall be recorded on the SIF and on the sample identification label of the sample and (2) the name and address or name and store number of the proxy site shall be entered in the facility name field.

5.1.7 Personnel at the collection sites may randomly select a sample carton/container and have it available for the sampler to pick up at the site, only if a sampler is not provided access to the collection facility. Although many collection sites do not allow collectors access to the inside of their facilities, this collection method shall be an exception and shall be used only when necessary.

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5.1.8 If a sample collector calls ahead to have the product available upon arrival, the collector shall request that such product be stored in a refrigerated area until pick up.

5.2 State Sample Allocation

5.2.1 Each participating State shall be assigned a number of samples to collect per commodity each month. This number shall be determined by the Monitoring Programs Office (MPO) Program Administrative Director, in consultation with the USDA National Agricultural Statistics Service (NASS) statistician.

5.2.2 The assigned number of samples per month is based on State consumption/population. This number shall remain constant from month to month throughout the calendar year, unless otherwise indicated.

5.2.3 The State Sampling Manager may authorize the collection of single, double, or triple samples from each site until the required number of samples is obtained. If double or triple sampling is performed, the sample collector shall ensure that each sample is taken from a different grower, packer, or distributor. If a product with a different grower, packer, or distributor cannot be found (preferred selection), it is acceptable to sample a second product with a different lot number. When two or more samples are collected from the same site on the same day with these distinctions, differentiation shall be made between the samples by placing an "A," "B," or "C" in the Source ID Code box of the e-SIF and on the sample identification label. If special sampling or different labeling distinctions are requested by MPO, the sample collector will find instructions on individual commodity Fact Sheets. [Refer to Section 5.6.2 for further details on double or triple sampling.]

5.2.4 States performing MDP sample collection may be required to ship samples to one or more State or Federal laboratories for analysis. Specific information regarding such assignments is provided in the "MDP Sample Shipping Assignment Charts" (refer to Section 5.7).

5.3 State Sample Collectors List

5.3.1 Each participating State shall maintain a list of personnel involved in the collection of MDP samples. This list shall include the following:

- Name
- Assignment of sampling sites, cities, and geographical regions (if appropriate)

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- Whether the employee works on MPO full-time or part-time
- The estimated number of full-time equivalents (FTEs) used to fulfill the requirements of MDP sampling. This number shall include ALL aspects of sampling, i.e. sample collection, management of the program, tracking samples, clerical duties, etc.

5.3.2 MPO shall be notified of changes to the sample collectors' information or FTEs as they occur.

5.4 Master List of Sampling Sites

5.4.1 Each State participating in MDP sample collection shall use its Pesticide Data Program (PDP) master list of sampling sites for MDP sample site selection. If a State does not have a PDP program, that State shall be responsible for developing and maintaining a master site list that includes all MDP collection sites. The MDP Master List of Sampling Sites for each State shall be set up with the approval of the NASS statistician.

5.4.2 The master site list shall include the following information for each sampling site:

- Site code
- Region or other geographical division (if applicable)
- Facility name and mailing address
- Date of inclusion or date of deletion from the site list, when known, clearly marked as such [Refer to Section 5.4.13 and 5.4.14 for requirements on the recording of new and deleted sites.]
- Type of facility (e.g., terminal market, distribution center, retail/wholesale market, etc.)
- Relative volume information (Refer to Section 5.5 for method of calculation)

5.4.3 The number of collection sites for each commodity will vary from State to State, and specific guidance on whether to include particular sites will be available from the MPO Sampling Manager and NASS statistician on a case-by-case basis. A State's internal SOPs shall explain the basic criteria used to determine which sites to exclude.

5.4.4 Small, remote sampling sites that are too expensive or difficult to access to collect a sample may be deleted from the State's sampling site by the State Sampling Manager. However, the State Sampling Manager shall notify the MPO Sampling Manager, or designee, and the NASS statistician of such change.

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5.4.5 For all types of sampling facilities, States shall assign each site a unique numerical reference code per MPO instructions. At terminal market locations, each vendor will be assigned a unique site code. This "site code" will be included as part of the sample's permanent identification number.

5.4.6 If site codes are assigned based on a particular organizational structure, rather than random numerical or alphabetical order, this numbering system shall be easily identifiable on the site list. For example, a State may divide its sites into geographical regions and assign the site codes accordingly (e.g., 100's for Region 1, 200's for Region 2, etc.).

