

**AGRICULTURAL MARKETING SERVICE  
SCIENCE AND TECHNOLOGY PROGRAMS**

**RESPONSES TO PUBLIC MEETING QUESTIONS REGARDING THE  
MICROBIOLOGICAL DATA PROGRAM**

**1. How will the data be used? Data collected must be useful for reducing foodborne illness.**

*Food Marketing Institute  
International Fresh-cut Produce Association  
California Strawberry Commission  
United Fresh Fruit and Vegetable Association  
California Cantaloupe Advisory Board and the California Melon Research Advisory Board*

MDP is a baseline survey designed to provide the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), the produce industry, and others with data on the incidence of microorganisms on fresh produce. Data collected will be used for research, risk modeling and outreach to stakeholders as it pertains to good agricultural practices.

Unlike other federal monitoring programs, MDP will provide a nationally valid and consistent data set. Samples will be taken at wholesale markets and supermarket distribution centers, on a year-round random basis and over at least two growing seasons. The data will reflect the differences in microbial load on produce samples across varying conditions of production, transport and storage. The data will also provide an understanding of the microbial ecology of fresh fruits and vegetables moving in the farm to table continuum, and how that may be changing over time.

**2. AMS should build on the existing FDA sampling and collection program. The AMS program is duplicative of the FDA Center for Food Safety and Applied Nutrition (CFSAN) produce microbiological sampling programs currently underway.**

*Food Marketing Institute  
International Fresh-cut Produce Association  
United Fresh Fruit and Vegetable Association  
California Cantaloupe Advisory Board and the California Melon Research Advisory Board  
California Strawberry Commission*

MDP is a “baseline” survey program while the FDA programs are designed for public health and regulatory objectives. MDP employs statistically reliable sampling plans at terminal markets and supermarket distribution centers to develop national estimates of the presence of microorganisms on specified products based on product availability in the marketplace. FDA’s surveys for imported and domestic produce tend to be designed differently with different intentions for the use of the data that are generated.

FDA's imported survey was initiated to provide needed data on the incidence and extent of pathogen contamination on selected imported produce. Sampling targeted as many country/producer combinations as possible. As such, 21 countries were represented. MDP sampling will examine imported produce in the proportion that it exists in the market place. MDP data will give FDA a broader picture of the condition of imported product as it is represented in the market place compared to domestic product.

FDA domestic product survey targets sample collection of each product to as large a number of growers as possible. MDP sampling is based on state populations and volume of product moved by the sampling sites, therefore larger sites are likely to be sampled more often. MDP will give the FDA complementary information near retail on the prevalence of foodborne pathogens and indicator organisms after transit, storage and handling.

**3. AMS should correlate the best practices under review by the National Agricultural Statistics Service with their potential for increasing or decreasing foodborne illness.**

*Food Marketing Institute  
International Fresh-cut Produce Association*

The Agricultural Practices survey performed by the National Agricultural Statistics Service (NASS) was completed in the year 2000 and there are no plans to repeat the survey. Since NASS collected data at specific farms and processing companies, it may not be possible to correlate MDP blind sample results with NASS' findings.

**4. How are produce items chosen and why not tailor the program to answer specific questions relative to produce items that are more likely associated with foodborne illness?**

*Food Marketing Institute  
Western Growers Association  
International Fresh-cut Produce Association*

MDP has been developed as a baseline survey to determine consumer exposure and is not related to regulatory action. To ensure that the data are useful for exposure estimates, it was initially determined that commodities would be selected according to consumption figures reported in the USDA Economic Research Service "Vegetables and Specialties Situation and Outlook Yearbook." Excluded from consideration were products that are usually cooked or have known antimicrobial activity. When the program was funded, Congress specified that the program provide information that would meet the needs of public health agencies, so meetings were held with FDA and CDC to determine the commodities in which they were interested. The commodities of interest were compared to the ranked list, and appropriate commodities were chosen.

