The United States Food and Drug Administration's Approach to Training International Suppliers in Food Safety and Security

James W. Rushing¹ and Christopher S. Walsh²

ADDITIONAL INDEX WORDS. good agricultural practices, GAP, good manufacturing practices, GMP

SUMMARY. In 1998 the U.S. Food and Drug Administration (US-FDA) published formal guidelines for the microbial safety of fresh produce. The guidelines identify and suggest the use of good agricultural practices (GAP) and good manufacturing practices (GMP) for producers and handlers. To extend this important information to international producers and suppliers, an agreement was made to create a GAP and GMP training program through the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). JIFSAN combined resources of US-FDA, the University of Maryland, and other universities to reach audiences outside the U.S. with food safety information. The program is based on the train-the-trainer concept. Its success depends on the ability of the newly trained program participants to reach key audiences in the target country. We present an overview of the development of a training manual and its content, the selection of a teaching team and target countries, and the methods for implementation of the training. Examples of activities in various countries are summarized. Results of a program review conducted in 2004, following nine program deliveries, are also discussed. Future needs are identified and current programming plans are provided.

One of the primary missions of the US-FDA is to protect the U.S. consumer by working to ensure the safety of our food supply. In today's global marketplace, this has become almost an overwhelming task. The National Geographic Society (NGS) today recognizes 191 independent nations (NGS, 1999). U.S. Department of Agriculture (USDA) statistics indicate that we import food from approximately two-thirds of those countries. In recognition of the many challenges involved in assuring the safety of our global food supply, US-FDA developed the strategy of forming partnerships with public and private entities that share the common goal of overseeing the delivery of safe and wholesome food to our population.

The partnership having the greatest impact on the fresh fruit and vegetable industries internationally has been the alliance between US-FDA and the University of Maryland (UM)

codified in the JIFSAN. Established in 1996, JIFSAN is a multidisciplinary research and education program. It represents a cooperative effort between the US-FDA Centers for Food Safety and Applied Nutrition (CFSAN) and Veterinary Medicine (CVM) and UM. The educational mission today involves several universities from the land-grant system. JIFSAN fosters the missions of US-FDA and UM through the creation of strategic partnerships to increase the quantity and quality of research that will provide the basis for sound public health policy. Opportunities exist for collaboration with other U.S. federal and state agencies, private industry, consumer and trade groups, and international organizations. This review article focuses only on JIFSAN activities pertinent to fresh produce.

In 1998 the US-FDA published formal guidelines for the microbial safety of fresh produce (US-FDA, 1998). "The Guide," as the publication is known, defines GAP and GMP that producers and handlers should follow. Eight general subject areas were addressed: agricultural water; processing water; animal manure and municipal biosolids; health and hygiene of workers; sanitary facilities; field sanitation;

cleanliness of packing and storage areas and; transportation systems. Although similarities exist between the Guide and Hazard Analysis Critical Control Point (HACCP) principles for food processors (USDA, 1998), the Guide more specifically addresses the needs and concerns of the fresh produce industry.

Land-grant universities responded quickly to the need for extending this information to industry audiences within the U.S. Two examples of effective outreach programming are the National GAP Program at Cornell University (Bihn et al., 2004; Rangarajan et al., 2003) and the southern-region outreach program administered by North Carolina State University (Osborne et al., 2003). In both of these programs, partnerships were established with collaborating universities throughout the U.S. Training materials addressing principles defined in the US-FDA Guide were also developed and made available to extension professionals and to the fresh produce industry. These efforts raised awareness of the importance of food safety and provided managers with the tools needed to implement essential practices to minimize the risk of microbial contamination.

Although effective in the U.S., these domestic programs could not address the needs of foreign produce suppliers. International programming presented a significantly greater challenge for the US-FDA. First, funding for such programs was not easily accessible due to federal spending guidelines. Further, the US-FDA does not have an extension outreach system comparable to that of the land-grant university system, which traditionally allowed multiple visits to a single site. Clearly, international audiences would need to be reached with a more comprehensive and intensive program based on GAP and GMP principles. The concept that was chosen was to develop a train-the-trainer program in food safety of fresh produce. It would entail the dispatch of a group of trainers to a target country and provide training to selected, qualified individuals who would in turn deliver this information to appropriate audiences within their own country. This program would be delivered through JIFSAN.