5.4.7 Changes to the master site list shall be made as they occur. Information on site changes shall be provided to both the MPO Sampling Manager, or designee, and the NASS statistician. NASS must be aware that sites have been deleted or made inactive so that they are removed from the quarterly selection process. Likewise, if new sites are added or previous sites are reinstated as active, the MPO Sampling Manager, or designee, and the NASS statistician shall be notified as soon as possible because these sites should be included in the routine site selection process. If a State selects sites for sampling from its own Master Site List, notification of changes need only be reported to MPO as they occur.

5.4.8 MPO shall be responsible for updating the MDP database to reflect sampling site changes as they occur. MPO will send the State Sampling Manager an updated site look-up table for distribution to his/her sample collectors for import into their RDE electronic SIF system on handheld/laptop computers when new sites are added.

5.4.9 Periodically, MPO shall provide State Sampling Managers with a printout of their State's master site list, which will also include the codes for the collection sites, type of commodities sampled at each site (i.e., canned/frozen/fresh fruit and vegetables), and relative site size measures (refer to Section 5.5). The State Sampling Managers will be responsible for comparing the database printouts with their records to detect any discrepancies, and send revisions to the MPO Sampling Manager, or designee. MPO will make corrections, as needed, to update the information and prepare it for downloading by the RDE contact.

5.4.10 Site codes shall be assigned only once. If the physical location and facility remains the same (only the name changes) the site may retain the original site number. The old and new name should be shown on the master site list for referencing samples collected prior to the name change.

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5.4.11 If the site name remains the same, but the physical location of the facility is moved to a new address, a decision on the assignment of the original or a new site code will be made by the MPO Sampling Manager in consultation with NASS on a case-by-case basis.

5.4.12 If a site has been deleted from active sampling, and is later reinstated, it must retain the same site number as before.

5.4.13 Additions to a master site list shall be given a new number never used before, with the date of addition provided. When locations are added to a master site list, *each new location's corresponding relative volume information shall also be provided.* The revised master site list and annual volume information shall be included with the Quarterly Sampling Plan when it is provided to NASS.

5.4.14 Deleted sites must remain on the master list, but shall be marked through with a single line and dated to signify they are no longer included in active sampling. Deleted sites may become "active" again later if appropriate. The site code, and all other information pertaining to a deleted site, shall remain on the master site list for future reference. The reason for deleting the site (i.e., no longer carries commodities needed, no longer wishes to participate in the program, occasionally denies access, etc.) shall be provided in a cover memorandum.

5.5 Relative Volume Information for Sampling Sites

5.5.1 Each State shall provide comparative volume information (quantity of the produce distributed compared to other sites) for each of the sampling sites on its master site list. The State, in collaboration with the NASS statistician, will determine the "size measure" (comparative volume number) for the random selection of the sites. It is very important that States keep the NASS statistician up-to-date on any changes in the sites that will affect the size measure. *These measures must be reviewed and updated as changes occur.* If the State Sampling Manager encounters any problems in obtaining this volume information, he/she should inform the MPO Sampling Manager or the NASS statistician. It is the responsibility of the State to provide comparative volume information on its Master site List and to update it with MPO and the NASS statistician as changes occur.

5.5.2 The size measures shall be the basis of random site selection. For example, on a scale of 1 to 10, a site distributing 100,000 pounds of produce may be given a size measure of 10, whereas a site distributing 10,000 pounds of produce may be given a size measure of 1. The site with a site

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measure of “10” will then be ten times more likely to be selected during any one month than the site with a measure of “1.”

5.5.3 Internal SOPs for each State shall explain how the size measures were determined. States have the option, if they desire, of using the services of the NASS statistician to perform the quarterly site selection for them. If a State chooses to select their own sites, they shall confer with the NASS statistician to determine the statistically defensible method to use.

5.5.4 Size measures shall be included on the master site list or on a separate document and provided to MPO. Sample collectors should also have this information with them in the field to aid them in making alternate site selections that are closely equivalent in size to the primary site.

