



FDA's Produce Safety Activities

BY NEGA BERU, PH.D. AND PETER A. SALSURY
 SERIES EDITOR: CATHERINE "KITTY" BAILEY, M.ED.

The safety of imported and domestic fruits and vegetables is a priority for the U.S. Food and Drug Administration (FDA). This article will discuss recent activities the agency has initiated to assure that consumers receive safe produce. These activities include the development of guidance for industry, the sampling survey of imported and domestic produce and outreach and training activities with interested stakeholders.

PRODUCE SAFETY ACTIVITIES

Fresh fruits and vegetables are important to the health and well-being of the American consumer and we enjoy one of the safest supplies of fresh produce in the world. However, although low, the proportion of foodborne illness associated with both domestic and imported fresh fruits and vegetables has increased over the last several years. This may be due, in part, to an increase in consumption of fresh produce in the U.S., changing patterns in the supply of fresh produce making it available year-round, and a population that is increasingly vulnerable to foodborne illness as both the average age and the number of persons with weakened immune systems increases.¹⁻³

As part of the effort to improve the safety of imported and domestic fresh produce, FDA's Center for Food Safety and Applied Nutrition (CFSAN) and the U.S. Department of Agriculture (USDA) issued guidance to industry on Oct. 26, 1998, entitled "*Guide To Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*." This guidance document ("the guide") discusses microbial food safety hazards and good agricultural

and management practices common to the growing, harvesting, washing, sorting, packing and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form to minimize microbial food safety hazards from consumption of fresh produce. The produce guide is guidance only, not a regulation. Both domestic and foreign fresh fruit and vegetable producers can use this voluntary, science-based guidance to help ensure the safety of their produce.

Government food safety agencies recognize that the agricultural community has made a significant effort to adjust and adopt Good Agricultural Practices (GAPs) to help minimize microbial food safety hazards in produce. Several fresh fruit and vegetable trade organizations, universities, state and local government agencies and countries exporting produce to the U.S. have taken strong leadership roles in assisting growers, packers and shippers in identifying potential hazards associated with their operations. These efforts have included the development of safety and quality assurance programs, Good Manufacturing Practices (GMPs), and good agricultural and management practice guidance documents; the funding of agriculture research studies; and the sponsorship of educational initiatives. The intent of the guide is to build on those earlier and continuing efforts and to develop national guidelines to enhance the consistency and scientific basis of food safety initiatives throughout the country.

The following are important considerations when using this guide:

1. The guide focuses on microbial hazards for fresh produce and does not specifically address pesticide residues or chemical contaminants. Growers, packers and shippers should strive to establish practices that do not inadvertently increase other risks to the food supply or to the environment.
2. The guide focuses on risk reduction and not risk elimination. Current technologies cannot eliminate all potential food safety hazards associated with fresh produce that will be eaten raw.
3. The guide provides broad, scientifically based principles. Operators should use the guide to help assess microbiological hazards that apply to their own operations and implement appropriate and cost-effective risk reduction strategies.

In addition, the guide includes eight basic principles:

Principle 1. Prevention of microbial contamination of fresh produce is favored over a reliance on corrective actions once known contamination has occurred.

Principle 2. Growers, packers, or shippers should use good agricultural and management practices to minimize hazards in fresh produce.

Principle 3. Fresh produce can become microbiologically contaminated at any point along the farm-to-table food chain. Human or animal feces are the major sources of contamination associated with fresh produce.

Principle 4. Minimize the potential for microbial contamination from water used with fresh fruits and vegetables.

Principle 5. Practices using animal manure or municipal biosolid wastes should be managed closely to minimize the potential for microbial contamination of fresh produce.

Principle 6. Worker hygiene and sanitation practices during production, harvesting, sorting, packing, and transport of fresh produce play a critical role in minimizing the potential for microbial contamination.

Principle 7. Follow all applicable local, state, and federal laws and regulations, and corresponding or similar laws, regulations or standards for operators outside the U.S., that apply to agricultural practices.

