

U.S. Department of Agriculture

Agricultural Marketing Service

Microbiological Data Program

Public Meeting Notes<sup>1</sup>

January 10, 2002

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<sup>1</sup> Based on transcript of meeting, which is available on request.

## **OPENING**

Dr. Robert Epstein, Deputy Administrator, Science and Technology (S&T), Agricultural Marketing Service (AMS), United States Department of Agriculture (USDA), welcomed everyone to the Microbiological Data Program (MDP) public meeting and thanked attendees for taking time from their busy schedules to join the meeting. A number of documents related to this meeting are provided as handouts and are available on the AMS Internet website at [www.ams.usda.gov/science/mpo/publicmeeting.htm](http://www.ams.usda.gov/science/mpo/publicmeeting.htm). These documents include the meeting agenda, a quick fact sheet, a sampling overview, and Dr. Epstein's presentation. Comments or input regarding the program may be submitted through the close of business, January 22, 2002. Due to the current mail situation, it is advisable to fax (202-720-6496) or e-mail ([Robert.Epstein@usda.gov](mailto:Robert.Epstein@usda.gov)) comments.

Guests from other Federal agencies/departments were introduced: Phil Kott, USDA, National Agricultural Statistics Service (NASS); Dr. Nega Beru, Food and Drug Administration (FDA), and Dr. Colleen Crowe, Centers for Disease Control and Prevention (CDC).

## **REMARKS**

### **A.J. YATES, ADMINISTRATOR, AMS, USDA**

Mr. A.J. Yates, current AMS Administrator and former Deputy Secretary of California Department of Food and Agriculture, was introduced. Mr. Yates thanked everyone for attending the public meeting and explained that the primary purpose for this meeting is to outline the plans for implementing MDP and to provide an opportunity for feedback on how AMS can make this a successful program. Mr. Yates noted that agriculture produces not only a bountiful supply of commodities, but also a quality product; however, over the last number of years the incidence of foodborne illnesses has risen. In response, Congress funded a monitoring program for foodborne pathogens and indicator organisms on domestic and imported fruits and vegetables. AMS has worked with CDC, FDA, USDA/NASS, State Departments of Agriculture, industry, and academia to formulate the best program possible to ensure the safety of the American food supply.

MDP is designed to collect statistically reliable data in order to develop national estimates of bacterial contamination with regard to selected produce. MDP is a data gathering program, rather than a regulatory or enforcement program. MDP is expected to provide an understanding of the microbial ecology of fresh fruits and vegetables and to identify trends. The information collected is expected to provide a more substantive basis for risk assessment, as well as consideration of any policy designed to improve the safety of produce in the United States.

## **OVERVIEW OF USDA MICROBIOLOGICAL DATA PROGRAM**

### **DR. ROBERT EPSTEIN, DEPUTY ADMINISTRATOR, SCIENCE & TECHNOLOGY, AMS, USDA**

This presentation covers the following areas: program background and objectives, participating States, sampling system, laboratory operations, quality assurance (QA)/quality control (QC)

program, data review and reporting, and a summary. The complete presentation may be accessed at the AMS internet website previously specified.

In fiscal year 2001, the Agriculture Appropriations Bill provided 6.23 million dollars for the establishment of MDP, with the intent that funds be shared with participating States. AMS was charged with the implementation and development of the program as a baseline survey. In fiscal year 2002, an equivalent amount of money was provided to continue this survey for pathogens and indicator organisms in the food supply. However, additional language was inserted in the 2002 appropriation and reads as follows:

“Conferees expect the Microbiological Data Program to produce national, consistent, and statically 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.”

AMS is very interested in public input regarding the program. MDP has been designed as a fluid program, amenable to change with appropriate notice, and operation principles can be amended to provide more meaningful data over time.

Program objectives are to provide comprehensive data on pathogens and indicator organisms in fresh fruits and vegetables in the United States and to establish benchmark data for Federal Agencies, State Public Health Agencies, industry, and other interested parties to assess potentially harmful foodborne microorganisms. AMS is acting as a data collection agency, with other agencies/departments responsible for formulating and conducting policy. Uniform procedures for sampling, testing, and reporting are in place to ensure data integrity and procedures are in place to institute any corrective actions necessary.

Participating States include: New York, Maryland, Florida, Ohio, Michigan, Wisconsin, Texas, Colorado, Washington, and California. These States represent all regions of the country and approximately 50% of the population. Shaded areas on the map shown in this presentation indicate distribution areas for participating States. For example, New York distributes substantial product to western New England, Maryland to Delaware and northern Virginia, and Colorado to Wyoming and New Mexico. California distributes to Nevada and Hawaii and Washington to Alaska, so that the participating States are also representative of areas beyond their borders. In other monitoring programs, we have observed that the product collected in the 10 participating States is not significantly different from product available in the marketplace in other States, making it unnecessary to sample from all 50 States.