5.6 Quarterly Selection of Sampling Sites and Dates

5.6.1 Sampling Sites for Commodities:

5.6.1.1 Collection sites for MDP samples will be as close to the point of consumption as possible.

5.6.1.2 Sites shall be chosen for the entire quarter. Afterwards, they may be separated into three distinct subsets of equal size at the convenience of the State (e.g., based on geographical location). The three groups may then be randomly assigned in a one-to-one manner to each of the three months in the quarter. Alternatively, the NASS statistician will randomly assign selected sites to months (this list may be the same that is used for the Pesticide Data Program). For every month in a quarter a commodity is double sampled, the number of subsets is increased by one. When there is triple sampling, the number of subsets is increased by two.

5.6.1.3 Each participating State has the option of seeking advice and/or assistance from the NASS statistician regarding the quarterly site selection process. Even if a State chooses to perform its own quarterly site selection, the NASS statistician should be provided with all relevant information regarding the site selection process for his/her approval.

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5.6.1.4 No site, regardless of its size measure, shall have more than two samples of each commodity collected from the same site in a given month. Exceptions will be approved by MPO and the State Sampling Managers.

5.6.1.5 States should make every reasonable effort to ensure that the assigned number of samples is collected. Good communication between the sample collectors and their Sampling Managers, as well as between the State Sampling Managers and the laboratories is essential for detecting and correcting problems with missing, unavailable, or damaged samples. State Sampling Managers are encouraged to request assistance from MPO, if needed, to facilitate this process.

5.6.1.6 The selection of an alternate site number shall be totally objective in nature, with no pre-determination made regarding the date of last sampling, variety of commodity available, etc.

5.6.1.7 When more than one commodity is scheduled for sampling at the same site on the same date, all may be sampled from the primary or an alternate site/vendor, based on availability. All do NOT have to be sampled at the same site.

5.6.1.8 If the alternate site/vendor also does not have the commodity(ies) needed, the sample collector may procure samples from another site of similar size as long as the site has not been sampled for the same commodity during the sample selection period (usually a month, but this can be a fraction of a month when the product is scheduled for double or triple sampling).

5.6.1.9 For primary and alternate site sample collection procedures, sample collectors should refer to MDP SAMP-PROC-02, Section 5.4, Sampling Procedures for Fresh Commodities.

5.6.2 Double or Triple Sampling

5.6.2.1 Double or triple sampling refers to extra samples collected during a specified period of time in an emergency situation [refer to MDP SAMP PROC-05] or to make up for times (most likely, seasons) when certain commodities are unavailable and therefore are unable to be collected. Extra sampling will generally occur during a commodity's peak availability months.

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5.6.2.2 Double or triple sampling must be approved by MPO and NASS statistician, and coordinated with the laboratory(ies) receiving the samples.

5.6.2.3 Double sampling is defined as the collection of twice the assigned monthly number of samples per commodity; for example, double sampling of a commodity for Florida, currently collecting 7 samples per month, would entail the collection of 14 samples for that commodity that month.

5.6.2.4 Triple sampling is defined as the collection of three times the assigned monthly number of samples per commodity; for example, triple sampling of a commodity for Michigan, currently collecting 6 samples per month, would entail the collection of 18 samples for that commodity that month.

5.6.2.5 Double or triple sampling shall be conducted during the entire designated collection time period unless otherwise directed by MPO.

5.6.2.6 Each extra sample shall be collected at a different site OR on a different day than the regularly collected sample of the same commodity. *More than one sample must not be collected from the same site on the same day.* [Refer to Section 5.2.3 for exceptions].

5.6.2.7 Extra samples may be collected at proxy sites only as specified on a commodity's Fact Sheet. A proxy site for a particular distribution center will be considered a completely different site than the primary distribution center site.

5.6.2.8 The sample collector shall ensure that all requested sample information is recorded correctly on the Sample Information Form. Omission of pertinent data may void the extra sample and resampling may be required.

5.6.3 Sampling Dates for Commodities:

5.6.3.1 The MPO Sampling Manager, or designee, will assist in the coordination between the State Sampling Managers and laboratories to agree on the selection of specific sampling weeks for the collection of the assigned number of samples per commodity. When

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coordinating sampling weeks, each participant must also be made aware of any Federal or State holidays or other days when samples cannot be received at the laboratory.

