Improving the Safety and Quality of Fresh Fruits and Vegetables: A Training Manual for Trainers
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Introduction

The health benefits associated with regular consumption of fresh fruits and vegetables have been clearly demonstrated and encouraged by national and international nutrition and health authorities. However, there has been an increase in the number of outbreaks of illness associated with the consumption of fresh produce. Several outbreaks have received broad media coverage, raising concerns about the potential safety of fresh fruits and vegetables. The fact that fresh produce is not processed, a step which reduces or eliminates food safety risks, has led the industry, regulatory authorities and the scientific community to focus research and educational efforts on steps that help prevent the occurrence of contamination that might cause illness.

Background

In 1996, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) was established by agreement between the University of Maryland and the U.S. Food and Drug Administration (FDA). JIFSAN is a jointly administered, multidisciplinary research, education and outreach program. It has a foundation of public and private partnerships that provide the scientific basis to help ensure a supply of safe, wholesome food as well as to provide the infrastructure for contributions to national food safety programs and international standards. JIFSAN fosters the missions of the University and FDA through its many collaborative relationships. One of its missions is to deliver training programs and supporting materials that focus on the safe production and handling of fresh fruits and vegetables.

In 1998, the FDA issued the document Guidance for Industry – Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, hereafter referred to as the Guide. This document addressed microbial food safety hazards, good agricultural practices (GAP) and good manufacturing practices (GMP) common to the growing, harvesting, cleaning, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form. This voluntary, science-based guidance was designed to be used by domestic and foreign fresh fruit and vegetable producers and handlers to help ensure the safety of their produce. The guidance is consistent with U.S. trade rights and obligations and does not impose unnecessary or unequal restrictions or barriers on either domestic or foreign industries.

About This Manual

This manual was developed to serve as the basis for JIFSAN and other training programs for GAP and GMP of fresh fruits and vegetables. It provides uniform, broad-based scientific and practical information in a Train-the-Trainer approach. Although the primary user of this manual is the JIFSAN training team, the intent is that there will be many secondary users that would include managers of production and handling operations, Extension workers, and anyone else who has the responsibility of conducting food safety training for fresh fruits and vegetables. Thus the first objective of the manual is to provide a teaching tool that serves as the foundation for JIFSAN to train trainers in countries that export foods to the U.S and the second objective is to provide a resource that assists these newly trained trainers with developing and conducting their own courses.

The scope of information provided in this manual is international. The principles of safe production and handling presented herein will apply uniformly throughout the world, including areas within the U.S. It addresses microbiological, chemical and physical hazards that exist everywhere and offers the best available information for controlling these hazards.

This training manual focuses on risk reduction, not risk elimination. Current technologies cannot eliminate all potential food safety risks associated with the consumption of raw produce. Instructors and trainees should work together during the course to identify risks and practical management strategies for reducing those risks.

Finally, the material in this manual is guidance, not regulation. It should be applied as appropriate and feasible to individual fruit and vegetable operations. For readers who are interested in specific regulations, refer to the

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Logistics and budget may influence the amount of time available for teaching. In this case it is important to establish priorities for training needs and focus on the topics that represent the greatest food safety risks for the location.

JIFSAN instructors have developed a detailed set of PowerPoint presentations that accompany each of the manual sections. These presentations are made available to the audience when the course is delivered. Trainees are encouraged to utilize these presentations, with modifications as needed, to conduct their own training courses.

Practical, hands-on activities are invaluable to the learning process and instructors are encouraged to incorporate as many of these as possible into the course. The practical exercises included in the manual are by no means comprehensive. Trainees may develop their own exercises specific to challenges in their locations.

Finally, users of this manual should be alert for new information and technological advances that expand the understanding of factors associated with food safety risks. Awareness of these factors will allow updating the recommendations and information in this manual as appropriate. The JIFSAN team is committed to keeping the training content as current as possible.

Additional Resources section to find sources of relevant information.

**Structure of the Manual**

The basic elements, or principles, of fresh produce safety and related training practices are covered in the first seven sections. Topics included are: the importance of training, GAP, GMP, pesticides, food quality, developing a training program, and food laws and regulations.

In each of these sections, the primary food safety and training concerns are identified. The scientific basis for safety management and training practices is discussed. Information, including cases studies when possible, is provided to assist trainees with developing their own courses. Recommendations for the safe production and handling of fresh fruits and vegetables are provided. Sections are organized with headings and sub-headings that will assist the user with locating information of interest.

The eighth section consists of a series of practical exercises that trainers may use in the classroom or field to reinforce important food safety concepts. Included are experiments, demonstrations, discussion questions, problem solving activities, and a field site visit guide.

The ninth and final section is a list of information resources. The amount of food safety information available today is enormous and it would be impossible to include paper copies of all supporting materials. Since most relevant practical information is available on websites at no cost to the user, a detailed list of websites with descriptions of the content are provided, with the acknowledgement that new information is developed on a regular basis and users should explore the web periodically for updates.

**Conducting a Training Course**

Training needs vary by country and by location within a country. Teaching resources and presentation styles also may vary depending upon cultural and political circumstances. Identification of needs and delivery methods is a part of course planning.

Typically, a JIFSAN Train-the-Trainer course based on the content of this manual requires five days for presentations on the principles, execution of classroom demonstrations, a field site visit, work on a case study in the classroom, and presentation of case study conclusions by trainees. The manual is structured such that adjustments to scheduling can easily be implemented based on the needs assessment.
The Importance of GAP and GMP Training to Improve the Safety and Quality of Fresh Fruits and Vegetables

Module 1  Why We Must Conduct Training
Module 2  Safety Hazards in Fresh Produce
Module 3  Fresh Produce Safety and Consumer Health
Module 4  Impact of Produce Safety on Commerce
Introduction

With a few exceptions, most of the world’s population has access to at least a limited supply of fresh fruits and vegetables. The production of fresh produce requires that people grow and handle these products. These individuals may have little or no specific knowledge of Good Agricultural Practices (GAP) or Good Manufacturing Practices (GMP). Basic food safety education is critical for those who are unaware of GAP or GMP. For those having at least some familiarity with food safety practices, periodic reinforcement of that knowledge is a necessity. Training is the primary means available to ensure that workers understand the importance of food safety and have the skills to utilize their knowledge.

Disparities in Education and Level of Skill

It is useful for managers to understand that there is a distinction between education and training. While the different definitions for each might be considered a matter of semantics, there are considerations that impact the effectiveness of training programs.

Education is the assimilation of knowledge. Formal education is acquired in school, but informal education through self-study or by simply observing one’s surroundings can be as important as a formal program. Thus, education can be considered a general process whereby people gain knowledge of facts, principles, events, concepts, etc.

Training is an educational process, but it typically has a specific focus on helping the trainee to acquire a skill or to raise the level of a skill. This Manual is part of a Train-the-Trainer course, designed to assist managers with acquiring the skills to train workers in their employ. Managers may train employees by speaking, showing visual aids, demonstrating a task, assigning reading to trainees or through any other means that help impart knowledge that will enhance the workers’ skills for doing their jobs.

The level of education and skill of agricultural workers in non-management positions varies widely. At one extreme are those with no formal education at all, while others may have spent considerable time in school. It is important to “level the field” of knowledge so that all workers have a similar degree of appreciation for the principles of food safety. This can best be achieved through training programs conducted within the company that include pertinent information that all employees need to know.

Cultural and Ethnic Considerations

In many countries immigrants are recruited for the agricultural work force. In some cases the workers migrate within their own country from less developed regions to regions that are more technologically advanced. These newcomers to an area may have very little experience with handling food on a large scale or under conditions of far greater sanitary expectations than their own. Trainers will be more effective if they take time to understand the cultural and ethnic differences and norms that may exist within a group of trainees and the expectations of both the company and its customers. Behavior that could be considered routine in a worker’s native country or region might be a food safety violation in another location.

Trainers must not only be sensitive to these types of situations but anticipate significant barriers to effective implementation when they are discussed in training programs.

Language and literacy barriers are the most obvious challenges for training. We cannot always expect that a worker can quickly learn the language of the location to which they have migrated. Companies must be willing to invest in trainers who are able to communicate effectively with the work force and provide culturally relevant training materials that support learning.

A good example of a cultural difference is the use of toilet facilities and personal hygiene practices. Many locations in Asia, Latin America and Africa do not have toilet facilities that are designed or supplied in the way to which we are accustomed in North America or Europe. Immigrant workers likely will not understand that expected toilet practices in their new home are not only different, but are
required, in order to comply with the requirements for food safety. Trainers must use consideration and sensitivity when discussing such topics of a highly personal nature.

Another example of an ethnic concern is that of religion. Some religious practices entail changes in diet or personal behavior and if these impact the work environment then consideration and compromise must be afforded. While not necessarily a matter of food safety, these practices are very important for many people and should be respected by employers to every extent possible.

**Legal Requirements for Training**

In the U.S. some training is mandated by law for topics that are critical to the health, safety and civil rights of the employee. The government has required, appropriately, that workers must be provided information for their own protection as well as for the protection of their coworkers. Sexual harassment, occupational safety hazards involving machinery or chemicals, workman’s compensation, workplace injuries, etc., are topics about which workers have a right to know. Since training related to these topics is required for every employee, it affords employers an opportunity to incorporate segments on food safety during the same training periods.

Fruit and vegetable companies commonly offer programs on personal health and hygiene as well as general orientation for GAP and GMP when new employees report to work. Some states require that food handlers, particularly restaurant workers, have specialized training. An example of such a program is called Serve-Safe, which may be offered through University Extension programs.

The requirements regarding food safety practices as well as training needs are likely to change. It is important to keep abreast of legal requirements for your operation and make necessary adjustments. For any training program, periodic reinforcement training is required.

**Return on Investment (ROI) for the Corporation**

All companies are concerned about profit. It is essential to the sustainability of the company. All activities within a business, including training, entail cost. Typically, when a company has to expend a significant amount of capital there is concern for the Return on Investment (ROI), e.g., how will the company profit or otherwise benefit from the expenditure.