Principle 8. Accountability at all levels of the agricultural environment (farm, packing facility, distribution center and transport operation) is important to a successful food safety program. There must be qualified personnel and effective monitoring to ensure that all elements of the program function correctly and to help track produce back through the distribution channels to the producer.

The guide discusses all stages of the farm-to-table food chain. Being aware of, and dealing with, the common risk factors outlined in the guide will result in a more effective, cohesive response to emerging microbial safety issues. Operators should encourage the adoption of safe practices by their partners, including transporters of produce, distributors, exporters, importers, retailers, food service operators and consumers, to ensure that each individual effort will be enhanced.

Research and risk assessment on fresh produce safety will be incorporated in CFSAN's multi-year research planning process. The overall goal of this research is development of intervention and prevention strategies, to reduce the incidence of foodborne illness, which may be applied by small, as well as large, firms. Research will also support development of improved detection methods targeted to sources of contamination. As new information and technological

advances emerge, the agencies will revise the guide or provide additional guidance documents, as appropriate.

IMPORT PRODUCE SURVEY

To assist in the development of new policy for produce safety, the agency needed data on the incidence and extent of pathogen contamination on selected imported produce. In March 1999, FDA initiated a 1,000-sample survey that focused on high-volume, imported fresh produce. Twenty-one countries were represented in the collection and sampling.

The objectives of the survey were three-fold. The first objective was to collect and analyze samples of imported fresh produce to determine the incidence of microbial contamination on these commodities. Second, the goal was to undertake appropriate regulatory follow-up when violative samples were found in order to protect U.S. consumers and to foster implementation of corrective measures to minimize microbial contamination of fresh produce. Third, the objective was to obtain data to focus future research, risk assessment, industry training and food safety policy to reduce foodborne illnesses caused by contaminated fresh produce. However, the sampling survey was not an attempt to detect every incidence of low-level, sporadic contamination, but rather, to detect those levels of contamination that might result from a failure to follow GAPs and GMPs as specified in the FDA guidance.

Criteria for Selection of Commodities in Survey. Five risk factors were considered in ranking commodities to determine which ones would be selected for the produce survey. The risk factors used were epidemiological outbreak data; structural characteristics; growing conditions; processing; and consumption rates. Each factor was given 1 (low risk), 2 (medium risk) or 3 (high-risk) points based on the associated risk.

Salmonella, *Escherichia coli* O157:H7 and *Shigella* were selected as the pathogens on which to focus, because many of the outbreaks of foodborne illness asso-

ciated with fresh and minimally processed produce have been traced to produce contaminated with these pathogens. Based on import information and the results of the criteria for ranking produce, the following products were identified to be collected and analyzed for *Salmonella*, and *Escherichia coli* O157:H7—broccoli, cantaloupe, celery, cilantro, culantro, loose-leaf lettuce, parsley, scallions (green onions), strawberries and tomatoes. All commodities, except for cilantro, culantro, lettuce and strawberries, were to be analyzed for *Shigella*. (Note: When the survey began, FDA had not validated the *Shigella* method for these commodities.)

Ground Rules. Before the sampling started, ground rules for the import survey were established and included:

- Samples had to be collected from products in import status
- Products would be sent to FDA laboratories for analyses
- Importers were not required to hold produce at the border while waiting for results
- Importers could distribute products at their own risk
- 125 samples of each product would be collected
- Products would be collected from several shippers
- FDA would not collect repeat samples of the same product/grower combination
- Products would be collected aseptically
- Sample size: one sample would consist of approximately 10 one-pound sub-samples

Ground rules were established for sample preparation. Samples had to be prepared in a manner that closely simulates actions taken by consumers, such as washing and trimming. Thus, there was no additional preparation required for broccoli, strawberries and cantaloupe; any remaining root from scallions, cilantro and parsley, or damaged outer leaves and those with visible dirt from lettuce, were removed; and the outer three to four stalks of celery underwent a light

rinse to remove visible dirt.