**5. Why not include sprouts since this will have an immediate impact on improving public health.**

*Food Marketing Institute*

The sprout problem is well documented and there is considerable research currently being performed on this product by other agencies. There would be no immediate impact on improving public health to add sprouts to MDP because it is already under substantial investigation. Sprouts may be considered in future plans, if additional data are needed.

**6A. What is the use of testing for generic *Escherichia coli* (*E. coli*) since its testing will yield little useful information?**

*Food Marketing Institute*

*Western Growers Association*

*International Fresh-cut Produce Association*

*California Strawberry Commission*

*United Fresh Fruit and Vegetable Association*

*California Cantaloupe Advisory Board and the California Melon Research Advisory Board*

*U.S. Apple Association*

Generic *E. coli* are of interest as a screen to determine whether samples should be subjected to further testing for pathogenic serotypes. As suggested by this question, it is the pathogenic *E. coli* that is of particular interest.

According to CDC, there are several possible indicators used in environmental monitoring, including coliforms, "fecal coliforms," and generic *E. coli*, that could be measured. Generic *E. coli* is the most specific indicator of contamination with mammalian/avian feces and is a more specific indicator than either of the others. Generic *E. coli* counts are of interest as a possible proxy and screen for the possible presence of pathogens. Testing for generic *E. coli* serves as a screen for the further determination of pathogenic species, such as enterotoxigenic, enteropathogenic and enteroinvasive. It should be emphasized that all mammals, including humans, have harmless generic *E. coli* in their gastrointestinal tract as part of their normal biota. It is the pathogenic types that are of direct interest in pathogen reduction strategies.

**6B. The reporting of generic *E. coli* results could scare consumers away from purchasing produce. AMS should only report findings of pathogenic *E. coli* and the levels at which they were found in the sample.**

*Western Growers Association*

*International Fresh-cut Produce Association*

*U.S. Apple Association*

*California Cantaloupe Advisory Board and the California Melon Research Advisory Board*

*Western Growers Association*

Final reports will focus on the results of pathogenic *E. coli*. Generic *E. coli* are of interest as a screen to determine whether samples should be subjected to further testing for pathogenic serotypes.

**7A. Congress directed AMS to develop a data collection program, not a regulatory enforcement program, yet it appears that states will use this information for that purpose.**

*Food Marketing Institute  
International Fresh-cut Produce Association  
U.S. Apple Association*

In adherence to the congressional language of a “blind survey,” MDP sample collection forms have been modified to remove any information regarding grower, packer or distributor. MDP cooperative agreements with the participating states will have language reflecting this program requirement.

**7B. AMS needs to work closely with their state partners to ensure that the blinding of samples is done correctly.**

*Western Growers Association  
California Strawberry Commission  
United Fresh Fruit and Vegetable Association  
U.S. Apple Association*

AMS has provided language to the states requesting that information on packer, grower and or distributor be omitted from the sampling form provided to AMS. This language will be incorporated into AMS’ agreements with the participating states.

**8. AMS did not invite the produce industry or any other public groups to provide input during the program development.**

*Western Growers Association  
U.S. Apple Association*

In addition to the public meeting of January 10, 2002, AMS has provided the following MDP outreach activities to stakeholders:

- In February 1999, a survey was sent to 44 microbiologists in the food safety field requesting answers to specific questions concerning the scientific parameters that should be used in the MDP. The responses were considered in the program development.
- Letters were sent to the presidents of industry associations announcing MDP and inviting them to participate in the development of the program – dated November 30, 2000, with a response date of December 15, 2000. Letters were sent to Western Growers Association,

International Fresh-Cut Produce Association, Produce Marketing Association, Florida Fruit and Vegetable Association (FFVA), Texas Produce Association and United Fresh Fruit and Vegetable Association (UFFVA). AMS received one response.