Fresh fruit and vegetable samples are collected at distribution centers and terminal markets at the wholesale level, just before distribution to the consumer. The system is designed to be comprehensive, reliable, and objective. Samples are randomly collected, without bias toward

origin or crop variety, except for special surveys where it may be important to do so - for example, in the case of high seasonality, differentiation between national and foreign produce or foreign produce from certain parts of the world may be desirable.

Standard operating procedures (SOPs) for sampling are in place and used by all participating States. Product is collected while in commerce and samples are collected blind, per Congressional language. Blind is defined as no collection of information regarding grower, packer, or distributor. Information regarding State/country of origin, however, is collected if available, although it is understood that there may be re-labeling in certain circumstances.

The number of monthly collection sites are apportioned by State population: California -14, Colorado – 2, Florida – 7, Maryland – 4, Michigan – 6, New York – 9, Ohio – 6, Texas – 8, Washington – 4, and Wisconsin -2, for a total of 62 site samples per month. States provide annual volume information for each site, which is used by NASS to “weight” sites to determine probability of selection. Larger sites are more likely to be selected than smaller sites. This framework may be adjusted on a commodity basis to compensate for seasonality. There are currently 574 sites in the sampling system across the 10 states. The participating State agencies are responsible for compiling and maintaining lists of sampling sites. States randomly assign various weeks of the month for commodity collection.

Sample collections are performed by trained State inspectors utilizing aseptic techniques (e.g., sterile latex gloves, sterile bags). Samples are shipped in insulated containers with cold packs and temperature controls at time of collection and on arrival at the laboratory are in place – the target is less than or equal to 15 degrees Celsius to prevent additional growth of any organisms present. Any post-harvest treatments, such as irradiation, chlorination, or ozone treatments, are noted on the sampling form and documented chain of custody procedures are in place.

The collection schedule specifies 62 site samples per month per commodity. One site sample equals three sub-samples – three individual samples are taken at each site, for a total of 186 sub-samples per commodity per month, or 2,232 commodity sub-samples per year. The maximum target for site samples is 744 per year. A recently published article detailed a new European Union risk assessment program which uses a similar approach to mimic product availability to the consumer.

Practice samples for MDP were collected and analyzed during 2001, beginning with romaine and leaf lettuce in April 2001. Tomatoes (domestic/imported) were added in June 2001 and celery in October 2001. Cantaloupe is planned for April 2002 addition based on comments received from various groups.

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. This system more accurately mirrors U.S. changes in consumption patterns based on commodity availability. A detailed sampling rationale is available in the Sampling Overview, located on the previously mentioned website.

The microorganisms intended for isolation are: generic *E. coli*, quantitatively, using Most Probable Number (MPN), with cultural methodology utilized for verification and *Salmonella* (positive/negative) by Enzyme Linked Fluorescent Immunoassay methodology (bioMerieux, VIDAS screen) and cultural confirmation. *Shigella* is planned for addition during spring/summer 2002 and will be performed on a positive/negative basis using polymerase chain reaction (PCR) methodology developed by FDA.

*E. coli* isolates are sent to an Agricultural Research Service (ARS) laboratory for antibiotic resistance testing and to Pennsylvania State University for serotyping (antigen/antibody classification system). Additionally, these isolates are maintained in a stock culture collection at the AMS Eastern Laboratory, where detection of pathogenic serotypes (not O157:H7) is performed with guidance from CDC. *Salmonella* isolates are also sent to ARS for antibiotic resistance testing and to ARS/Animal and Plant Health Inspection Service laboratories for serotyping. An isolate is also included in the AMS Eastern Laboratory stock culture collection. *Shigella* isolates will require preservation of the wash solution. Present methodology does not provide for isolation of the organism, only indicates presence or absence. If and when a method is found to reliably isolate the organism, the preserved wash solutions will be used as a source for the organisms. These pathogens are poor competitors and it is anticipated that cultures preserved in the stock culture collection will be available to researchers for further study.