Food safety training clearly has a cost, but it is an activity for which it is difficult if not impossible to calculate an ROI in terms of dollars. For other activities in a company we might measure an increase in production efficiency as a result of training. Such a measurement is not possible for food safety programs, however estimates of the cost of compliance and the cost of failures to implement GAP and GAP programs are found in publications from the United States Department of Agriculture Economic Research Service (USDA ERS) and from other sources. We might speculate that an outbreak of foodborne illness traced to a specific company will result in a loss of an estimated amount of money. However, we cannot be sure of the amount that a company might lose nor can we be sure that training will actually prevent an outbreak from occurring.

In the absence of a calculated ROI, why then do we train? There are several reasons, all of which are intuitively justifiable:

- Customers who purchase produce are entitled to a safe product. Marketing of adulterated (for our purposes this means the presence of chemical, biological or physical contamination) is illegal in the U.S. and is regulated in many countries. Company managers should feel a moral and ethical obligation to protect the health and safety of consumers.
- Training is one recognized step toward ensuring the sustainability of the company by exercising due diligence in food safety and minimizing the chance of being responsible for illness or outbreaks traced back to the operations.
- Training demonstrates to workers that a common purpose exists within a company that includes not only the need for profit but the need to provide safe food to consumers. Participation of managers in training programs will reinforce the necessity of training for the workers.
- Training is a forum, or meeting place, for workers to share experiences and learn from each other. A work environment in which people are encouraged to share knowledge conveys the importance that all workers must share the responsibility for food safety.
- There are many testimonials among companies which have invested in GAP and GMP training that as food safety
Performance increases a companion increase in quality and reduction in product loss is routinely experienced.

**Conclusion**

Training is an essential process to ensure that workers have a uniform foundation of skills for the safe production and handling of food. The remaining Modules in this Section address the scientific, health and business issues that reinforce the need for training.

**Summary**

Training is an educational process that is designed to increase the trainees’ knowledge for the purpose of learning new skills, the ability to perform these skills, or improving their existing skills.

All workers, including managers, should be trained and practice learned skills.

Cultural and ethnic concerns should be considered in the design and implementation of a training program.

There are legal requirements for certain types of worker training. This provides a platform for employers to include food safety training.

The ROI for food safety training cannot always be easily calculated, but there are numerous direct and indirect benefits to companies that conduct training.
Introduction

A food safety hazard, in simplest terms, is something that could cause harm to the consumer. There are three generally recognized categories of hazards that are associated with all foods, including fresh produce: biological, chemical and physical.

Throughout this Manual, the reader will be reminded that prevention of the occurrence of a hazard is favored over any type of remedial action to correct a problem after it has occurred. This is especially true for biological hazards (microorganisms) because there is no “kill step” for inactivation of all microbes that can be present on fresh produce. The key to prevention is education and effective training followed by implementation of the lessons learned, verification of the implementation of GAP and GMP, and periodic reinforcement of training.

Biological Hazards

All of the biological hazards discussed in this Module are microorganisms. They are so small they can be seen only through a microscope, with the exception of molds which, following growth from a microscopic spore, can be seen with the unaided eye. Microorganisms are classified into five major categories: bacteria, viruses, parasites, yeasts and molds. All will be discussed in more detail throughout this Manual.

Many microorganisms can exist as a single cell, but they may have the ability to reproduce rapidly to large numbers within a matter of hours if conditions are favorable. They may be found everywhere in nature or may be restricted to certain environments or even regions. Many have the ability to adapt to changes in the environment or have mechanisms to survive environmental extremes and other stresses in preharvest and postharvest handling.

Most microorganisms are not harmful to humans and many serve purposes that are beneficial to human health and activities. They are involved in the production of fermented foods and beverages such as cheese, bread, alcohol and sauerkraut. They may be naturally selected, as in plant or animal breeding, or manipulated by biotechnologies so that they can produce specific enzymes, antibiotics or other medicinal products. They may also function as microbial pesticides and for bioremediation of environmental pollutants.

In the soil, microbes can break down organic matter and they are involved in nitrogen and phosphorus fixation and phosphorus uptake by plants. Microorganisms play many beneficial roles in nature that are neither known nor understood by most people. The vast majority of microorganisms cannot be grown under laboratory conditions but perform immensely important ecological and agricultural roles.

Ample scientific evidence confirms that fresh fruit and vegetables are not normally contaminated with human pathogens. These pathogenic microorganisms ultimately have to be introduced onto the produce from an external source. This can occur during any phase of production through the use of untreated or inadequately composted manure, contaminated irrigation water, from dust carried on the wind, deposits of feces left by animals, by human hands, or perhaps through other transfer mechanisms that are not presently known. It can also occur during the harvesting and handling of produce through unsanitary practices, such as the failure of workers to wash their hands properly or from field containers that are not adequately cleaned and sanitized.

The fecal-oral route of contamination is a key concern. This simply means that fecal contamination on the produce is consumed and results in illness of the consumer. Implementation of GAP and GMP is intended to help prevent this contamination from occurring.
Bacterial Hazards

Bacterial pathogens are a part of our environment and the potential always exists for them to contaminate fresh produce. Following are some of the pathogenic bacteria that have been associated with fruits and vegetables.

- *Salmonella* species
- *Shigella* species
- *Escherichia coli* (pathogenic and toxigenic)
- *Campylobacter* species
- *Yersinia enterocolitica*
- *Listeria monocytogenes*
- *Staphylococcus aureus*
- *Clostridium* species
- *Bacillus cereus*
- *Vibrio* species

Knowledge of where specific bacteria are found in the environment can help us to assess local hazards and develop strategies for the prevention of contamination. It also is extremely useful for investigating and determining the source of pathogens when an outbreak of illness or intoxication occurs.

Some bacteria typically reside in the soil, such as *Clostridium botulinum, Bacillus cereus* and *Listeria monocytogenes*. Since plants are grown in the soil, except for those that are produced in hydroponics systems, we must make every effort to exclude or remove soil from harvested product. We also should avoid, to the extent that it is possible, having soil contaminate the edible portions of the plant during production. An example of this would be the splash that occurs with overhead irrigation. Soil removal through the cleaning of produce is discussed in Section III.

Other pathogenic bacteria can reside in the intestinal tract of humans and/or animals. These include certain species or types of *Salmonella, Shigella, Yersinia, Campylobacter, Listeria* and pathogenic *Escherichia coli*. *Shigella* is specifically associated with humans so investigators of an outbreak of illness caused by *Shigella* would look for ways that the product could have been contaminated directly by people or from human waste or untreated wastewater.

Certain pathogenic *E. coli* are associated with ruminant animals, such as cattle, so investigators would look to animal operations as a source of the pathogen. Clearly we should work to prevent the entry of any animal into production areas, but there are numerous routes for contamination mentioned earlier, especially from confined or concentrated numbers of such carriers of pathogens.

Water is critical for the production of fresh produce, but is subject to contamination. Pathogenic bacteria can reach sources of water during a flood, by normal run-off of rain water, from agricultural run-off, or by having animals enter water directly. Contaminated water should not be used for irrigation, to mix pesticides, for frost protection or for any other purpose that would expose water to the edible portions of the plant. Management of water quality and testing for contamination are discussed in later Sections. Bacterial contamination also can occur through other avenues during normal harvesting, handling, distribution and marketing operations that are discussed in Section III.

The virulence of bacteria, e.g., the number that must be present to cause illness, varies with the type of bacteria and the age and health of the infected person. For example, *Shigella spp.* are highly virulent and as few as 10 cells might cause illness. With other bacteria millions may be required to cause illness directly or to produce sufficient toxins to cause illness. Young children, infants, pregnant women, older people and people who are already ill or immune-compromised are more susceptible to infection than a healthy young adult. However, it is important to note that in several large outbreaks the primary victims of illness were middle-aged female adults, presumed to be a consequence of the demographics of consumption.

Bacteria that have contaminated fresh produce may be able to reproduce on the surface of the product or within the product if the tissue has been injured or if water-soaking has occurred. Although it is difficult to prevent reproduction, we can reduce the rate of population growth in some cases by controlling nutrient availability, temperature, humidity, pH and oxygen.

For example, harvest and handling injury that ruptures cells provides a point of entry for bacteria and a medium for bacterial growth. We should design handling systems so that such injuries are avoided.

Reproduction of some pathogens is temperature-dependent so refrigeration is a means of reducing the rate of population growth or preventing it entirely on crops that are not chilling-sensitive. Although refrigeration below 5°C may essentially stop the growth of some pathogens, studies have shown that certain pathogens survive longer under refrigeration than at ambient conditions. This reinforces the
Consider *E. coli*, which has a generation time that ranges from 15 to 20 minutes under optimal conditions of unrestricted growth (nutrients are not limiting). As shown below, a single cell can reproduce to form more than one million bacteria in 7 hours (6-log increase) and in 10 hours the population exceeds one billion cells (9-log increase).

<table>
<thead>
<tr>
<th>Time (hrs)</th>
<th># of Bacteria</th>
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<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>2</td>
<td>32</td>
</tr>
<tr>
<td>3</td>
<td>256</td>
</tr>
<tr>
<td>4</td>
<td>2,048</td>
</tr>
<tr>
<td>5</td>
<td>16,384</td>
</tr>
<tr>
<td>6</td>
<td>131,072</td>
</tr>
<tr>
<td>7</td>
<td>1,048,576</td>
</tr>
<tr>
<td>8</td>
<td>16,777,216</td>
</tr>
<tr>
<td>9</td>
<td>134,217,728</td>
</tr>
<tr>
<td>10</td>
<td>1,073,741,824</td>
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The above data reinforce the concept that prevention of contamination and minimizing survival following a contamination event are essential to the safety of the product. Hypothetically, if only one bacterium is present and conditions are favorable for multiplication, a virulent population can develop within a relatively short time.

The multiplication process for bacteria usually takes place in a series of steps or phases as shown in the graph below. Knowledge of the population growth process can provide insight into opportunities for prevention or control of the

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importance of the principle that contamination should be prevented.

