



USDA Microbiological Data Program

Public Meeting
January 10, 2002
Washington, D.C.



Outline

- Background
- Objectives
- Participating States
- Sampling System
- Laboratory Operations
- QA/QC Program
- Data Review and Reporting
- Summary



Background

- FY 2001: Agriculture Appropriations Bill provided \$6.23 million for establishment of the Microbiological Data Program (MDP).
- USDA Agricultural Marketing Service (AMS) is charged with development and implementation of MDP
- FY 2002: Agriculture Appropriations Bill provides \$6.23 million for continuation of MDP



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FY 2002 Congressional Language

“Conferees expect the Microbiological Data Program to produce national, consistent, and statistically reliable data that may be used for research and risk analysis purposes by federal agencies such as USDA, FDA, and CDC, state health departments, researchers, and other stakeholders. AMS is encouraged to contract for the data collection with organizations that have demonstrated research and technical competence, and that are not barred by statute from administering a blind microbiological survey program for fruits and vegetables. Expects AMS to hold a public meeting, within 60 days of enactment, to present a detailed data collection proposal and seek input from all interested parties.”



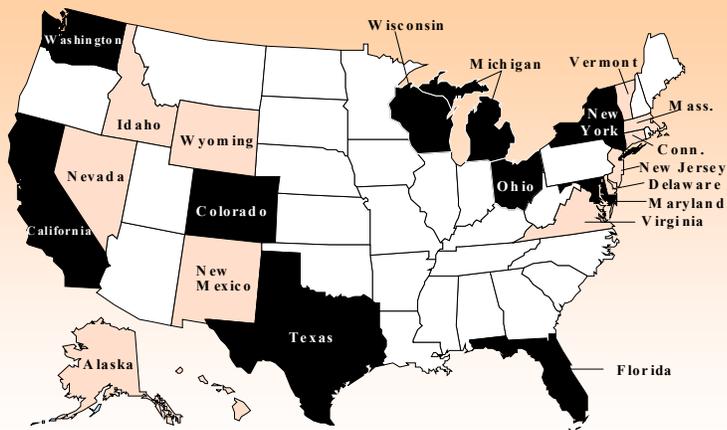
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Objectives

- Provide comprehensive data on pathogens and indicator organisms on fresh fruits and vegetables in the United States
- Establish benchmark data for Federal Agencies, State Public Health Agencies, industry, and other interested parties to assess potentially harmful foodborne microorganisms
- Provide uniform procedures for sampling, testing, and reporting



MDP Participating States



■ MDP States
■ Distribution Areas





MDP Sampling System

- Collect fresh fruit and vegetables
 - Distribution Centers and Terminal Markets
- Comprehensive, Reliable, and Objective
- Random collection without bias toward origin or crop variety (except for special surveys)
- Standard Operating Procedures
- Product collected while in commerce

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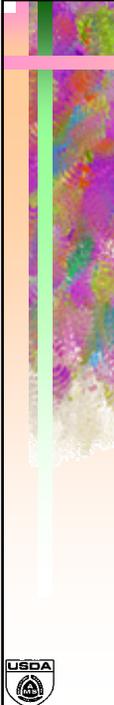


MDP Sampling System

- Blind samples, as per Congressional language
- Number of sites apportioned by state population

California-14	Colorado-2	Florida-7
Maryland-4	Michigan-6	New York-9,
Ohio-6	Texas-8	Washington-4
Wisconsin-2		
- May adjust the sample framework to compensate for seasonality
- Random sampling without bias toward national or state origin or crop variety.

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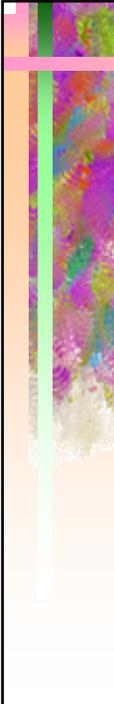


MDP Sampling System

- States provide annual volume information for each site
- USDA National Agricultural Statistics Service (NASS) “weight” sites using volume figures to determine the probability for selection
- Larger sites more likely to be selected than smaller sites



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MDP Sampling System

- Annual volume information is used to “weight” the site to determine the probability for selection. For example, a weight of “10” may be given to a site that distributes 100,000 pounds of produce annually and a weight of “1” may be given to a site that distributes 10,000 pounds of produce.
- The probability- proportionate-to-size method of site selection then results in the larger site (distributing 100,000 pounds) being 10 times more likely to be selected for sampling than the smaller site (distributing 10,000 pounds).

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MDP Sampling System

Sample Collection:

- Participating State agencies are responsible for compiling and maintaining lists of sampling sites.
- States are required to provide AMS and USDA's NASS with annual site volume information.
- Over 570 sites in the system.
- States randomly assign various weeks of the month for commodity collection.

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MDP Sampling System

- Standard Operating Procedures
 - Criteria for site selection
 - Specific instructions for collection, shipping, handling
 - Documented chain of custody
- Performed by trained State inspectors
- Aseptic techniques (e.g., sterile latex gloves, sterile bags)
- Temperature controls (at time of collection, refrigeration during shipment, on arrival)
- Post-harvest treatments (e.g., irradiation, chlorinated water, ozone) noted



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MDP Sampling System

Collection Schedule

- 62 site samples/month/commodity
 - One (1) site sample equals three (3) sub-samples
 - 186 Sub-samples/commodity/month (2,232/commodity/year)
 - Maximum target 744 site samples per year
- April 2001: Romaine Lettuce, Leaf Lettuce
- June 2001: Tomatoes (Domestic and Imported)
- October 2001: Celery
- April 2002: Cantaloupe



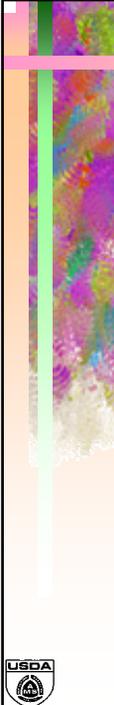
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MDP Sampling System

- MDP may adjust the sample collection framework (weighted sampling scheme) to compensate for commodity seasonality.
- Certain commodities may be collected at one-half, single, or double the routine monthly rate to reflect market availability.
- System more accurately mirrors U.S. changes in consumption patterns based on commodity availability.