EARLY PROGRAM DEVELOPMENT. In early 1999, JIFSAN began an activity under the heading of "Enhanc-

¹Clemson University, Coastal Research and Education Center, 2700 Savannah Highway, Charleston, SC 29414. To whom reprint requests should be addressed; e-mail: jrshng@clemson.edu

²University of Maryland, Department of Natural Resources and Landscape Architecture, 2102 Plant Sciences Building, College Park, MD 20742-4452.

ing the Safety of Fresh Produce at the Source: Training Modalities and Methods, Needs and Opportunities.” This initial effort brought together a team to develop an international training program. A series of conferences were held in 1999 that included U.S. and international participants from various related disciplines. A number of options for training methods were considered, including train-the-trainer, videoteleconference, internet-based instruction, CD-ROM modules, etc. Country-specific concerns were also discussed, including the types of support systems available within target countries, the expertise available, and the most appropriate technology for program delivery.

Many questions arose. Which countries should receive the first training? Should the emphasis be on the most developed, the least developed, or simply those with the highest produce rejection record? Should demonstration models be established? Can some of the education take place in the U.S. or should all of it be done in-country? Will regional training be an option? What international plans are already under way by other groups or individuals? Can a core course be developed around which country-specific adjustments can be made? If so, what should the core contain? Who could deliver such a course?

Clearly a teaching tool (e.g., a manual) was required. JIFSAN negotiated a sub-contract with the University of Arkansas to develop a manual to be used as a basis of a core course. An oversight committee of several specialists from the land-grant universities also was formed to assist with reviewing the manual and planning for implementation of training programs. The manual was entitled “Improving the Safety and Quality of Fresh Fruit and Vegetables: A Training Manual for Trainers” (JIFSAN, 2002). It is structured into six sections. The introductory section addresses the importance of training and is followed by sections on GAP, GMP, food laws and regulations, safety and quality assurance issues, and concludes with a section on the development of an effective training course. The body of the manual contains approximately 200 pages of text with appendices that include practical exercises, demonstrations, and additional resources from the US-FDA archives. The manual was written in English and has to date been

translated to Spanish, Portuguese, and Korean. It is copyrighted but freely available on the web in English and Spanish (JIFSAN, 2002).

CHOOSING LOCATIONS FOR FIRST DELIVERIES. The first step in delivery is to choose the target country. As per the memorandum of understanding between US-FDA and UM, it is US-FDA’s responsibility to choose a site based on the perceived needs of the country and its potential impact on the health and safety of the U.S. consumer. The locations chosen to date are shown in Table 1.

The pilot delivery was conducted in Port of Spain, Trinidad-Tobago in Dec. 2000. There were several reasons for this choice. The eastern Caribbean had been making a significant effort to export fresh produce to the U.S., particularly cilantro (*Coriandrum sativum*), parsley (*Petroselinum crispum* var. *crispum*), and other minor crops. The region had experienced severe flooding in 2000 and many fields were presumed to have been contaminated from flooded septic tanks in the rural areas, presenting a need for GAP and GMP information. Finally, these are English-speaking countries, which facilitated JIFSAN’s need to have immediate feedback from the audience regarding the course content and delivery. The situation was ideal for JIFSAN to assist the region and for the audience to assist JIFSAN with improving the course.

The second course was conducted in Petrolina, Pernambuco, Brazil, in the northern semi-arid region of that

country. Exports of mangoes (*Mangifera indica*) from this area to the U.S. had been steadily increasing, but outbreaks of salmonellosis in the U.S. had been linked to the consumption of imported mangoes. During the course of the epidemiological investigation, the need for GAP-GMP training in Brazil became clear and JIFSAN responded to the need with a program in 2001.

These first two programs provided a great deal of useful information for JIFSAN and for the teaching team. At the time of the deliveries, the manual was not yet completed and the teaching team was large and not well coordinated. The use of PowerPoint (Microsoft Corp., Redmond, Wash.) was not yet commonplace so there was an assortment of slide presentations, overhead projections, etc. A course outline had been prepared based on the draft of the manual that was available at that time. Each time the course was offered, and as the manual reached a final version, the course outline was revised to reflect these changes. The current outline is shown in Table 2.

ADDRESSING SPECIFIC NEEDS. The first clear need for specialized training arose with the order of “detection without physical examination” (DWPE) placed upon the cantaloupe melon (*Cucumis melo* Cantaloupensis group) industry in Mexico following investigations by the U.S. Centers for Disease Control (US-CDC) and US-FDA (US-CDC, 2002; US-FDA, 2002). Several outbreaks of salmonellosis linked to the consumption of

Table 1. Locations and dates for international train-the-trainer programs on good agricultural practices and good manufacturing practices offered by the Joint Institute for Food Safety and Applied Nutrition from 2000 to 2005 and course locations projected for 2006.