Manipulation of any of the above factors is commodity specific. In the case of temperature, quality of the product may be compromised at unfavorable temperatures. A management strategy must be used that is appropriate for the product. For example, the optimum temperature for growth of *E. coli* is 37°C (98.6°F) but it can multiply in the range of 10 (or slightly lower) to 46°C (50 to 114.8°F). Cooling will slow reproduction but some commodities may be injured if they are cooled to a point that *E. coli* reproduction stops.

Likewise, manipulation of oxygen levels, humidity or other environmental factors mentioned above must take the quality of the product into consideration. Low oxygen may not significantly affect bacterial pathogens responsible for most produce-related illnesses. In general, temperature control is the primary means of influencing pathogen growth.

Bacteria reproduce through a process known as binary fission, shown in the following graphic. A single cell divides in two. These two cells divide again and the products of that division divide again. The population thus increases rapidly in a logarithmic pattern.

The time needed for a bacterial cell to divide, or for a population of bacteria to double in size, is known as the generation time. Generation times vary for the specific type of bacteria and are influenced by the availability of nutrients and the environmental conditions discussed previously.

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**Binary Fission**

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rate of reproduction. In order to keep the population from reaching a level that could cause illness, it is necessary to keep the initial number low through prevention and to implement strategies to keep the population in the latent or lag phase. Unfortunately, as discussed above, growth is not a requirement for highly virulent pathogens or certain sub-types of pathogens, for which very low numbers are sufficient to cause illness or death.

Parasitic Hazards
Parasites are organisms that live and grow in another living organism, called the host. They may be passed from one host to another through some non-host vehicle. Because produce is often eaten raw, it can serve as a vehicle to pass a parasite from one host organism to a human host where it can cause illness.

Vehicles for contamination of produce include water or equipment directly contaminated with fecal material, infected food handlers, and animals in the field.

Environment has a significant effect on a parasite’s ability to survive. They do not grow on produce and some may not survive outside the host for a significant period of time. The ones that can survive outside the host are the ones that are problematic for the produce industry.

Following is a list of parasites most commonly associated with human infections. From this list, *Cyclospora* has been the one most often associated with outbreaks of illness associated with the consumption of fresh produce.

- *Cryptosporidium*
- *Cyclospora*
- *Giardia*
- *Entamoeba*
- *Toxoplasma*
- *Sarcocystis*
- *Isospora*
- *Helminthes:*
  - Nematodes (i.e., *Ascaris lumbricoides*, *Thricuris trichiura*)
  - Plathelminthes (i.e., *Fasciola hepatica* and *Cysticercus* spp.)

Viral Hazards
Viruses are extremely small infectious particles that for the sake of simplicity we will also refer to as microorganisms. As with many parasites, they are unable to reproduce outside of a living cell. Therefore they do not grow in or on foods. However, raw fruits and vegetables may become contaminated with viruses by exposure to contaminated water, mechanical transfer from various contaminated environmental sources, or directly during handling by infected people, the same paths that were noted earlier for bacteria and parasites.

Once the viruses infect a susceptible person consuming the raw produce, they begin to reproduce and illness can occur. The time from infection to onset of illness may vary greatly depending on the virus. Norovirus can cause illness within 36 hours, but several weeks typically are required for Hepatitis Virus A. Since an infective dose of most viruses is extremely small, 10 viral particles or even fewer, prevention of produce contamination is critical to controlling viral disease. Human susceptibility to viral illness depends on the age and health of the infected person, as discussed previously. Viruses that have been reported to be transmitted by foods include:

- Hepatitis A
- Norwalk virus and Norwalk-like virus
- Rotaviruses, astroviruses, enteroviruses (polioviruses, echoviruses and coxsackie viruses), parvoviruses, adenoviruses and coronaviruses

Sources of Biological Hazards
The characteristics of some human pathogens, symptoms of the diseases they cause and examples of the sources of contamination are found in materials referenced in the Additional Resources section. A few examples are
summarized in the Table below, which shows the causal agent, the number of reported cases during the time period reported, and the reservoir for the agent. Note that these data are for all foods, not just produce.

<table>
<thead>
<tr>
<th>Agent</th>
<th>Cases</th>
<th>Reservoir</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norwalk-like viruses</td>
<td>9,200,000</td>
<td>Human</td>
</tr>
<tr>
<td>Campylobacter spp</td>
<td>1,963,141</td>
<td>Poultry</td>
</tr>
<tr>
<td>Salmonella, Non-typhoidal</td>
<td>1,341,873</td>
<td>Animal</td>
</tr>
<tr>
<td>Clostridium perfringens</td>
<td>248,520</td>
<td>Soil, human, animal</td>
</tr>
<tr>
<td>Giardia lamblia</td>
<td>200,000</td>
<td>Human, animal</td>
</tr>
<tr>
<td>Staphylococcus</td>
<td>185,060</td>
<td>Human</td>
</tr>
<tr>
<td>Toxoplasma gondii</td>
<td>112,500</td>
<td>Cat</td>
</tr>
<tr>
<td>Shigella spp</td>
<td>89,648</td>
<td>Human</td>
</tr>
<tr>
<td>Yersinia enterocolitica</td>
<td>86,731</td>
<td>Pig</td>
</tr>
<tr>
<td>Escherichia coli O157:H7</td>
<td>62,458</td>
<td>Cow</td>
</tr>
</tbody>
</table>

Note that Noroviruses are responsible for the overwhelming majority of illnesses caused by microbiological hazards. Outbreaks on cruise ships, not likely associated directly with fresh produce consumption, have been widely publicized. Two of the microorganisms that have received the most negative publicity in recent outbreaks associated with consumption of fresh fruit or vegetables, Salmonella and E. coli, actually have caused much fewer cases of illness than the Noroviruses.

Specific diagnosis of illness requires clinical testing. However, managers should be trained to recognize general symptoms of illness so that potentially infected food handlers can be prevented from having contact with fresh produce. This is discussed in the following Module.

**Control of Biological Hazards**

Many of the control strategies that will be discussed in this course are designed first to prevent contamination and secondly to reduce or keep the initial numbers of microorganisms as low as possible in the event that some contamination occurs. These include strict implementation of GAP during production and GMP during all handling steps. A broad range of topics will be addressed, such as controlling microbial hazards from water, soil and site selection, use of manure and biosolids, worker health and hygiene, provision of appropriate sanitation facilities, sanitation practices in all handling facilities and the development and implementation of Sanitation Standard Operating Procedures (SSOP).

Many of the diseases that have been linked to consumption of fruits and vegetables caused by pathogenic bacteria, parasites, and viruses are transmitted via the fecal–oral route. It is important that individuals handling produce at every stage, from field to table, have a good understanding of proper hygiene practices, including handwashing. Training of workers, coupled with education of consumers, is important for reaching the goal of safe food.

A final note about biological hazards is to emphasize that washing does not effectively remove all microbes from the surface of fruits and vegetables. It can substantially reduce the numbers if the wash water is of good quality, especially when combined with mechanical action, such as brush washing for tolerant commodities. But managers should not expect that washing can ensure the safety of the product. This is discussed in further detail in Section III.

**Chemical Hazards**

Chemical hazards in fresh produce can come from three general sources: naturally occurring substances, agricultural chemicals, and non-agricultural pollutants. Harmful chemicals have been associated with acute toxic responses and with chronic illnesses.

There are many compounds in nature that cause harm to people if inhaled, ingested, or by contact with the skin, eyes or mucous membranes. Allergens can cause rapid and acute chemical toxicity. Among plant foods, peanuts are one of the more common foods that cause allergies. Mycotoxins (i.e., aflatoxin), mushroom toxins, phytohemagglutinin and some alkaloids all are naturally occurring substances that can be toxic to people. The injury caused by some natural plant-associated toxins is triggered on skin by exposure to sunlight.

People who are sensitive to any natural substance must take precautions to avoid exposure. In the case of known allergies, people should consider having suitable medical remedies available, such as injectable epinephrine, in the event of accidental exposure. Producers and handlers of fruits and vegetables should inspect fields and harvested products for any sign of contaminants with potential allergens or toxic agents.

Agricultural chemicals of concern include pesticides, fertilizers and in animal production, antibiotics. Pesticides are the greatest concern for fruit and vegetable producers.
Growers should always read and follow the instructions on pesticide labels. Handlers of pesticides should have suitable protective clothing and equipment and take care to use protective measures diligently. They should never eat or smoke when handling pesticides. Section IV of this Manual provides a thorough discussion of pesticide issues.

Agricultural chemicals should be stored in suitable secure facilities. During application, workers should take care not to expose themselves or others who might be downwind of an application. All employees should respect re-entry intervals before returning to a treated field. To avoid exposing consumers, pesticides should be applied at recommended rates and the time-to-harvest intervals must be adhered to. Random checks of pesticide residues may be conducted at points of entry into the U.S. and many state agencies have routine checks of products at the point of sale.

Heavy metals are one example of non-agricultural chemical hazards. Lead, zinc, cadmium, mercury, arsenic and cyanide all are a concern for agricultural producers. Growers should know the history of their fields, especially if they have ever been used for storage or disposal of toxic waste. Heavy metals may be a hazard if municipal waste biosolids are applied to agricultural soils as a compost or thermally treated amendment, or as a land-based disposal method for which some regional authorities provide incentives. Some plants have the capacity to assimilate heavy metals from the soil, potentially posing a risk for consumers.

Heavy metals leaching from biosolids storage areas may contaminate groundwater and surface water that ultimately is used for irrigation or other production or postharvest operations.

Some elements are present in fungicides and nutritional sprays, in which case the label will specify all necessary precautions. Washing and disposal of containers must be done properly. Labels on containers specify appropriate disposal practices.

Other chemical hazards are found in products that are routinely used in agricultural production and handling. Lubricants, cleaning compounds, disinfectants, paints, refrigerants, and rodent and insect control materials may all be used routinely in food systems. Workers must be trained in the proper use of these materials. Chemicals used in a location where contact with food might occur should be approved as food grade chemicals and should be labeled as such.