5.6.3.2 States may "group" more than one commodity for collection on the same day at the same site.

5.6.3.3 States that collect samples, but have their analyses performed by one or more other laboratory facilities, shall ensure that they adhere to the same schedule as other States shipping the same commodity to that laboratory, unless approved in advance by the receiving laboratory(ies).

5.6.3.4 State Sampling Managers and laboratories shall agree between them upon sampling dates by the 1st of the month prior to the start of the next quarter. This collaboration will allow the States time to finalize their sampling schedules and post them to MPO's Extranet site by the 15th of the month prior to the beginning of the next quarter. [Refer to Section 5.4.7 for notification for States that select sites from their own Master Site List.]

5.6.3.5 Samples must be collected on a Monday of the specified collection week and shipped the same day as collection for delivery at the receiving laboratory on Tuesday. Exceptions to this schedule must first be approved by the receiving laboratory.

5.6.3.6 Collected samples must not be mailed the day before a Federal or State holiday. However, States that "hand" deliver samples directly to the laboratory may arrive the day before a holiday if prior arrangements have been made with the laboratory.

5.6.3.7 Additional information regarding sample collection, packaging, and shipping will be provided in writing by the MPO Sampling Manager, or designee, 30 days prior to the beginning of the next quarter.

5.7 Quarterly Sampling Schedules, Fact Sheets, Laboratory Mailing Addresses, and Shipping Assignment Charts

5.7.1 Forty-five (45) days prior to the beginning of each new quarter, the MPO Sampling Manager, or designee, will provide State Sampling Managers and Laboratory Directors with a draft of the proposed MDP Quarterly Sampling Schedule, new Fact Sheets (when applicable), laboratory mailing

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addresses, and Shipping Assignment Chart for commodities to be collected in the new quarter. State Sampling Managers and Laboratory Directors will review the documents through communication with each other and offer comments to the MPO Sampling Manager, or designee, within 2 weeks of receipt of the documents. The final MDP Quarterly Sampling Schedule, new Fact Sheets, laboratory mailing addresses, and Shipping Assignment Chart will be distributed 30 days prior to the beginning of the new quarter

5.7.2 The Shipping Assignment Chart is updated quarterly to reflect program changes, and is provided to the State Sampling Manager for distribution to the sample collectors. The Shipping Assignment Chart indicates the sample amounts required by the MPO Program Administrative Director, not those required by the State. If a State has specific needs other than those shown on the Shipping Assignment Chart, the State Sampling Manager may choose to create a smaller, individualized chart for his/her particular State.

5.7.3 State Sampling Managers shall post final copies of their monthly schedules onto MPO's Extranet site two weeks prior to the beginning of each new quarter. MPO's Sampling Manager shall post final copies of all sampling documents to the Extranet site three weeks prior to the beginning of the new quarter. MPO's Sampling Manager shall ensure that MPO-posted documents are updated on the Extranet site as changes occur.

5.7.4 The State Sampling Schedule shall be divided into the three months of the quarter.

5.7.5 Each month's schedule shall include at least the following information:

- Sampling dates and commodity(ies) to be sampled
- Primary site numbers for each commodity
- Alternate site numbers where applicable

5.7.6 State Sampling Schedules should never include any sites known to be inactive or that have declined participation in the program. For these reasons, site lists need to be kept current and the MPO Sampling Manager, or designee, and NASS statistician informed of any changes [refer to Section 5.4.7 for notification for States that select sites from their own Master Site List].

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Revision 3

- Updated references in Section 4.
- Updated revision number and effective date.
- Added sample definition to Section 5.1.
- Added in Section 5.1 that collectors may use proxy sites for the selection of some MDP commodities when approved by MPO.
- Added in Section 5.1 that collectors may make a sample selection from the store's front shelf if the commodity is in a sealed container and all necessary sample information can be verified.
- Instructions added for sampling at proxy sites.
- Sections 5.2 and 5.6 further explain double and triple sampling procedures, when needed.
- Changes in sample collector information (additions, FTEs, etc.) shall be made to MPO as they occur, not quarterly.
- As stated in Section 5.4 (e), terminal market vendors will have unique site code numbers.
- In Section 5.5, relative volume changes sent to MDP and NASS as they occur, not by a particular date.
- Sampling Managers shall post completed schedules on Extranet in lieu of mailing them to MPO and labs.
- Enhanced clarifications by word changes in many sections.
- Made formatting changes.