- Media Advisory- Press Announcement-February 5, 2001, #040-01
- AMS met with industry representatives on January 29, 2001. (UFFVA, Western Growers, and the Food Marketing Institute).
- Presented an outline of MDP at National UFFVA meeting- March 16, 2001
- AMS/Science and Technology (S&T) met with representatives from Northwest Horticultural Association and FFVA in April 2001.
- June 20, 2001, meeting with FDA, CDC, AMS and industry groups represented by the Food Marketing Institute (FMI), UFFVA, and other organizations.
- Standard Operating Procedures drafts were sent to Western Growers, FMI, and UFFVA.
- Meeting with industry representatives and AMS officials on January 30, 2002.

**9. The public meeting timing was not convenient for industry representatives.**

*Western Growers Association*

*International Fresh-cut Produce Association*

*California Cantaloupe Advisory Board and the California Melon Research Advisory Board*

*U.S. Apple Association*

The Conference Report for the fiscal year 2002 appropriation was provided to AMS on November 14, 2001, with the requirement that a public meeting be held within 60 days. To comply with the congressional requirement, AMS had to hold the meeting by mid January 2002. AMS scheduled the meeting for January 10, to allow a week to reschedule the meeting due to inclement weather. Physical arrangements had to be made for the meeting, and a Federal Register Notice had to be written and cleared prior to publication. The meeting notice was hand carried to the Office of the Federal Register on December 21, and placed on public display that afternoon. It was published in the Federal Register on December 28. Also AMS staff called and e-mailed stakeholders to inform them of the meeting and solicit participation. The option of participating by telephone was offered to all interested parties. If the participant wished to make a presentation at the meeting, a separate phone line was provided to allow for two-way communication. Participants who participated at the meeting by phone line were invited to ask questions during the question and answer session. The USDA presentation was posted on the AMS website prior to the January 10 meeting. The FDA and CDC presentations were posted on January 16, and comments were posted when received from stakeholders.

**10. How does the currently proposed collection of samples and analysis provide meaningful data to public health officials, scientists, growers or consumers?**

*Western Growers Association*

The number of foodborne illnesses associated with domestic and imported fresh fruits and vegetables has increased in recent years. Some microorganisms once thought under control may be adapting to their environments, may be developing resistance to conventional food processing operations, or may be re-emerging with increased pathogenicity. To respond to these concerns, Congress appropriated funds to AMS for a microbiological data collection program on domestic and imported fruits and vegetables. The program is designed to provide nationally valid microbiological baseline data for selected produce. Through this baseline data, which will provide clearer definition of the nature and scope of the problem, if any, industry and public health authorities will be better able to focus their efforts to address microbiological concerns.

**11. The number of organisms detected/unit of consumed material needs to be reported.**

*Western Growers Association*

FDA and CDC both indicated that there is no need at this time for enumeration of pathogens on produce, only the presence or absence of the specific pathogen. If data indicate the need for pathogens enumeration, a separate specific study may be implemented in the future.

**12. There has been insufficient communication between AMS, CDC and FDA concerning the respective data needs.**

*Western Growers Association*

AMS has had numerous meetings and phone conversations with CDC and FDA in regards to the MDP program. Both agencies designated liaisons to work with AMS on MDP's objectives and planning initiatives. AMS also has met with representatives of USDA's Cooperative State Research, Education and Extension Service (CSREES) to ensure coordination of research they fund and MDP. Further coordination among researchers will be realized through sharing of MDP data via the USDA/HHS Joint Institute for Food Safety Research.

**13. The shipping of samples at 15°C will permit the growth of *E. coli* and skew the data.**

*Western Growers Association*

*International Fresh-cut Produce Association*

*California Strawberry Commission*

*United Fresh Fruit and Vegetable Association*

*California Cantaloupe Advisory Board and the California Melon Research Advisory Board*

The temperature of most terminal markets and produce warehouses is approximately 15°C (59°F). However, at some open-air terminal markets produce is exposed to ambient temperatures that may

reach 80°F in summer months. AMS ships samples chilled with ice packs to slow microbial growth and to keep sample temperature below that of the terminal market, at 15°C or below; thus, any additional growth that occurs would simulate the produce being held another day at the market. Temperatures upon arrival at the laboratory are generally below 15°C when produce has been held at or below this temperature when sampled. If produce has been exposed to warmer temperatures at sampling, then samples cannot always be brought down to the target temperature without causing freeze damage which renders samples unsuitable for testing. Sample temperature is taken upon arrival at the laboratory and entered in the database. Effects of temperature on the levels of microorganisms found on samples will be carefully examined.