Packing and packaging materials are potential sources of chemical hazards and these must not be allowed to enter foods. Plastics, vinyl chloride, paints and dyes, adhesives, lead and tin all are used in different types of packaging materials. Suppliers of materials should provide letters of guarantee that their products are manufactured in a manner that does not present hazards for consumers. Information regarding the potential for chemical transfer following exposure to heat, solvent vapors, oxidizing or reducing agents, or UV light should be provided.

Physical Hazards

Physical hazards are differentiated from biological and chemical hazards in that they cause physical injury rather than illness. These might be introduced into food at numerous points in the production and handling chain.

Perhaps the most common physical hazard in agricultural operations is metal. Nails, staples, bolts, screws, washers and other types of hardware are needed to construct pallets and fabricate or repair machinery. Pieces of scrap from maintenance operations, such as broken chain links, filings and fragments from metal cutting, drilling, or welding can be present. Many packing facilities now use metal detectors to scan the packed boxes for potential hazards before the product is shipped. First aid supplies, such as band-aids, are available with metal strips in the fabric so they will be found by the metal detector.

Glass is instantly recognizable as a physical hazard. Breakage can result in cuts or gashes and injured workers will bleed. Blood presents a serious secondary biological hazard in food facilities. Pieces of glass or glass grit that fall into the food product can be ingested and cause injury to consumers. Lamps and light bulbs are now manufactured with protective coating to prevent the dispersal of glass fragments if breakage occurs. Additional protection from fracture-resistant fixture coverings is desirable.

Some elements are present in fungicides and nutritional sprays, in which case the label will specify all necessary precautions. Washing and disposal of containers must be done properly. Labels on containers specify appropriate disposal practices.

Bottles and jars brought in to the work place by employees must be restricted. Other glass items include windows, lights on forklifts, cameras, computer screens and thermometers. Managers of food facilities should develop a glass register that accounts for all glass and brittle plastic in the facility and conduct periodic inspections to note if any breakage has occurred. Glass policy is discussed further in Section III.

Wood also presents a physical hazard. Splinters can injure workers as well as consumers if they enter the food. Further, wood is porous and difficult to clean, thus it can...
harbor microbes. Field crates, boxes, packing crates, construction materials, pallets, etc. all are potentially problematic and companies should implement policy to reduce the use of wood to the extent possible.

Plastics, although preferable to wood, present some of the same hazards mentioned above. The clear advantage to replacing wood with plastic is that plastic is much easier to clean and sanitize. However, plastics may increase the severity of managing a fire on the premises due to hazardous smoke and intense heat release. Local ordinances should be checked for storage and location of large inventories of plastic bins, totes and pallets.

Stones, while not commonly cited as a cause of injury, can be a hazard as well. Crops that are grown close to the ground and are mechanically harvested, such as leafy greens, can collect rocks or pieces of soil that can move through the handling chain to the consumer.

Personal effects such as rings, earrings, watches, hair clips and other jewelry should not be allowed in the workplace because of the potential for having them fall into the product. Watches are not permitted because they typically have glass or brittle plastic crystals. Other forms of physical hazards often encountered in packing facilities include pens and pen caps, brads and staples, and wire banding remnants.

**Conclusion**

Producers and handlers of fresh fruit and vegetables should conduct a systematic and comprehensive risk assessment for their operations and develop procedures to minimize the potential exposure of consumers to hazards. This is addressed in more detail in a later Module on SSOP development.

**Summary**

A hazard is something that can cause product adulteration and potentially result in harm to the consumer.

The three categories of hazards associated with fresh fruit and vegetables are biological, chemical and physical.

The primary biological hazards are microorganisms. These include bacteria, parasites, viruses and some fungi or molds that produce allergens.

Many microorganisms are beneficial to man and are used in the production of fermented foods and beverages.

Pathogenic bacteria do not normally exist on fresh produce, but some types are common in the environment and can inadvertently reach the surface of the product.

This Manual is dedicated to the principle of preventing contamination on produce rather than relying on remedial action to remove contaminants.

Bacteria can grow extremely rapidly and management strategies should be designed first to prevent contamination, secondly to limit survival, and thirdly, to inhibit the growth (in the case of bacteria) of any contamination that may have occurred.

A single bacterium, for example *E. coli*, can reproduce under optimum conditions to reach a population of over one million cells within 7 hours.

Parasites are microorganisms that live in other living organisms, referred to as the host. Human hosts can become ill if infected with parasites.

Viruses are extremely small infectious particles that can reproduce only if they are inside a host cell. Human cells can support the growth of pathogenic viruses.

There are many sources of microorganisms. These include people, birds, and wild and domestic animals.

There are many mechanical or physical carriers (vectors) of fecal contamination. These include people, birds, wild and domestic animals, insects, slugs, and virtually anything else that moves, wiggles or crawls.

Water, if contaminated, can be a vehicle for spreading microbial contamination.

Washing does not effectively remove all microorganisms from the surface of a product, although it can substantially reduce the population.
Improper washing can move contamination from the surface to the interior of fresh produce.

Chemical hazards may be naturally occurring substances, agricultural chemicals and lubricants or non-agricultural pollutants.

Pesticides and all other agricultural chemicals must be handled strictly according to label specifications.

Allergens are chemical hazards that can cause rapid, acute illness. Other chemical hazards can cause chronic illness.

Physical hazards cause injury rather than illness. These include metal, glass, wood, plastic, stones and personal effects such as jewelry.
Introduction

In 1999 the U.S. Centers for Disease Control (CDC) estimated that 76 million cases of foodborne illness occur in the U.S. each year. This projection from actual statistics of clinical cases meant that approximately one in four persons became sick from food contamination. Today there are various agencies and consumer groups in the U.S. that give estimates of the number of people who contract foodborne illness and most of those estimates are higher than the 1999 statistics indicated. Many countries do not have a reliable reporting system for disease incidence and so it is thought that internationally the numbers are higher than in the U.S. Regardless of which country has the most illnesses it is clear that the problem is the source of billions of dollars in lost productivity and other forms of cost burden to society.

History of Surveillance for Outbreaks of Foodborne Illness

An outbreak of foodborne illness is defined as two or more cases of a similar illness resulting from the ingestion of a common food. Since many people having mild symptoms are not diagnosed for the specific cause of disease, it is reasonable to assume that very large numbers of illnesses go unreported. These unreported cases should be kept in mind when considering outbreak data.

The reporting of foodborne and waterborne diseases began in the U.S. approximately 80 years ago. State and territorial officers had become concerned about the high morbidity and mortality caused by infantile diarrhea and typhoid fever. They recommended that cases of “enteric fever” be reported and investigated in order to obtain information about the roles of milk, food and water on the incidence of illness. This information would provide the basis for public health action and the development of policies to help control illness.

In 1925 the U.S. Public Health Service (PHS) began to publish summaries of outbreaks of gastrointestinal illness attributed to milk. In 1938 PHS added all foods to the reports. These early surveillance efforts led to the implementation of pasteurization for milk and other foods.

Surveillance methods evolved and in the 1950s the National Office of Vital Statistics reviewed outbreak reports and published annual summaries in Public Health Reports. This responsibility was assumed by CDC in 1961. Eventually the annual reporting system was supplemented with the Morbidity Mortality Weekly Report (MMWR), containing details of individual investigations and pertinent statistics. This has continued until the present day.

In the mid 1960s the quality of investigative reports began to improve greatly with the involvement of state and federal epidemiologists in outbreak investigations. Since 1973 CDC has maintained a collaborative surveillance program for data collection and timely reporting to the public. Beginning in 1978, outbreaks of waterborne and foodborne illnesses have been addressed in separate annual summaries.

State and federal agencies are constantly working together to refine their investigative techniques and to coordinate their efforts to protect consumers. Three important purposes have been served: disease prevention and control; knowledge of disease causation; and administrative guidance in the development of regulations or other practices to help ensure the safety of food and water.

In the 1970s, about two outbreaks per year were associated with the consumption of fresh produce, accounting for approximately 2% of total outbreaks. By the early 1990s, about 16 outbreaks of illness appeared annually in surveillance reports, accounting for 6% of the total. More recent data (2004) suggest that fresh produce accounts for at least 12% of the total number of outbreaks.

These increases in the numbers of produce-related outbreaks have placed pressure on the fruit and vegetable industries to analyze their production and handling systems for any potential weaknesses that could lead to contamination of their products. It also has led to greater involvement of public agencies and institutions to assist industry in this important role. This Manual is one result of those efforts.
Having established that the numbers, causes and types of foodborne illnesses are increasing, now consider the actual symptoms that people experience when they are ill. This will help managers and their employees relate to the seriousness of the problem and the real need for the implementation of GAP and GMP to help minimize disease occurrence.

**Symptoms of Illness**

Vomiting, diarrhea and general gastroenteritis are, perhaps, the mildest symptoms of illness. This may be accompanied by headache, body aches, fever and general discomfort often described as “flu-like” symptoms. Depending on the pathogen and the general health of the victim, more serious symptoms may ensue such as reactive arthritis, kidney or liver failure, still-births, premature labor or other chronic neurological disorders.

For most adults in industrialized countries, symptoms are certainly unpleasant but are mild, self-limiting and not usually life threatening. The consequences are much more serious for susceptible persons such as the elderly, the very young, pregnant women, those with compromised immune systems or victims already suffering from a serious condition. In these cases, permanent disabilities or even death may occur.

In developing countries, diarrhea, especially in infants, is a major public health problem. It has been estimated that over 3 million infants die each year from this cause and that over one million additional children under the age of five will contract disease that causes severe diarrhea but not death. Infants have little capacity for recovery without professional medical assistance. In children who
survive with chronic diarrhea, malnutrition and secondary infections can lead to a degenerating condition and premature death.