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Laboratory Operations

Microorganisms to be Isolated

- *Escherichia coli* (generic)
 - Most probable number (MPN)
 - Cultural methodology
- *Salmonella*
 - Positive/negative
 - Enzyme Linked Fluorescent Immunoassay methodology (bioMerieux, VIDAS screen)
 - Cultural confirmation



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Laboratory Operations

Microorganisms to be Isolated

- *Shigella* – Spring/Summer 2002
 - Positive/negative
 - Polymerase chain reaction (PCR) methodology
 - Food and Drug Administration methodology



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Laboratory Operations

Disposition of Isolates

Escherichia coli

- Tested for antibiotic resistance
 - Agricultural Research Service (ARS) Laboratory
- Tested for serotypes (antigen/antibody classification system)
 - Pennsylvania State University
- Inclusion in stock culture collection
 - AMS Laboratory
- Detection of pathogenic serotypes NOT 0157:H7
 - AMS Laboratory [with guidance from the Centers for Disease Control (CDC)]



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Laboratory Operations

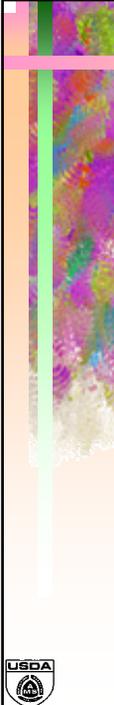
Disposition of Isolates

Salmonella

- Tested for antibiotic resistance
 - ARS laboratory
- Tested for serotype
 - ARS laboratory/Animal Plant Health Inspection Service laboratory
- Inclusion in stock culture collection
 - AMS laboratory



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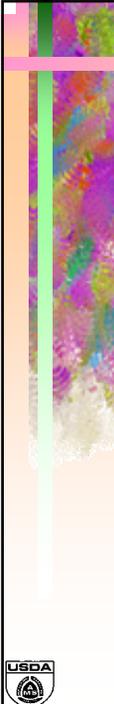
Laboratory Operations Disposition of Isolates

Shigella

- Preservation of wash solution
 - AMS Laboratory
 - Present methodology does not provide for the isolation of the organism, only indicates presence or absence. When a method is found to reliably isolate the organism, the preserved wash solutions will be used as the source for the organisms
- Cultures preserved in the stock culture collection will be available to researchers for further study



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QA/QC Program

- Standard Operating Procedures
- Method Validation Protocols
- Participation in Check Sample Program
- Laboratory Quality Assurance Officer (QAO)
- Data Review and Reporting



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QA/QC Program

Standard Operating Procedures

Sampling

- Sampling Plans and Documentation
- MDP Sampling Procedures on Site
- Packing and Shipment of MDP Samples
- Chain of Custody for MDP Samples

Laboratory Operations

- Infrared Thermometer Use
- Sample Wash Procedures
- Microbiological Media
- Shipping Microbiological Cultures

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QA/QC Program

Standard Operating Procedures

Analytical Methods

- Escherichia coli* MPN Method
- Salmonella* VIDAS Method
- Salmonella* Cultural Method

Data Handling and Reporting

- Microbiological Data and Results Reporting

Quality Assurance

- Laboratory Practices and Equipment
- Preventive Maintenance
- Proficiency Test Samples

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QA/QC Program

Method Validation Protocol

- All MDP laboratories to use the same methods
- Minimum of 3 laboratories to validate method before MDP acceptance
- SOP will be written after appropriate validation of a new method
- Side-by-side comparison of method to standard cultural method in each laboratory



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QA/QC Program

Participation in Check Sample Program

- Proficiency test samples will be prepared using microorganisms with markers by the QA section of the AMS Eastern Laboratory
- Proficiency test samples will be sent to each MDP laboratory twice a year
- Results will be reviewed by MDP headquarters staff



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QA/QC Program

Laboratory Quality Assurance Officer (QAO)

- Each laboratory will designate a QAO to be responsible for compliance with program requirements
- QAO is independent and not involved in laboratory analyses
- QAO duties include
 - Ensuring that internal SOPs are developed for daily operations
 - Monitoring laboratory operations for QA/QC compliance and taking corrective actions when needed
 - Ensuring documentation is maintained and current



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Data Review and Reporting

Sample Collection



- 10 Collection States
- 570 sites

Laboratory Analysis



- Laboratories: 8 States + 1 Federal (USDA)

Lab Remote Data Entry



- Custom RDE software
- Electronic transmit

Data Receipt at HQ



- Received via Internet

Data Review



- Microbiologist Review

Data Reporting



- Data Reconciliation



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Data Review and Reporting

- Data requests will be provided to data users
 - Federal Agencies
 - State Agencies
 - Grower Groups
 - Consumer Groups
 - Consulting Firms
 - Academia
 - Media
- FDA to receive data quarterly
- Condensed database will be available on MDP website
 - <http://www.ams.usda.gov/science/mpo/mdp.htm>



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Summary

- Enhance government's ability to respond to food safety issues.
- Provide year round comprehensive data on pathogens and indicator organisms for development of risk assessment models
- Establish benchmark data to assess occurrence of potentially harmful foodborne microorganisms



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