**14. Will information such as country of origin be noted?**

*Western Growers Association*  
*International Fresh-cut Produce Association*  
*California Cantaloupe Advisory Board and the California Melon Research Advisory Board*

Yes. This information should be on the box containing the produce and will be captured on the sampling form.

**15. AMS should allow the whole program to be peer reviewed by scientists with experience in sampling and analyzing fresh produce for pathogens.**

*Western Growers Association*  
*International Fresh-cut Produce Association*  
*California Strawberry Commission*  
*United Fresh Fruit and Vegetable Association*

All the Standard Operating Procedures (SOPs) and significant documents for the program are posted on the Web site ([www.ams.usda.gov/science/mpo/mdp.htm](http://www.ams.usda.gov/science/mpo/mdp.htm)). AMS' SOPs were reviewed by FDA, CDC, participating state microbiologists, industry and academicians. Comments were evaluated and as appropriate incorporated into the SOPs.

**16. Different methods are required for the isolation of generic and pathogenic *E. coli*.**

*Western Growers Association*

Experienced microbiologists generally agree that with the exception of *E. coli* O157:H7, which does not grow well at 45°C and is β-glucuronidase negative, all other pathogenic *E. coli* can be isolated in the same manner as non-pathogenic generic *E. coli*. Therefore, the isolates from the generic isolation method will contain these pathogens if they are present. Furthermore, the pathogenic species fall into specific serogroups (Edwards and Ewing's *Identification of Enterobacteriaceae*, 4<sup>th</sup> edition, William H. Ewing). Once the isolates are serotyped, those that fall into the appropriate serogroups will be tested at the AMS Eastern Laboratory, Gastonia, NC, for specific pathogenic factors using a CDC provided multiplex Polymerase Chain Reaction (PCR) methodology. In addition, mixed cultures containing multiple serotypes of *E. coli* will also be subjected to the CDC multiplex PCR.

**17. Is the MDP data being collected at the appropriate point in the supply chain? Samples need to be taken from various steps along the pathway from farm to table to assist in the development of risk assessments.**

*International Fresh-cut Produce Association  
California Strawberry Commission  
United Fresh Fruit and Vegetable Association  
California Cantaloupe Advisory Board and the California Melon Research Advisory Board  
U. S. Apple Association  
Western Growers Association*

The sampling design for MDP provides for the collection of samples at wholesale markets and supermarket distribution centers, on a year-round random basis and over at least two growing seasons. Samples thus will be collected as close to the consumer level as is practicable. The number of samples collected by each of the participating states will reflect state population and thus permit estimation of consumer exposure to microorganisms of interest.

Within the level of funding that has been provided the MDP program will be able to gather and analyze samples in a manner that yields statistically reliable results at the national level, and will allow meaningful estimates of exposure and assessments of risk. This, in turn, will permit more precise focus on the types of produce and kinds of microbial contamination for which potential sources within the marketing chain could be further examined.

**18. What will AMS recommend to the industry if there are positive results if you have no idea where the contamination came from?**

*International Fresh-cut Produce Association*

AMS' role with the MDP is to develop baseline data that will permit inferences about national exposure to foodborne microorganisms on produce. MDP is not designed to draw inferences about microorganisms on individual production lots of produce. Results will also allow for more informed research and risk modeling.