Not all foodborne disease symptoms are restricted to gastrointestinal distress. The World Health Organization (WHO) estimates that 2-3% of all cases lead to more serious, chronic conditions having long-term effects if the victim survives. *Clostridium botulinum* causes a severe neuro-paralytic disease that is often fatal. Effects of *Listeria monocytogenes* can vary from mild flu-like symptoms to severe meningitis and meningoencephalitis. This is especially serious for pregnant women who may experience abortion, stillbirth or premature labor. *Hepatitis* infections can cause permanent liver damage requiring a transplant. Pathogenic *E. coli* infections can lead to kidney failure and death from toxins. A kidney transplant may not be sufficient to restore the full life expectancy to the patient.

The preceding information, if presented effectively by managers to employees, should be sufficient to illustrate the importance of food safety and bring about changes in behavior that can help prevent the contamination of food.

**Factors Affecting the Progression of Foodborne Illness**

The development of illness in an infected individual and the resulting expansion of the incident into an outbreak are dependent on the interaction of three main factors. First is the host, which is the human being, and the age and health of the host. Second is the pathogen plus the evolution of virulence and resistance in the host-pathogen relationship. Finally, there is the environment in which the host and pathogen coexist.

Several host factors have been mentioned previously. An additional consideration is the change in eating habits in the U.S. and many other countries. There is a greater tendency toward eating outside the home, including visits to fast food restaurants, salad bars, take-out restaurants and purchase of ready-to-eat meals from supermarkets. In these cases the consumer is relying on the hygienic practices of others during food preparation to ensure the safety of food.

Environment also is a factor. In tropical regions the risk of illness may be increased due to warm temperatures that are conducive to pathogen growth in the water, soil and on the product, especially if handling practices are inadequate. Other concerns relate to the dramatic increases in international trade among most countries of the world. Our food supply today is a global supply so consumers are potentially exposed to microorganisms from many locations.

Another environmental concern is the large-scale intensive production of animals and the resulting increase in the amount of animal manure that must be managed. In 1997 data, it was estimated that there were 5 tons of animal manure produced in the U.S. per person per year. This amount of animal waste is 130 times greater than the amount of human waste. Since some types of animal manure are excellent sources of fertilizer for production of food crops, some of it inevitably is used for this purpose. As noted previously, some animals are hosts for human pathogens and manure can be a pathogen source. Section II of this Manual covers the methods for composting and otherwise handling manure in a manner that does not present risk for contamination of fruit and vegetable production areas.

Finally, the microbes associated with foodborne illness have the ability to evolve. The Table on the following page lists the biological hazards in 1900 compared to 2000. Few of the microorganisms are the same. In fact, Norwalk virus, which is the greatest cause of gastroenteritis, was not identified until 1972.

**Estimated Cost of Foodborne Illness**

Determining the cost of foodborne illness must include human, social and financial impacts. The 1999 report mentioned earlier in the Introduction to this Module stated
An outbreak of foodborne illness is defined as two or more cases of similar illness resulting from the ingestion of food contaminated by the same microorganism.

Surveillance and reporting of foodborne diseases in the U.S. has been under way for approximately 80 years with steady improvement in effectiveness.

Outbreaks associated with the consumption of fresh produce have increased significantly during the past two decades.

Improvements in surveillance and diagnostic techniques have helped to reveal that outbreaks have increased both nationally and internationally.

Some pathogens have the ability to adapt to their environment and new, emerging diseases are the result.

Symptoms of foodborne illness may include any or all of the following: vomiting, diarrhea, headache, body aches, fever, flu-like symptoms and more serious acute and chronic disorders.

The development of disease in an individual is influenced by interactions between the host, the pathogen and the environment.

Foodborne illness entails large costs for individuals and for society.

Training programs should emphasize the severity and cost of foodborne illness in order for trainees to understand the full importance of food safety programs.

<table>
<thead>
<tr>
<th>Biological Hazards 1900 vs 2000</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1900s</strong></td>
</tr>
<tr>
<td>Botulism</td>
</tr>
<tr>
<td>Brucellosis</td>
</tr>
<tr>
<td>Cholera</td>
</tr>
<tr>
<td>Hepatitis</td>
</tr>
<tr>
<td>Scarlet fever (streptococcus)</td>
</tr>
<tr>
<td>Staphylococcal tuberculosis</td>
</tr>
<tr>
<td>Typhoid fever</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

that there were 76 million cases of foodborne illness annually. The report goes on to state that this leads to 323,000 hospitalizations and 5,000 deaths at a cost of $6.5 billion. Clearly these statistics are merely estimates of personal and economic losses that cannot possibly be corroborated in specific terms.

There are specific costs that we can list with certainty, even though the dollar amounts are lacking. Costs to individuals include absenteeism from work and lost wages, the expense of travel to seek treatment, the ensuing medical services and the greater pain and suffering that accompany treatment for chronic illnesses.

The death of a loved one cannot be described in terms of economic loss for the family. Our legal system of necessity must place monetary value on the loss of a life, but for the family this is of little comfort.

There are large costs to society as well. Government and business share the cost of medical treatment. Businesses lose immediate sales and in the long term market share may never be recovered for a commodity that has been categorized as a high-risk food. There is the cost of traceback to determine the source of illness, wages to caregivers and the impact on health care resources. Legal fees, insurance payments and increases in insurance premiums all are associated with almost all outbreaks today.

These costs should be emphasized in training courses. Employees who are made to feel the personal nature of foodborne illness are more receptive to training and more likely to adopt safe practices. Everyone is impacted by foodborne illness.
**Introduction**

Food production and related agricultural industries play a significant role in the economy of practically all countries. Events that negatively impact the health or purchasing decisions of consumers can also impact the profitability of industries that provide food. The economic consequences can be disastrous, not only because of the immediate loss of revenue, but because the loss of jobs for agricultural workers and affiliated industries affects families and society as a whole. These effects can be long term. This Module can provide only a superficial perspective of the economic impact of an outbreak of illness, but sources of information are provided so that trainers can develop their own case studies for training programs.

**International Overview**

The National Geographic Society recognizes almost 200 independent nations in the world. The USDA Agricultural Marketing Service statistics suggest that the U.S. imports fresh fruit and vegetables from approximately two thirds of these countries. Clearly the food supply of the U.S. is a global supply.

Import-export statistics for other countries are equally compelling. Recent international data are available online (FAOSTAT) from the Food and Agricultural Organization (FAO) Statistical Yearbook 2005/2006. Profiles for individual nations contain details of the gross domestic product and the percentages that are attributed to individual agricultural industries.

The following Table illustrates the importance of agriculture to the economies of selected countries in the Caribbean and Latin America in 1999. Note that the percentage of Gross Domestic Product (GDP) varies from a low of 2% for the island nation of Trinidad-Tobago to 34% for Nicaragua. These figures represent not only the value of the product but the income of agricultural workers as well.

It also is important to consider the percentage of the population that is employed in agricultural industries. In parts of Latin America half of the work force is dedicated to agricultural enterprise. An outbreak of illness resulting in suspension of trade can lead to widespread unemployment and financial hardship for families.

**Value of Agriculture to the Economies of Selected Countries**

<table>
<thead>
<tr>
<th>Country</th>
<th>GDP 1999 Billions USD</th>
<th>GDP Agriculture</th>
<th>Employment Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belize</td>
<td>0.74</td>
<td>22%</td>
<td>38%</td>
</tr>
<tr>
<td>Brazil</td>
<td>1,057.00</td>
<td>14%</td>
<td>31%</td>
</tr>
<tr>
<td>Chile</td>
<td>185.10</td>
<td>6%</td>
<td>14%</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>26.00</td>
<td>14%</td>
<td>20%</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>43.70</td>
<td>14%</td>
<td>17%</td>
</tr>
<tr>
<td>Guatemala</td>
<td>47.90</td>
<td>23%</td>
<td>50%</td>
</tr>
<tr>
<td>México</td>
<td>865.50</td>
<td>5%</td>
<td>24%</td>
</tr>
<tr>
<td>Nicaragua</td>
<td>12.50</td>
<td>34%</td>
<td>42%</td>
</tr>
<tr>
<td>Trinidad and Tobago</td>
<td>9.41</td>
<td>2%</td>
<td>10%</td>
</tr>
</tbody>
</table>

Exports of agricultural products from the countries listed above are crucial to the ongoing viability of their respective economies. The Table on the following page summarizes the relative importance of those exports. In several cases exports comprise half or more of the total value of agriculture. The continued acceptability of these exports by the importing countries is crucial for economic stability and sustainability.

Countries importing products also have strong economic reasons for demanding safe food. The infrastructure that supports import industries, e.g., transportation, marketing, etc., can be severely damaged by a sudden halt in trade. Outbreaks of illness that erode consumer confidence in a product or a country’s ability to provide safe product lead to major losses in revenue.

Consumers in the U.S. are accustomed to a year round supply of fresh fruits and vegetables. Latin America and the Caribbean are the primary suppliers of many of these products during the winter season in North America. The value of this trade has steadily increased and today is worth...
several billion dollars annually. Food safety has become a primary consideration for the continuation of trade.

### Summaries of Selected Food Safety Incidents

The number of foodborne illness outbreaks associated with consumption of fresh produce is still relatively low. However, as consumption has increased and epidemiological techniques have improved, the number of reported outbreaks also has increased. Following is a list of commodities and the number of associated outbreaks occurring from 1996-2006. Most of these incidents received widespread publicity with a corresponding negative economic impact on the industries. Imported and domestically produced commodities both were implicated and there is little evidence that imported products are substantially less safe than domestic products.