The QA/QC program includes five components: SOPs; method validation protocols; participation in the check sample program; laboratory quality assurance officer (QAO) requirements (must be independent from direct laboratory management); and data review and reporting. SOPs are living documents, meant to be changed and amended accordingly with appropriate documentation and archived. Sampling SOPs include: Sampling Plans and Documentation; MDP Sampling Procedures on Site; Packing and Shipment of MDP samples; Chain of Custody for MDP Samples; and Infrared (IR) Thermometer Use (to document temperature both at sampling and receipt in the laboratory). Laboratory Operations SOPs include: Sample Wash Procedures; Microbiological Media; and Shipping Microbiological Cultures. Analytical method SOPs include: *E. coli* MPN Method; *Salmonella* VIDAS Method; and *Salmonella* Cultural Method. Data handling and reporting and QA SOPs include: Microbiological Data and Results Reporting; Laboratory Practices and Equipment Preventative Maintenance; and Proficiency Testing Samples.

For the method validation protocol, all laboratories use the same methods and a minimum of three laboratories is required to validate methods prior to acceptance. Following appropriate validation of a new method, an SOP is written specifying all method procedures. For additional laboratories to adopt the methods, side-by-side comparisons with the present methodology must be performed. Initial triplicate validations provide the assurance that the techniques used are viable for adoption and use by other laboratories. For proficiency testing, samples will be prepared by the QA section of the AMS Eastern Laboratory using microorganisms with markers. Test samples are planned for a minimum of twice per year, with results reviewed by MDP headquarters staff. Any deficiencies will initiate immediate corrective action.

Each laboratory will designate a QAO responsible for compliance with program requirements. The QAO must be independent from and not directly involved with laboratory analysis. Other QAO duties include: ensuring that internal SOPs are developed for daily operations; monitoring laboratory operations for QA/QC compliance; ensuring that corrective actions are instituted when needed; and ensuring that documentation is maintained and current.

An electronic data reporting system, remote data entry (RDE), is in place and used by each reporting laboratory. Encrypted results are transmitted electronically to MDP headquarters, where they are received via internet. Staff microbiologists review the data prior to upload to the central database. Once the data is uploaded to the central database, data reconciliation procedures are performed to further ensure data integrity.

Data requests are provided to users including: Federal Agencies, State Agencies, grower groups, consumer groups, consulting firms, academia, and media. FDA will receive all data quarterly. The condensed database will be available on the MDP website, <http://www.ams.usda.gov/science/mpo/mdp.htm>

In summary, we hope to enhance, with your input and guidance, the government's responsibility and ability to respond to food safety issues, to provide year round comprehensive data on pathogens and indicator organisms for development of risk assessment models, and to establish benchmark data to assess occurrence of potentially harmful foodborne microorganisms.

**FDA'S IMPORTED AND DOMESTIC SURVEY: NEED FOR DATA ON INCIDENCE OF MICROBIAL CONTAMINATION**

**DR. NEGA BERU, DIRECTOR, DIVISION OF PLANT PRODUCT SAFETY, OFFICE OF PLANT AND DAIRY FOODS AND BEVERAGES, CFSAN, FDA**

Dr. Beru provided an overview of FDA's microbiological surveys of imported and domestic foods. The complete presentation may be accessed at the previously specified AMS Internet website.

**SPROUTS, SALADS AND CIDERS: THE GROWING CHALLENGE OF FRESH PRODUCE-ASSOCIATED FOODBORNE INFECTIONS**

**COLLEEN CROWE, FOODBORNE AND DIARRHEAL DISEASES BRANCH, CENTERS FOR DISEASE CONTROL AND PREVENTION**

Ms. Crowe gave an overview of fresh produce associated outbreaks from CDC's perspective. The complete presentation, including notes, may be accessed at the previously specified AMS Internet website.

**COMMENTS**

**DR. DONNA GARREN, VICE-PRESIDENT FOR SCIENTIFIC AFFAIRS, UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION (UFFVA)**

Dr. Garren provided comments regarding MDP on behalf of the United Fresh Fruit and Vegetable Association. These comments may be accessed at the previously specified AMS Internet website.

**MDP – A PERSPECTIVE FROM THE STATE OF FLORIDA**

**DR. JOANNE BROWN, DIRECTOR, MICROBIOLOGY LABORATORY, FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES**

Dr. Brown provided comments regarding MDP on behalf of the Florida Department of Agriculture and Consumer Services. These comments may be accessed at the previously specified AMS Internet website.

**COMMENTS**

**DR. EDITH GARRETT, PRESIDENT, INTERNATIONAL FRESH-CUT PRODUCE ASSOCIATION (IFPA)**

Dr. Garrett provided comments regarding MDP on behalf of the International Fresh-Cut Produce Association. These comments may be accessed at the previously specified AMS Internet website.