Ground rules were established on actions to take if there were positive findings from a sample analysis. These include recall, if product had been distributed, or detention, if the product was being held pending testing. For example, for *Shigella*, one positive sample meant that the shipment would be detained and the grower/product would be put on Detention Without Physical Examination (DWPE), which means that subsequent shipment is refused entry into U.S. commerce unless the importer presents evidence, such as test results, to FDA showing that the item meets U.S. safety requirements. DWPE can be imposed when violative findings for a grower/shipper are of a nature that suggests that future shipments from that grower/shipper may also be violative. DWPE is imposed to protect consumers from potentially contaminated subsequent shipments from that grower/shipper until the firm implements appropriate corrective measures. In the case of the import produce survey, if there were one positive finding for *Salmonella* or *E. coli* O157:H7, the shipment would be detained and additional sampling of the same product from the same grower/shipper would be conducted. If more than one positive subsample were found, the shipper or grower would be placed on DWPE. In addition, other actions that could be taken included identifying the grower and conducting an inspection of the farm or packinghouse.

Results of the Import Produce Survey.

Of 1,003 samples that were collected and analyzed, 96% were not contaminated with *Shigella*, *Salmonella*, and/or *E. coli* O157:H7. Forty-four samples (4% of the total number sampled) were contaminated with either *Shigella* or *Salmonella*, while none of the produce items were contaminated with *E. coli* O157:H7. The three produce items with the greatest incidence of pathogen contamination were cilantro, cantaloupe and culantro, accounting for 1.6%, 1.1%, and 0.6%, respectively, of the overall contamination

(4%). Of the 44 contaminated samples, 35 (80%) were contaminated with *Salmonella* and nine (20%) were contaminated with *Shigella*. (Detailed results can be found at www.cfsan.fda.gov.)

Twenty-one firms were placed on DWPE because their products were violative. Seven firms were placed on DWPE due to the presence of *Shigella* in one sample, while 14 firms were placed on DWPE due to the presence of *Salmonella* in two samples. One of these firms was placed on DWPE for the presence of both *Shigella* and *Salmonella*. (A product, shipper, grower or importer is removed from DWPE by FDA when the firm shows the agency that the condition(s) that caused the contamination have been corrected.) As of January 2002, 11 of the 21 firms were removed from DWPE.

Due to the high rate of pathogens (*Salmonella* and *Shigella*) recovered from cilantro, culantro and cantaloupe samples in the 1999 survey, there was a continuation of the imported produce survey in 2001 in order to obtain additional information on the incidence and the extent of pathogen contamination for these products. Tomatoes were not covered in the original import assignment but were added to provide complementary import information for comparison with information collected by the Year 2000 domestic produce assignment, which as discussed below does include tomatoes. Initiated in January 2001, this survey was to collect 300 samples. Results of this survey will be published on the CFSAN web page.

DOMESTIC PRODUCE SURVEY

CFSAN conducted a similar survey on the incidence and extent of pathogen contamination of selected fresh domestic produce to assist in determining the need for and development of additional food safety policy for produce. In May 2000, FDA initiated a 1,000-sample survey focused on high-volume domestic produce that is generally consumed raw.

The objective of this survey was to collect and analyze 1,000 samples for the

presence of *Salmonella*, *Shigella* and *E. coli* O157:H7. One hundred and twenty-five samples of each of the following commodities were to be collected: cantaloupe, celery, cilantro, green onions, loose-leaf lettuce, parsley, strawberries, and tomatoes. All samples (with the exception of strawberries due to the lack of a validated testing method) were analyzed for the presence of *Shigella*. This domestic survey differs from the import survey in two ways, First, domestic tomatoes replaced imported broccoli, and second, farm investigations were to be conducted on farms implicated in outbreaks or farms that grew produce that was found positive for pathogens in FDA testing. The purpose of the investigations is to determine and correct possible causes leading to contamination of the produce.