#### Outbreaks associated with FDA-regulated produce, 1996-2008*

<table>
<thead>
<tr>
<th>Produce</th>
<th>Number of Outbreaks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lettuce</td>
<td>15</td>
</tr>
<tr>
<td>Tomatoes</td>
<td>14</td>
</tr>
<tr>
<td>Romaine lettuce</td>
<td>6</td>
</tr>
<tr>
<td>Cabbage</td>
<td>1</td>
</tr>
<tr>
<td>Spinach</td>
<td>3</td>
</tr>
<tr>
<td>Cantaloupes</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Produce</th>
<th>Number of Outbreaks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Honeydew melon</td>
<td>2</td>
</tr>
<tr>
<td>Green onions</td>
<td>3</td>
</tr>
<tr>
<td>Mango</td>
<td>2</td>
</tr>
<tr>
<td>Almonds</td>
<td>2</td>
</tr>
<tr>
<td>Parsley</td>
<td>2</td>
</tr>
<tr>
<td>Basil</td>
<td>4</td>
</tr>
<tr>
<td>Green grapes</td>
<td>1</td>
</tr>
<tr>
<td>Snow peas</td>
<td>1</td>
</tr>
<tr>
<td>Basil or mesclun greens</td>
<td>2</td>
</tr>
<tr>
<td>Squash</td>
<td>1</td>
</tr>
<tr>
<td>Unknown</td>
<td>2</td>
</tr>
<tr>
<td>Others (Raspberries-4,</td>
<td>9</td>
</tr>
<tr>
<td>Raspberries/blackberries-1,</td>
<td></td>
</tr>
<tr>
<td>Berries-2, Pre-packaged salad-1,</td>
<td></td>
</tr>
<tr>
<td>Jalapeno/Serrano pepper-1</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>81</td>
</tr>
</tbody>
</table>

* The following caveats are to be cited when providing data on outbreaks due to FDA-regulated products:

1. The data only represent those outbreaks and illnesses associated with FDA-regulated foods and cosmetics.
2. The data do not contain information on outbreaks/illnesses where the point of contamination is the retail food setting or home.
3. The data do not include illnesses transmitted from person-to-person.
4. Illness data represent only the number of illnesses reported to CDC, FDA, and state/local health departments in association with an outbreak. The data do not include illnesses that may have occurred but were not reported, sporadic cases of illness, and illnesses not associated with a food vehicle.
5. Information on outbreaks/illness reported prior to 2004 has been compiled from paper records; information on outbreaks/illnesses since 2004 has been entered into the CFSAN Outbreak Surveillance Database.
6. The outbreaks tracked by FDA are a subset of all the outbreaks tracked by CDC. CDC also tracks outbreaks/illnesses where the point of contamination is the retail food setting or the home. Due to lags in reporting of...
Data provided by the Epidemiology Team, Center for Food Safety &Applied Nutrition, U.S. Food and Drug Administration

Following are brief summaries of six food safety incidents that occurred in the United States over the past two decades. All of these were widely publicized and the economic impacts were profound. Three of the outbreaks were caused by bacteria, one by a virus, one is connected with a parasite and the final case concerns the threat of a chemical hazard. In some cases the mode of contamination of products was never identified. Details of these events may be found on various FDA and CDC websites.

In 2008 an outbreak of illness caused by Salmonella Saintpaul was linked to the consumption of fresh tomatoes. The first illnesses were reported in April and the outbreak continued into June. Hundreds of cases were diagnosed in multiple states and in all likelihood thousands of additional mild cases were not reported. The FDA issued advisories to the public that certain types of tomatoes should not be consumed fresh. Sales of all tomatoes quickly decreased and almost completely stopped. Prior to the advisories, the wholesale value of tomatoes produced in Florida was over twenty dollars per twenty-five pound box. By June, the price had decreased to less than five dollars per box and remained at this price through most of 2008 due to eroded consumer confidence. Losses to the tomato industry were reported to be well over $100 million. Salmonella Saintpaul was never isolated from tomatoes and as the investigation proceeded there was a report that Serrano peppers imported from Mexico may have been the vehicle for the microorganisms. A definitive cause was never established.

In September of 2006 a major outbreak of illness caused by E. coli O157:H7 was associated with the consumption of fresh spinach produced in California. There were deaths and severe chronic illnesses as a result of infection. Although the source of the spinach was quickly identified, the spinach industry throughout the U.S. suffered a reduction in sales. The market volume for this product is still reported to be below its original amount three years after the outbreak. This was a rare case in which the causative agent was actually isolated from a bag of spinach that was in the possession of a consumer. The actual site of the contamination was never positively identified. The strain of E. coli was found in cattle operations and in wild animals near the farm. However, tests of soil and irrigation water from the implicated field were negative.

In 2003 outbreaks of Hepatitis A were linked to the consumption of green onions imported from Mexico. Two deaths were reported. The FDA issued import alerts and eventually the cantaloupe industry in Mexico was placed on detention without physical examination, which effectively halted all shipments. In 1999 Mexico had shipped over 400,000 cases of cantaloupes to the U.S. This decreased steadily to zero shipments in 2003 with the implementation of the detention order. FDA investigated Mexican farms and developed a plan that required evidence of adoption of GAP and GMP programs for producers and shippers as a prerequisite for the removal of detention. The cost of an incidence of this magnitude cannot be estimated. Several years were required for the Mexican industry to begin to recover its position in the market. A similar situation in 2008 resulted in an embargo of melons produced in Honduras that had economic effects on the Honduran industry comparable to the one described for Mexico.

In 1996 an outbreak of illness caused by the protozoan parasite Cyclospora cayetanensis was associated with the consumption of raspberries imported from Guatemala. Unfortunately, early press releases from state health officials in Texas associated the outbreak with strawberries, causing an economic disaster for California growers and shippers. Losses in California were reported to have exceeded $40 million in revenue, 5,000 lost jobs and a 10% decrease in production the following year. Investigations in Guatemala suggested that this waterborne parasite might have been transferred to raspberries through the use of contaminated water for irrigation or topical spray application. Exports from Guatemala were suspended during the investigations and the industry has never fully recovered its former market share. Growers in Guatemala
who shifted production to snow peas simply shifted the problem to this new crop and new outbreaks of *Cyclospora* illness occurred.

In March 1989 suspected terrorists phoned the U.S. Embassy in Santiago, Chile, with threats that they would contaminate grapes with cyanide. The U.S. government placed an embargo on the importation of Chilean grapes and the embargo soon was applied to other fruits as well. Other countries followed the lead of the U.S. and the entire fruit industry in Chile was effectively shut down for the remainder of the export season. Estimates of losses were as high as $1 billion. No illnesses were reported and no evidence of cyanide contamination was discovered. Scientists eventually concluded that grapes and other fruits would not be good candidates for the direct injection of cyanide, but the damage to the industry had already been done.

The above examples are intended only to demonstrate the challenges faced by the agricultural industry and by investigating agencies in the event of crisis. The difficulty in pinpointing the cause of an outbreak can result in dramatic losses for an industry that may not have been to blame.

**Summary**

Food production and related agricultural industries are an important part of the economy in most countries.

Latin America and the Caribbean are the primary providers of fruit and vegetables to the U.S. during the winter season, thus the economies of these regions are particularly susceptible to damage if an outbreak of illness is associated with their products.

Outbreaks of illness in the U.S. have been associated with imported and domestic products alike. There is no compelling evidence that imported products are less safe than domestic products.

In most outbreaks, the source and/or mode of contamination are never identified, usually because the product has been consumed before the investigation can be completed.
Section II

Good Agricultural Practices

Module 1  Site Selection and Soil
Module 2  Agricultural Water
Module 3  Fertilizers: Inorganic and Organic
Module 4  Animal Exclusion and Pest Control
Module 5  Worker Health and Hygiene
Introduction

Fresh produce is consumed raw. There is no absolute kill step, such as cooking, that will preserve the fresh characteristics of the product while ensuring its safety. Nor is there a cleansing step that can remove 100% of biological and most chemical contaminants. Thus prevention of contamination during production should be the first priority in a food safety program.

Fruits and vegetables most often are grown in an open environment where there are multiple opportunities for exposure to chemical and microbiological hazards. Greenhouses or other enclosed structures offer some protection but do not eliminate the risk altogether. The major concerns of the U.S. Food and Drug Administration (FDA) priority watch list for food safety are: waste, which includes manures, manure-based soil amendments, and various organic fertilizers; water; wildlife, and; workers. This Module and those that follow address practices for reducing risks associated with these FDA concerns during the production of fresh fruits and vegetables.

Hazard Analysis

The first step in developing a GAP program is to conduct a systematic review of the production environment and all crop inputs for the purpose of identifying any hazard that may present a potential risk for contamination of the crop. For example, the presence of fecal contamination from any source is a serious hazard that potentially involves all four of the concerns on the FDA list noted above. Chemical and physical hazards also may exist. A cursory inspection by an untrained observer may not predict all site risks. Farmers should request assistance from Extension personnel experienced in GAP planning and other food safety professionals to help with the identification of potential hazards.

Growers should begin by drawing a diagram of the site and surrounding areas. This diagram will be an invaluable point of reference for all ensuing considerations of hazard analysis. The local authorities that monitor or regulate land use may be able to provide a map. Eventually an official survey map or aerial photograph may be required and is highly desirable. However, the simple exercise of drawing a crude diagram will help identify details for the farmer that otherwise might not be noted by simply looking at a map provided from another person.

The example diagram on the next page shows the production fields, irrigation source, potential wildlife habitats, cattle production area, residential area, road, fences, and a general indication of the slope of the land. Although the diagram is crude, it contains a great deal of useful information that the grower may utilize in the development of a land management plan and food safety practices for the farming operation.

Land History

Knowledge and documentation of prior use of the land is required. Potential hazards may be undetected or unexplained (such as groundwater contamination) without this information. Additionally, knowledge of previous exposure of the site to any significant environmental event, such as flooding, gives further insight into the suitability of the site for farming.

In the event of flooding, individual assessment of each flooding event will be needed. The up-flow or land surface features and the time that has passed between floods, as well as the time that has passed since the last flood, are important. Flood prone areas generally are not suitable for fruit and vegetable production. Soil tests may be recommended after land has flooded, especially if there is an obvious hazard in the vicinity. For example, the presence of a nearby cattle operation would suggest the need for testing of pathogenic E. coli in fields that had flooded or were subjected to run-off from the cattle production area. Unfortunately, microbiological testing is not an absolute means of assuring that a field is safe, i.e. a negative test is not necessarily a confirmation that no pathogenic microorganisms are present. Flooding is discussed again later in the context of adjacent land use.