## **MDP – A PERSPECTIVE FROM THE STATE OF OHIO**

**DR. PHIL ENGLER, DIRECTOR, CONSUMER ANALYTICAL LABORATORY, OHIO DEPARTMENT OF AGRICULTURE**

Dr. Engler provided comments regarding MDP on behalf of the Ohio Department of Agriculture. These comments may be accessed at the previously specified AMS Internet website.

## **COMMENTS**

**DR. NANCY NAGLE, FOOD SAFETY ADVISOR, CALIFORNIA STRAWBERRY COMMISSION**

Dr. Nagle provided comments regarding MDP on behalf of the California Strawberry Commission. These comments may be accessed at the previously specified AMS Internet website.

## **QUESTION AND ANSWER SESSION**

If a policy/procedure is already established, we will answer your questions to the best of our ability. If the questions require further consultation with FDA/CDC/NASS, answers will be provided on the Internet. Certain questions may not be able to be answered because they are philosophical in nature and are beyond the congressionally mandated mission and scope of this program. We are required to collect baseline data – we're not the risk assessors and we're not the risk managers. We are required to collect samples blind, so we are not capturing information regarding grower, packer, or distributor. For baseline surveys, this information is not strictly required, although for trace back or epidemiology issues, it might be a relevant factor. For questions or comments, please identify yourself so that we can correctly capture the questions/comments and those on the telephone can hear us.

**Question/issue:** Appropriateness of point of sampling - distribution centers/warehouses rather than elsewhere along the food chain.

**Response:** The expertise that we have available right now is sampling at terminal markets and warehouse distribution centers. This sampling system is quantified and stratified. We realize the importance of sampling along the food chain; however, sampling at each link in the chain would be very expensive. According to NASS, the sample size at every point in the distribution chain would have to be greater than the overall sample size presently contemplated to pinpoint exact sources of contamination in a statistically reliable manner. This is impractical due to the expense associated with such intensive monitoring.

Also, if we sample prior to the terminal market/distribution warehouse point, time in storage and transit, storage/transit conditions, and how sampling is performed would become significant factors. If sampling at different points along the chain is deemed part of our mission, we will

initiate discussions with FDA, NASS, and CDC as to which points in the food chain would be valuable and whether this approach is feasible, objective, practical, and appropriate for making inferences from the data collected. The issue now is how to develop this program according to available resources.

**Question:** What training is provided for samplers?

**Answer:** We have a rigorous training and QA program. All samplers are certified State inspectors who are experts on sampling and undergo continuous training to update skills. Sampling meetings are held periodically with these State inspectors and we conduct onsite audits to review sampling and shipping procedures, similar to the Pesticide Data Program.

**Question:** If the samples are blind, how were the States able to perform follow-ups last year?

**Answer:** The follow-up actions referred to were based on policies in place during the practice phase last year. Reporting policies differed between States, based on their internal procedures and relationships with State Departments of Health. The Congressional language, put in place for 2002, resolves that issue. All MDP samples are now blind. This is not an enforcement program, but a data gathering program which is amenable to change, to fit the requirements and criteria of data that are needed by FDA to fill data gaps and respond to issues and to allow CDC to perform risk modeling work. So, States must adhere to blind sampling – the only origin data collected is State of origin and/or country of origin.

**Question:** Will chain of custody of the sample go backwards to the farm or will it only start at the point of sample collection?

**Answer:** Chain of custody will start only at the collection point and will continue through sample packing, transit, and testing. There will be no attempt to go backwards from the point of collection. That is the requirement for a blind survey.

**Question:** Is there any language in the contract between the Federal government and the States that will direct them as to what they may do with data collected on the basis of Federal funds?

**Answer:** Participating States must honor the language contained in the Congressional appropriation. That is a requirement of their participation in the program.

**Question:** How is import versus domestic origin ascertained?

**Answer:** Sampling is performed at terminal markets and distribution warehouses, where cartons are marked as to origin. Some cartons may undergo repacking; however, for most products, we clearly know whether they are of domestic or import origin.

**Question:** Will post-harvest treatments that have occurred to the sample be captured?

**Answer:** If labeled on the container, the information will be recorded on our sampling form. Sometimes the information is available and sometimes it is not, depending on the producer or packer.

**Question:** How did AMS decide on the list of commodities to be included in the program?

**Answer:** Commodity selection was done in consultation with FDA and CDC. High consumption products were chosen first, rather than minor commodities, which may be added to the program later, as resources become available. Sprouts have been discussed as a possibility for inclusion in the program, and will be considered as a potential future commodity, when resources became available. Addition of commodities is a matter of balancing available resources and priorities.