Location	Date
Port of Spain, Trinidad	4–8 Dec. 2000
Petrolina, Brazil	4–8 June 2001
Mayaguez, Puerto Rico	11–15 Mar. 2002
Boca Chica, Dominican Republic	15–19 July 2002
Puebla, Mexico	16–30 Aug. 2002
Culiacán, Mexico	17–21 Mar. 2003
Veracruz, Mexico	28 July–2 Aug. 2003
Lima, Peru	15–19 Sept. 2003
La Antigua, Guatemala	22 Mar.–4 Apr. 2004
Tegucigalpa, Honduras	14–18 June 2004
Suwon, Korea	8–12 Nov. 2004
Bangkok, Thailand	21–25 Mar. 2005
Bento Gonçalves, Brazil	9–13 May 2005
Guadalajara, Mexico	19–23 Sept. 2005
Morocco, El Salvador, and Mexico	projected for 2006

cantaloupes from Mexico led US-FDA authorities to implement the DWPE rule. Once implemented, DWPE requires countries to submit food safety plans to US-FDA and shipments are inspected at their port of entry. One of the secondary objectives of JIFSAN is to help maintain or aid in the resumption of flow of fresh produce into the U.S. by building the capacity of suppliers through educational programming. The existence of a DWPE in Mexico afforded JIFSAN an opportunity to test its ability to meet such a challenge.

In early programs, field trips were scheduled for mid-week (Table 2). In these early programs little interaction occurred as participants seemed reluctant to criticize producers from their own country. To break down this barrier, trainers were assigned specific tasks prior to the field trip. The ensuing site analyses and presentations by groups of students took their role from that of passive listeners to active participants. All indications were that the field trips had been an effective educational tool. Multiple sites were visited and student groups were formed in advance for the exercise. Students were provided with a questionnaire that for all practical purposes serves as an audit of GAP and GMP for the operation. Different groups were assigned different subject areas that they would focus on. After the trip they were provided ample classroom time to discuss and develop a food safety plan for their particular topic. Typical subject areas were agricultural water, processing water, field sanitation, packing facility sanitation, and worker health and hygiene. On the final day of the class a representative from each group gave a presentation to the full class on the food-safety plan they had developed, based on the actual operations they had observed during the mid-week visit.

In order to focus on the DWPE issue, a comprehensive case study for cantaloupe production and packing was also developed. As an alternative to the field trip, groups were assigned the task of analyzing the case study and focusing their attention on some specific aspect, as had been done for the field trips. This exercise was piloted in the Veracruz, Mexico, training held in 2003. Since the DWPE for cantaloupes was of great concern to most of the participants, they accepted this task enthusiastically. All indications were

Table 2. Outline for international train-the-trainer programs on good agricultural practices (GAP) and good manufacturing practices (GMP) offered by the Joint Institute for Food Safety and Applied Nutrition from 2000 to 2005.

Monday

Opening ceremony
Course overview stressing the importance of food safety training
GAP

Tuesday

GMP for packing, storage and transportation
Food laws and regulations, U.S. and international

Wednesday

Field trip to fresh fruit and vegetable production and packing facilities, *or*
Classroom exercise using case study analysis

Thursday

Quality, phytosanitary, and safety issues
Developing an effective training course
Implementing GAP and GMP
Group project—Discussion and preparation of farm evaluations

Friday

Group project—Student presentations of farm evaluations
Course evaluation
Examination and discussion of examination
Presentation of certificates and closing

that the case-study concept was an acceptable alternative to the field trip, particularly when a highly-sensitive issue such as the DWPE was at hand. The effectiveness of the field trips and case-study exercises was clearly expressed within post-training questionnaires completed by participants.

Following the Veracruz program, the train-the-trainer program was presented to representatives from five Andean nations in Lima, Peru. With the rapid growth of the asparagus (*Asparagus officinalis*) export industry in Peru and the increasing consumption of fresh, uncooked asparagus tips in the U.S., a case study for asparagus was developed. It was well received by the Lima participants and the delivery to a regional audience appeared to be effective.

COURSE REVIEW. In 2004 an external team was charged with the task of conducting a comprehensive review of the JIFSAN train-the-trainer program. The team visited four of the teaching sites (Puerto Rico, Trinidad, Brazil, and Mexico) to meet with organizers and participants from these earlier course offerings. The review also entailed an analysis of the manual, visuals used in program delivery, and the methods employed by the teaching team.

In-country participants in the review often emphasized that the

course was timely and well received. In some cases it provided their first comprehensive exposure to hazards and illness caused by human pathogens and to the GAP and GMP principles needed to minimize such hazards. Four key outcomes of the training are summarized as follows: implementation of fully functional food-safety programs is vital to the growth of export markets; barriers to food safety programs are not insurmountable and can often be achieved by simple and practical measures; JIFSAN materials provided a structured and organized platform for most aspects of a food-safety program, and; a long-term approach to food-safety education is required to overcome long-standing behaviors and traditions.