The potential of prior users of the land to compromise GAP presents risks to the current user. If the land was previously used for production of crops for human consumption, the farmer should search for records of past production...
waste management site was restricted to a small area, precipitation, wind, animal vectors, traffic or workers may disperse contamination over a larger area.

Industrial waste or incinerated waste can leave chemical residues that may not degrade for many years. Oil or gas extraction also may leave chemical contaminants in the soil. It is strongly recommended that soil tests for chemical contaminants be conducted prior to farming any land with questionable history.

Adjacent Land Use

Contaminants on land adjacent to cultivated fields may be dispersed into the crop production area. As noted earlier, precipitation, wind, traffic, animals and people are vehicles for the movement of contamination.

The presence of farm animals near the cultivated site increases the risk of product contamination. Barns or feedlots where animals are confined may increase risk compared to animals grazing on open pasture but all animal activity needs to be evaluated in the initial risk analysis.

Assessment of the location of the animals, their distance from the cultivated area, the nature of holding facilities, waste management and fly abatement, bird populations, drainage systems, and the direction of flowing water will help determine the potential for contamination. If the elevation of the cultivated area is lower than that of the
livestock production area, there is greater risk of run-off during a storm event. It may be necessary to construct physical barriers, such as terraces or channels, to divert water away from the crop area and any surface water sources used for crop management. Animal exclusion from cultivated fields is discussed further in a later Module.

Residential communities, or even a single home, also present risks for nearby production land. Homes in rural areas usually have septic tank and drain field which can fall into disrepair. Wastewater may run off into a production area, especially if the water reaches the soil surface due to a failure of the drain system. Household garbage or refuse also may find its way into the crop area as well as attracting animal pests.

Fences or other barriers may be needed to discourage people and domestic animals from having uncontrolled access to fields. Growers should be acquainted with their neighbors and have knowledge of the living conditions within the community. Open and amicable communication with neighbors can help the farmer prevent problems before they occur.

**Persistence of Contaminants in the Soil**

Chemical contaminants of an organic nature, such as pesticide residues, may gradually be degraded by sunlight, microorganisms, etc. and eventually be undetectable in soil. Inorganic chemical contaminates, e.g. heavy metals, do not degrade and their presence may preclude the use of the land for fresh produce production. A soil test will be necessary to confirm the absence of harmful residues.

Persistence of microbiological contaminants is affected by many factors, including time, temperature, relative humidity, tillage, sunlight and microbial competition in the soil. The interaction of these factors is complex and in most cases there is not an adequate amount of scientific information to allow accurate predictions for the survival time of human pathogens in the soil. This topic will be discussed in more detail in Module 3, which deals with organic fertilizers.

**Site Traceability**

The grower must have a system for tracing product back to the field in which it was grown and tracing forward to the buyer or receiver. A number or some type of code should be assigned to fields to facilitate traceability. Usually when the grower makes the first drawing or map of the farm, there will be obvious zones or divisions of fields within the production areas. Ditches, canals, fences, roads, well heads, or any other reasonably fixed or permanent demarcation can be used to designate the border of a field or zone. If no such lines exist, the grower must make arbitrary divisions and map these for future reference.

There are no regulations or specific recommendations regarding the size of the designated zones for traceability purposes. Common sense and practicality are the only guides for growers. The assigned code should be noted on all documents beginning with pre-plant field inspections and continuing through harvest and all subsequent handling steps until the time the product sold to the consumer. This must include identification of the harvest crew and harvest date for each lot.

**Audits, Inspections and Record Keeping**

Farmers today may be under constant pressure from regulatory agencies and the buyers of their products to review their production practices and keep records of all activities on the farm. This point will be reemphasized throughout this Manual.

Records of prior use of the land, the hazard analysis, pre-plant field inspections and any necessary soil tests are the minimum requirements related to soil and site selection. Growers are well served by having a thorough understanding of GAP and conducting self audits of their operations. Guidelines for self audits are available from numerous sources, including private auditing firms and public service agencies.
Summary

The four major concerns on the FDA priority watch list for food safety include waste, water, wildlife and workers.

During fruit and vegetable production there are multiple opportunities for contamination of the crop.

Growers must conduct a hazard analysis of their farm. It will useful to have input from a food safety professional to conduct this analysis.

Diagrams and maps of the production fields and adjacent areas will be invaluable to the grower.

Knowledge and documentation of prior use of the land is required. Waste disposal and animal production are two important aspects of land history that must be examined.

Adjacent land use also impacts the safety of production areas. Animal production areas and residential communities can present immediate risks to the farm.

Chemical and microbiological contaminants can persist in the soil for long periods of time and soil testing may be required to determine if land is suitable for fruit and vegetable production.

Growers must establish a system that will enable tracing of the product from the buyer or receiver to a specific production area.

Self audits and inspections will help growers to identify potential risks before they become problems for the safety of the products. Formal third-party audits may be required by buyers.

Records must be kept for all farming practices.
Introduction
Water is essential for the production of fruits and vegetables. It is used for various methods of irrigation, mixing and application of pesticides, liquid fertilizer application, frost protection, dust abatement, and evaporative cooling. Additionally, water is used by workers in the field for drinking, hand washing and cleaning of field equipment and sanitary facilities.

Water of unacceptable quality is a direct source of contamination for fresh produce. It also is an effective vehicle for the spread of contamination from one location to another. The severity of any microbiological hazard associated with poor quality water depends upon the type and number of microorganisms present and their capacity to survive and multiply on the product surface. Multiplication (growth) is not necessary for some pathogens to cause severe illness. For chemical hazards, the severity depends upon the concentration of the chemical in the water and its toxicity to humans.

The risk of contaminating a crop with water of inappropriate quality is influenced by the plant’s growth habit, morphology, the type and stage of development of the crop, the time between water exposure and harvest, and perhaps other factors. In spite of these or other considerations that might mitigate risk, growers should follow the rule that water of inferior quality is unacceptable for plant production unless remedial action is taken to reduce risk to an acceptable level.

Waterborne Contaminants
The following Table lists a few examples of waterborne human pathogens that have been associated with outbreaks of illness. The list is not comprehensive.

Examples of Microbial Hazards in Water

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Frozen</th>
<th>Cold (5°C)</th>
<th>Warm (30°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Giardia</td>
<td>&lt; 1 day</td>
<td>2 mo</td>
<td>&lt; 3 wk</td>
</tr>
<tr>
<td>Cryptosporidium</td>
<td>&gt; 1 year</td>
<td>&gt; 1 year</td>
<td>&lt; 3 mo</td>
</tr>
<tr>
<td>Salmonella</td>
<td>&gt; 6 mo</td>
<td>&gt; 9 mo</td>
<td>&gt; 6 mo</td>
</tr>
<tr>
<td>Campylobacter</td>
<td>2-8 weeks</td>
<td>&lt; 2 wk</td>
<td>&lt; 1 wk</td>
</tr>
<tr>
<td>Yersinia</td>
<td>&gt; 1 year</td>
<td>&gt; 1 year</td>
<td>&lt; 2 wk</td>
</tr>
<tr>
<td>E. coli O157:H7</td>
<td>&gt; 6 mo</td>
<td>&gt; 9 mo</td>
<td>&lt; 3 mo</td>
</tr>
</tbody>
</table>

Survival of Fecal Pathogens in Water

Some of the above microorganisms have the capacity to survive in water for extended periods. Water temperature is a factor in the length of time that fecal pathogens can remain viable. Below is a summary Table of some studies on the time that fecal pathogens can persist in water. Note that two of the pathogens most often associated with fresh produce contamination, *Salmonella* and *E. coli* O157:H7, both can survive at 5°C for over 9 months. Water in deep wells typically is cool. If wells are contaminated with either of these microorganisms, which can occur with flooding and run-off from nearby animal operations, pathogens can persist for extended periods. This illustrates the importance of water testing, discussed later in the Module.

Hazards Associated with Water Sources
Agricultural water comes primarily from three sources: surface water, ground water and public water supplies. Surface water includes rivers, streams, canals, swamps, lakes, ponds and man made reservoirs. Ground water comes from wells, which may be open or capped and may vary considerably in depth. Public water systems, e.g. municipal water, also are utilized and in this case the water quality is monitored and adjusted by the municipality. An additional water source, rainfall, is still the sole supply of water in some parts of the world. Hazards associated with these different water sources are discussed in the order of decreasing risk.
Surface water is presumed to be the source at greatest risk of contamination. Its microbial content may vary dramatically from thousands of organisms per milliliter in some sources to only minimal presence in other sources. Rainfall tends to reduce the numbers of microorganisms in smooth waters due to a natural purifying process. However, in some areas, rainfall has been shown to be the major factor in acute increases in contamination due to run-off from land surfaces. Regardless of the source, one can never assume that untreated surface water will have microbiological quality similar to municipal water or some other treated supply.

Contamination of surface waters may be permanent, cyclical or intermittent. Potential sources of biological contamination include raw human and animal wastes, sewage water discharges, pollutants from recreational use and adjacent land utilized for animal production, manure storage or waste disposal. Children in and around the fields and inadequate restroom and hand washing facilities that might drain into water are of particular concern. Wildlife is an additional source of contamination that is very difficult to monitor or control. Rodents, birds, reptiles, amphibians and even insects all are potential carriers of human pathogens and all are attracted to water. Restricted animal access to water is one way to reduce contamination risk and is addressed in Module 4.

Chemical hazards also may exist in surface water. These were covered in some detail in the previous Module on soil and site selection. When chemical contaminants are present in the soil they can eventually find their way into water. Nitrate run-off, improper disposal of pesticide containers, and run-off of petroleum products from roadways or from in-field repair of equipment, etc. are potential hazards of concern.