**19. How will contaminated samples be reported to state/local public health officials and suppliers? How will positive results for pathogen contamination be handled?**

*International Fresh-cut Produce Association*

MDP is designed as a baseline survey, not an enforcement program. It is designed to draw inferences about national exposure to microorganisms on produce, not inferences about microorganisms on individual production lots of produce. As congressional language clearly directs, blind sampling will be conducted, i.e. no information will be provided as to grower, packer or distributor. And, by the time a sample could be confirmed positive for a pathogen, the product would no longer be in the marketplace. FDA and CDC will be provided data quarterly, per their request.

**20. Who will provide training to assure consistent and accurate data reporting by the numerous laboratories throughout the United States that will be analyzing MDP samples?**

*International Fresh-cut Produce Association  
Western Growers Association*

MDP samples are tested by experienced microbiologists at AMS and state laboratories. These laboratories perform microbiological analyses for their respective programs on many types of food products. One of the objectives of MDP is to harmonize testing operations across all laboratories in the program to ensure consistent and accurate data reporting. To achieve this objective, MDP developed standard operating procedures (SOPs) that cover sample collection, testing and data reporting requirements that all laboratories must follow. Three levels of data review verify adherence to SOPs: on-site reviews by the technical program manager, by a designated quality assurance officer, and a review by an AMS quality assurance microbiologist. Equivalency across laboratories and laboratory performance will be monitored through proficiency samples. Laboratories will be subject to a yearly on-site review by microbiologists who have been trained as lead auditors to the AOAC International food laboratory criteria.

**21. The use of pathogen positive controls which have biological markers associated with them should be used.**

*International Fresh-cut Produce Association*

This suggestion regarding the use of markers will be adopted by MDP.

**22. Samples received at the laboratory for analysis that are overtly spoiled, bruised or mechanically damaged in transit should not be analyzed.**

*International Fresh-cut Produce Association*

MDP SOPs “MDP-LABOP-02” and “MDP-LABOP-05” preclude the testing of spoiled, bruised or damaged product. MDP procedures specifically state that samples that arrive to the laboratory bruised, damaged or spoiled will not be analyzed. These operating procedures also provide specific instructions to remove and discard outer leaves that exhibit freezer damage, obvious wilting, decay or that have obvious clumps of dirt clinging to them.

**23. The research project “Improving the Safety of Fruits and Vegetables: A Tri-state Consortium Proposal” appears to be duplicative and more actionable than MDP.**

*California Strawberry Commission  
United Fresh Fruit and Vegetable Association*

The Tri-State Fruit and Vegetable Safety Consortium is a project that seeks to address the issue of produce safety by performing research in three major vegetable and fruit producing States, California, Florida and Texas. It is not a national survey project. Their intention is to determine the

points during production and processing of specific fruits and vegetables where pathogens are or might be introduced and the effect that certain production, processing and environmental factors may have on contamination.

**24. The time interval of 72 hours from point of sampling is inappropriate.**

*California Strawberry Commission  
United Fresh Fruit and Vegetable Association*

MDP standard operating procedures were amended to require sample testing to begin within 24 hours from arrival at the laboratory.

**25. Appropriate methods for microbial detection can vary greatly by product type and characteristics. “Uniform” sampling protocols may not be appropriate across products.**

*California Strawberry Commission  
United Fresh Fruit and Vegetable Association  
Western Growers Association*

Uniform sample collection protocols are needed to safeguard integrity of the sample, to ensure that aseptic conditions are followed for all sampled products and to prevent accidental contamination during sample collection, shipping and handling. In preparing operating procedures for sampling, AMS consulted with other state and federal agencies engaged in public health programs. Samples are shipped chilled in order to inhibit microbial growth. To prevent freezing damage during shipping, AMS followed transportation experts’ recommendations on ideal temperatures specific to each product. Laboratory testing protocols are specific to each of the pathogens and products under evaluation. Thus, the laboratory method used to prepare samples for *Salmonella* analysis is specific for the product. Similarly, the method used for preparing samples for *Shigella* testing will be specific to each product tested. Prior to introducing a product and/or pathogen into the program, laboratories conduct preliminary testing to ensure that the analytical team engaged in testing of MDP samples is adequately trained to utilize the method and the analytical systems in the laboratory.