**Question:** What is the rationale for the selection of microbes to be tested?

**Answer:** Pathogens to be tested – generic *E. coli*, *Salmonella*, and *Shigella* - were decided in consultation with FDA and CDC. *E. coli* was included as an indicator organism.

**Question:** Generic *E. coli* is an indicator of general levels of sanitation. What is the value of using generic *E. coli* as an indicator organism?

**Answer:** This is a new program and we will need to generate adequate data in order to get a sense of the value of using *E. coli* as an indicator organism for fruits and vegetables. This practice will be re-evaluated as data is generated. Also, CDC is interested in *E. coli* pathogens that are not O157:H7. Isolates will be serotyped by the AMS Eastern Laboratory with the guidance of CDC.

**Question:** Only presence/absence of *Salmonella* will be determined. Aren't both qualitative and quantitative information needed to develop a public health policy that would further mitigate the potential risks of contaminated produce?

**Answer:** Quantitative analysis for *Salmonella* requires that MPNs be performed, which would be extremely resource-intensive. Quantitative analysis was discussed with FDA and CDC and the thought was “1 *Salmonella* is a contaminated product” and whether it's 1 or 10,000 in the sample is immaterial, 1 is not acceptable. However, if very few positives for *Salmonella* are found, making quantitative analysis of positive findings feasible, the policy may be discussed with FDA, CDC, industry, and consumer groups and modified.

**Question:** Why is antibiotic resistance testing being done and is the intent to link produce as a vehicle by which antibiotic resistant pathogens are being introduced into the food supply?

**Answer:** Resistance is clearly a growing problem requiring more research, but a link between the resistance associated with a particular fruit or vegetable and how it's introduced is not being pursued. We know that resistance is introduced from a variety of sources and this testing is expected to help us to determine the role played by fruits and vegetables. Also, the cost

is very minor. The Department of Agriculture participated in an exercise with the Department of Health and Human Services in which a plan of action for dealing with antibiotic resistance in organisms in the environment was developed. One portion of this effort is for MDP isolates to be tested by ARS for antibiotic resistance to obtain additional data for the ARS antibiotic resistance study.

**Question:** Do you currently use any markers in the positive controls so that you can assure that a positive finding in a sample is not the result of cross-contamination?

**Answer:** We have not yet used markers for *E. coli*, but that is a good thought and we will consider modifying our procedures to incorporate the use of a marker.

**Question:** How might this fit into new programs designed to prevent agricultural/bio-terrorism?

**Answer:** Prevention of bio-terrorism is not a specific goal of MDP; however the infrastructure - sampling plans, laboratory capacity, personnel, and procedures for shipping, chain of custody, and testing – is there, if needed, to begin analyzing large amounts of produce.

**Question:** From what we've discussed today, it appears that sampling has already begun. Is data available at this time? Will we have to go through FOIA?

**Answer:** We are currently working on practice samples to ensure that all procedural details are in place and working satisfactorily. The data collected to date are not statistically comprehensive and do not cover all the States. Once the data has been fully reviewed and cleared by the Department it will be posted on the web and a report written, just as for other programs, with the proviso of what these data actually represent.

**Question:** You mentioned that the comment period will be open until January 22, 2002. What is expected after that?

**Answer:** Last year, considerable time and effort was focused on developing program infrastructure, training personnel, establishing aseptic procedures and temperature controls, writing SOPs, and testing the entire system. This year, we plan to evaluate and streamline the program, retaining those elements which provide the most information while using the least amount of resources. We hope that some very constructive comments and positive ideas will emerge from this meeting. We must consider any comment received in the light of our mission, available resources, and the practicality of the suggestion for this program. We will evaluate and prioritize these items and add those that are feasible into the program, as time permits. This dialogue does not stop January 22<sup>nd</sup>. Continued public input is expected to enable us to design an enhanced program for 2002 and 2003, making MDP as effective as possible for as many stakeholders as possible.

**Conclusion:**

A number of documents related to this meeting are available on the AMS Internet website at [www.ams.usda.gov/science/mpo/publicmeeting.htm](http://www.ams.usda.gov/science/mpo/publicmeeting.htm). These documents include the meeting agenda, a quick fact sheet, a sampling overview, and presentations and comments from the various speakers at this meeting. A copy of the transcript of this meeting is available on request (refer to contact information below).

Public comments or input regarding the program may be submitted through the close of business, January 22, 2002. Due to the current mail situation, it is advisable to fax (202-720-6496) or e-mail ([Robert.Epstein@usda.gov](mailto:Robert.Epstein@usda.gov)) comments.