FDA has developed training for states, foreign governments, third parties and FDA staff to do farm investigations in conjunction with states, industry, and regulatory officials from Mexico and Canada. Farm investigations conducted by FDA, states, foreign governments and third parties focus on farm layout, manure management, sewage use, animal management, harvest tools and equipment, and processing and packing facilities. These investigations also include transportation, environmental and product sampling, water sources and worker health and hygiene. The purpose of these investigations is to determine the source, patterns and practices leading to contamination.⁴

Results of the Domestic Produce Survey.

Interim results of the domestic produce survey as of Nov. 30, 2001, show that 972 samples have been collected and 919 analyzed. Twelve samples were found to be positive for pathogens for a violation rate of 1.2%. The agency will prepare a summary and evaluation of the findings of this survey after the completion of the assignment. In the meantime, more detailed interim results can be found on the CFSAN web page.

TRAINING AND OUTREACH EFFORTS


Since 1999, FDA has conducted training and outreach activities to enhance the safety of fresh produce. In April 1999, FDA cosponsored a three-day workshop, "Enhancing the Safety of Fresh Produce at the Source: Training Modalities and Methods, Needs and Opportunities" with its federal partners in the Interagency International Work Group and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). The goal of this international workshop was to identify training needs for growers and producers who export fresh produce to the United States. The workshop attracted 175 participants from 24 countries on four continents and included government experts, education and training counselors, scientists, farmers, producers, worker groups, academic institutions and international organizations. In addition, FDA, through JIFSAN, has conducted and continues to conduct GAPs outreach in several countries.

FDA, in cooperation with the United Fresh Fruit and Vegetable Association, conducted GAP one-day training workshops across the U.S. during 2001. The workshops, attended by processors, researchers, government farm inspectors, manufacturers, quality assurance and food safety managers, vegetable growers, harvesters, retailers and farm managers, were held in Yuma, AZ; Oxnard, CA; McAllen, TX; Tampa, FL; Batavia, NY; and East Lansing, MI. As a result of these workshops, some participants said they would modify or enhance their own GAP programs by emphasizing and promoting more employee/supervisor training/education; improve recordkeeping/documentation; promote good worker hygiene; determine water sources; recognize, identify, and record illnesses in the field; and improve sanitation programs.

During the past two years, CFSAN staff have held briefings with industry trade associations and others to discuss fresh produce and answer their questions and concerns about the guide and the import and domestic produce survey. As

a result of these meetings, FDA and industry representatives have agreed that: (1) timely sharing of the results of the surveys will aid both government and industry in efforts to improve practices; (2) in addition to a visit to the farm associated with a violative sample, visits should also be made to growers of similar products also sampled but found free of pathogens; and (3) information should be shared and compared to determine any specific practices that may be affecting the pathogen level in the sampled products.

SUMMARY

Although the incidence of foodborne illnesses linked to fresh produce is low, over the last several years the proportion of foodborne illnesses associated with domestic and imported fresh fruits and vegetables has increased. Since October 1998, the FDA has released the "Guide To Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," conducted surveys of imported and domestic produce and provided training and outreach to stakeholders to enhance the safety of fresh produce. Results from the produce surveys and the training/outreach efforts will be used to assist in the development of food safety policy, to focus future research, risk assessment and industry training for the purpose of reducing foodborne illnesses resulting from contaminated fresh produce. In the near future, FDA intends to develop a guidance document for fresh-cut produce to advise producers of the steps they should take to reduce microbial hazards that could result from fresh-cut processing. 

Nega Beru, Ph.D., is the director of the Division of Plant Product Safety in CFSAN's Office of Plant and Dairy Foods and Beverages. Beru joined FDA in 1991. Prior to his current position, he worked in the Office of Premarket Approval for eight years, where among other duties, he managed industry consultations with FDA regarding foods derived from genetically engineered plants.

Peter A. Salsbury is a science policy ana-

lyst in FDA's Center for Food Safety and Applied Nutrition's Executive Operations Staff. He is responsible for food safety policy issues that include initiatives with FDA's Office of Regulatory Affairs (field operations) and activities with other federal, state and local government agencies. Salsbury has worked for FDA since 1987.

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