**26. The program should have review points built in so the value of the data can be assessed periodically at appropriate intervals.**

*California Strawberry Commission*

MDP is designed to be flexible and is designed to incorporate frequent reviews. The program plans are adjusted every six months or sooner if necessary. The program is currently designed to keep commodities in the program for two years to ensure that test results reflect variations in climate and growing conditions.

**27. The money currently obligated for the MDP should be allocated so that the resulting data can be used by the Food and Drug Administration, the Agricultural Research Service, and more importantly the produce industry to advance our collective understanding of produce safety and to identify research needs for the future.**

*United Fresh Fruit and Vegetable Association*

The MDP has been designed in consultation with federal and state public health agencies, other USDA agencies, and interested stakeholders. The purpose of the program is to develop baseline data that will be useful to researchers, the public health community, and, most importantly, the produce industry in assessing consumer exposure to microorganisms on produce at the national level.

**28. The Cantaloupe and Melon associations were not directly contacted though cantaloupe is scheduled to be sampled in the spring.**

*California Cantaloupe Advisory Board and the California Melon Research Advisory Board*

The decision to include cantaloupe in the program was made based on the recommendation of industry representatives. In general, AMS monitoring programs request input from industry groups when their direct involvement is needed for sampling or to resolve a specific crop issue. If requested, AMS will provide preliminary information to industry if any trends or unusual findings are reported.

**29. Dr. Trevor Suslow's research shows that the testing methods proposed by AMS would lead to many false positives due to many naturally occurring microorganisms that mimic pathogenic *Salmonella* in the standard analytical methods used by AMS.**

*California Cantaloupe Advisory Board and the California Melon Research Advisory Board*

The methodology for cantaloupe has not yet been chosen. AMS has contacted Dr. Suslow and will give careful consideration to his work. It is unlikely that the MDP program would be reporting false positive results for *Salmonella* regardless of the method chosen for screening, since isolation and identification of the pathogen must be accomplished before the sample is designated as positive for the organism. The organism is then serotyped for further confirmation.

**30. Why are microbes to be tested for antibiotic resistance given the rare instances antibiotics are used in the production of any produce?**

*California Cantaloupe Advisory Board and the California Melon Research Advisory Board*

We acknowledge that antibiotics are not used in the production of melons and cantaloupes. We also recognize that the natural habitat of pathogens such as *Salmonella* and some *E. coli* does not include plants. These organisms come from animal sources. If these organisms are found on the melons and cantaloupes, they were deposited by wastewater, run off water, animals or humans. The presence of

antibiotic resistant microorganisms is of great concern to the medical community. An interagency task force has been initiated to address antimicrobial resistance and to develop a Public Health Action Plan. The task force includes representatives from CDC, USDA and the National Institutes of Health. The Surveillance section of the action plan developed by the task force involved a variety of actions that would help determine the extent of the problem. The organisms to be isolated under the MDP are among those identified for surveillance in the Action Plan. Information generated through MDP will be added to an ARS database to provide information on the extent and source of the antibiotic resistance problem.

**31. It is suggested that AMS test the interior of lettuce leaves as *E. coli* O157:H7 was experimentally found to be taken into the interior of the lettuce leaves.**

*Consumers Union*

We have read the research paper that gave rise to this question, and agree that the results are very interesting. However, after discussions with other researchers in this subject area, it was determined that additional research findings on this phenomenon are needed before we can incorporate the procedure into MDP. We will continue to monitor the scientific data on this subject as it is published, and will reconsider this methodology periodically.

**32. Only *E. coli* O157:H7 should be tested or alternatively all human pathogenic *E. coli* strains could be tested for.**

*International Fresh-cut Produce Association*

AMS will consider testing for all pathogenic *E. coli* and will consult with FDA and CDC to determine whether to test for *E. coli* O157:H7 among the pathogenic strains.