The expected multiplier effect varied tremendously among countries. In some there was minimal activity toward information transfer while others had conducted workshops, one-on-one training, field days, radio programs, etc. To date, approximately 500 people have been trained directly in the 13 JIFSAN programs. It is safe to assume that some percentage of those trainers have in turn conducted their own training programs. It is impossible to arrive at a specific number of people who have been impacted by JIFSAN.

REVIEW TEAM RECOMMENDATIONS. A number of pre-training, or

administrative, considerations were identified by reviewers. The team suggested that the decision for country selection should be based on the potential multiplier effect as well as the export volume and outbreak information. Priority should be given to host countries that have an extension model to indicate that there is an established infrastructure for dissemination of knowledge. Greater emphasis should also be given to a pre-trip analysis of the agricultural and economic conditions within the host country. This would allow instructors to tailor the course to suit the country's needs and educational delivery systems.

Many suggestions were offered for improvement of the training materials and presentation. The length and content of the course should be tailored to suit the needs of the host country, which would be based on the profile developed prior to the training. An improved and harmonized application in presentation platforms in PowerPoint would also be desirable. In conjunction with this, a complete review of graphic and photographic material in the presentations is needed with attention to quality, relevance, and clarity of the intended message. Current science should be used as the basis for any recommendation. The section on adult learning was identified as one that particularly needed improvement.

It would also be helpful and motivational to include an economic component (e.g., a cost-benefit analysis regarding the implementation of a food-safety program). This addition would be feasible if it could be based upon the cost of past outbreaks to any specific industry exporting fresh produce to the U.S.

Post-training follow-up also was

emphasized by the review team. JIFSAN needs to make a greater effort to maintain contact with host countries and hold the funded participants accountable to their commitment to provide training within the country. It would be useful for JIFSAN to host or facilitate a strategically located meeting where the most active course participants could come to share their experiences and present their self-generated training materials. Long-term commitment from JIFSAN will be needed to effect attitudinal and cultural changes against a background of traditional behaviors. An advanced train-the-trainer course should also be considered for countries that have made progress with food-safety programs and in doing so have identified special needs for additional training.

FUTURE DIRECTION. The future of the JIFSAN train-the-trainer program will be guided by the recommendations of the review team. Some recommendations of the team already have been implemented. For example, an advanced course enrolling previous participants from Mexico is planned for that country in 2006. JIFSAN will also continue to create new partnerships in additional countries to facilitate its long-term educational goals.

Conclusion

Participants in countries who have received JIFSAN training have demonstrated an understanding of the train-the-trainer concept and most have welcomed the guidance that has been provided. There is ample reason to believe that the U.S. consumer already has benefited from the programs in that there is much greater awareness of the importance of food safety in many of the countries that export food to the U.S.

Literature cited

- Bihn, E.A., R.B. Gravani, D.L. Scout, K. Rosberg, A. Rangarajan, and M.P. Pritts. 2004. GAPs resource manual. Good agricultural practices for fresh fruits and vegetables. Cornell Univ., Dept. of Food Sci., Ithaca, N.Y.
- Joint Institute for Food Safety and Applied Nutrition. 2002. Improving the safety and quality of fresh fruit and vegetables: A training manual for trainers. 19 May 2006. <http://www.umd.jifsan.edu/GAPs_train_the_trainer.html>.
- National Geographic Society. 1999. Atlas of the world. 7th ed. Natl. Geographic Soc., Washington, D.C.
- Osborne, D.J., D.C. Sanders, J.W. Rushing, and D.R. Ward. 2003. Creating food chain security and food safety: The southeastern regional fresh produce food safety program. J. Assn. Food Drug Offic. 67:10–21.
- Rangarajan, A., E.A. Bihn, M.P. Pritts, and R.B. Gravani. 2003. Food safety begins on the farm: A grower self assessment of food safety risks. 19 May 2006. <http://www.GAPs.cornell.edu/pubs_fsb_fws.html>.
- U.S. Centers for Disease Control. 2002. Multistate outbreaks of *Salmonella* serotype Poona infections associated with eating cantaloupe from Mexico—United States and Canada, 2000–2002. Morbidity Mortality Weekly Rpt. 51:1044–1047.
- U.S. Department of Agriculture. 1998. Hazard analysis and critical control point principles and application guidelines. J. Food Protection 61:1246–1259.
- U.S. Food and Drug Administration. 1998. Guide to minimize microbial food safety hazards for fresh fruits and vegetables. 19 May 2006. <<http://www.cfsan.fda.gov/~acrobat/prodguid.pdf>>.
- U.S. Food and Drug Administration. 2002. FDA issues import alert on cantaloupes from Mexico. FDA Talk Paper T02-40. 19 May 2006. <<http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01167.html>>.