Flowing surface water in a river, stream or canal may travel long distances before it is utilized for crop production. It is important to identify upstream sources of potential contamination to this flow. Elimination of the contamination may involve sediment trapping or modification of the flow pattern, which is relatively simple with canals but may be much more complicated in a natural setting. If the contamination source cannot be eliminated, suitable treatment is required before using the water for agricultural purposes. Verification of the treatment method also is required and is discussed later in this Module.

Ground water is generally believed to be less likely than surface water to be contaminated with pathogens. As water filters through layers of soil, clay and rock the organic content is reduced before it reaches the sub-surface reservoir. Testing of well water has verified that this usually is true. However, shallow, old or improperly constructed wells may become contaminated with chemicals or microbes from the surface water intrusion.

It is well beyond the scope of this Manual to present all of the engineering considerations that factor in to the design of a well. However, growers should be aware of potential hazards associated with wells when developing their GAP program. The graphic below depicts a well that is not properly constructed.

Note first that the well casing has not been properly installed, i.e. the outer perimeter of the casing is not sealed. Rather, the area around the casing is packed with gravel or some other porous material. Flooding, either from heavy rainfall or from other surface water sources that ingress into the field, facilitates movement of contaminants to the well head where they can flow directly into the aquifer below.

Another serious hazard is the location of a septic tank and drain field near the well. Contaminated water percolates to the clay layer, moves laterally to reach the well casing and finally moves downward to pollute the aquifer. A general

Illustration of an Improperly Designed Well and Several Potential Hazards
All water sources should be inspected and tested regularly for the potential hazards noted previously. All monitoring procedures should be described in the relevant SSOP and records of the inspection, tests, unusual occurrences or repairs should be maintained.

**Hazards Associated with the Use of Water**

Agricultural water quality requirements and the severity of potential hazards can vary depending on the purpose for which the water is used, the degree of contact the water has with the edible portion of the plant, the growth habit and surface properties of the crop and the time that elapses between water contact and harvest. In this discussion we describe the various uses of agricultural water in some detail, identify potential hazards associated with water use, and offer suggestions for managing those hazards.

Every farm is different and growers must tailor their water management plan to suit their particular operations, region and climate.

Concurrent with water use considerations, GAP includes soil and water conservation practices such as channel construction, drain control structures, diversion tanks, etc. Terraces, vegetation strips and other physical barriers should be considered in the event of run-off from the cultivated fields. This is an especially important topic for farms that are located near other farms or near natural bodies of water. Under ideal conditions, growers will be able to produce their crops with minimal impact upon the surrounding environment.

**Irrigation**

Irrigation is defined as the controlled application of water for the purpose of providing the moisture levels needed for appropriate development of the plant. Irrigation may be applied to the open field, within an enclosed structure such as a greenhouse, or in the case of containerized production, water is typically applied in low volume directly to the container.

There are various methods for irrigation which growers will select according to the environment, water source and availability, climate, soil characteristics, type of crop and cost. Different methods present different concerns for product safety. Quality of the water may dictate the preferred method of irrigation delivery. In general, methods that result in contact between water and the edible portion of the crop present the highest risk of contamination.
Overhead irrigation is sometimes referred to as sprinkler irrigation, although not all types of sprinklers are necessarily overhead. Water is delivered through a pressurized network of pipes to sprinklers, nozzles, or jets which spray the water into the air to fall upon the plants. This is, in effect, a simulation of rainfall. Obviously a relatively high volume of water is required. Much of the water can evaporate before reaching the soil and is wasted, particularly during dry windy weather. Plants are drenched, so the quality of water is an important concern because water of poor quality directly contaminates the crop.

Micro-sprinklers, as the name implies, are small sprinklers that typically are only a short distance above ground. They can spray water over a circumference of a meter or more and are most commonly used for vine or tree fruits because they can be placed under the canopy of the plants. Since water is applied close to the ground, less volume is required compared to overhead systems and typically there is little contact between the fruit and water.

Trickle, or drip, irrigation is applied through emitters or holes installed in tubes that may be placed along the surface of the ground or may be buried near the root zone of the growing plants. In vegetable production, drip tubes may be placed on top of the soil, installed sub-surface below the root zone, or used in combination with plastic mulch so that all of the water is effectively trapped in the soil. This is the most efficient means of irrigation. Water is not lost directly to the air and a low volume of water will satisfy the needs of the plant. With sub-surface placement, except in rare exposed areas, water does not come into contact with fruit or vegetables growing above ground so that the microbiological quality of the water is of less concern than with irrigation methods mentioned previously. The cost of tubing, emitters and plastic mulch is high but crop yields also may be higher. The cost of waste disposal can be a factor. Drip irrigation is a component of precision farming and managers must take care to meter precise amounts of water into the soil.

Surface, furrow or flood irrigation is the direct application of water to the soil surface either through furrows or by controlled flooding of the entire field. Various applications of these methods are employed for fruits, tree nuts and vegetables. Direct contact with the edible portion of the plant is minimal, as with furrow irrigated staked tomatoes, or there is no contact at all in the case of tree fruits and nuts. However, any contamination in the water is widely distributed over the soil which becomes a concern if the product itself is ever brought into contact with soil by farm operations or workers. This is a concern for tree nuts that may fall onto the soil.

Seep irrigation is the controlled delivery of water from canals that are in close proximity to the field. Water seeps from the canal through the soil to reach the root zones of growing plants. The depth of the water in the canals must be controlled carefully in order to provide adequate amounts of irrigation without water-logging the soil and creating an anaerobic environment for the roots. The irrigation water, theoretically, would never reach the soil surface or come in contact with the edible portion of the plant. In addition, depending on soil properties, significant filtering of bacteria and parasites (viruses to a lesser extent) will occur as the water seeps through the soil.

Hazards associated with irrigation are influenced by the water source and quality, the amount and frequency of application, the irrigation method, soil drainage properties, and the time that elapses between irrigation and harvest. Growers should consider all of these points in the development of their SSOP for agricultural water use. Records should be kept of the amount and purpose of water used, the dates of applications and any unusual occurrences such as breaks in main water lines causing localized flooding. These records may be a legal requirement, particularly in areas of limited water supply.

**Frost Protection and Evaporative Cooling**

Untimely frost or freezing weather, typically in the spring of the year, may require that plants be protected from damaging cold. Overhead irrigation is applied and a layer of insulating ice forms on the plant. Due to the heat released by freezing, the temperature underneath the ice remains at or near 32°F (0°C) while the air temperature above the plant may be several degrees below freezing. Strawberries and some species of citrus are two crops that can tolerate this freeze protection strategy.

During very hot weather, overhead irrigation may be used to cool plants that are very sensitive to heat. As the water evaporates from the plant surface it will reduce the surface temperature (evaporative cooling).

Water quality is of utmost concern in frost protection and evaporative cooling. If fruits are present they are literally bathed in the water. Typically, well water of high quality is used for these production management practices.
**Pesticide Mixing and Application**

Potable water is strongly recommended for the mixing and spray application of pesticides and foliar nutrients. When chemicals are applied directly through irrigation systems the process is sometimes called chemigation or fertigation. Outbreaks of illness have been associated with the use of inappropriate quality water for pesticide application because the edible portion of the plant is directly exposed to water. The presence of soluble foliar nutrients may enhance the growth of microbes that reside on the product surface.

Pesticide applicators should be trained and certified to handle chemicals. Spray drift and run-off from the field can injure workers or other crops that are near the application area. Excess chemicals on the product are a food safety hazard. Careful attention to dosage rates, re-entry and harvest intervals, etc. is required. Growers must follow label instructions. This is an absolute requirement for farming. Pesticide concerns are addressed later in Section IV.

**Backflow Prevention**

Once water has been removed from its source and is on its way to the crop, care must be taken to ensure that there is no backflow of water to the source. This can be achieved with the use of air-gaps or backflow prevention devices.

Backflow prevention is required by law in the U.S. and it should be practiced by all growers. Regular inspection of devices by a certified professional is required to ensure that they are functioning properly. A certificate of the inspection must be kept in the farming records.

**Microbiological Testing of Agricultural Water**

The most common source of microbiological contaminants in agricultural water is fecal material. Most of the bacteria in the feces of humans and other warm blooded animals are not pathogenic to humans. They are simply released into the environment with feces and cause no harm. However, relatively high numbers of fecal bacteria in the environment are an indication that pathogens are more likely to be present.

Routine testing for specific pathogenic bacteria, such as *E. coli* O157:H7 or *Salmonella*, is not generally appropriate unless there is some history of contamination to justify these tests. A more practical approach is to test for the indicator bacteria such as generic *E. coli*. If these counts become elevated then more specific tests may be justified. Unfortunately, tests for fecal bacteria indicators are too often a poor indicator of fecal pathogens and do not reveal the presence or confirm the absence of pathogenic viruses or parasites. This is a significant limitation of water testing programs.

Microbiological determinations are time consuming and obviously add to the cost of farming. They are not practical for daily monitoring activities but periodic testing can help identify changes and trends in the microbial load in water, e.g. for understanding seasonal variations of the source and tracking the safety of water. Once growers become accustomed to seeing that their water is of a certain quality based on test results, they will more readily identify results that are unusually high, take steps to determine the source of contamination and make adjustments in management practices to minimize risk.

Testing, whether process testing (verifying antimicrobial dose) or microbiological assessments, is the only means of verifying that a water treatment is effective. It is essential to keep all records of water tests. These will be useful in the event of an outbreak of illness. The SSOP should require that growers document the frequency of testing, the location of sampling, and the results of every test.

Growers should keep in mind that the microbiological characteristics of water may vary with the time of year and source of the water. Warm temperatures are conducive to bacterial population growth so higher counts might be expected in surface water in the summer compared to winter. Further, surface water is expected to have higher bacterial counts than ground water so growers should not necessarily be alarmed if they compare surface water tests to well water tests.

High counts in ground water would be a cause for concern and investigation of potential contamination sources would be appropriate, as discussed earlier with regard to well water. However, it is important to note that general or total bacterial populations are not the currently accepted criteria for assessing safety. Though not perfect, irrigation standards are based on levels of generic *E. coli*. The World Health Organization (WHO) maintains an international standard of 1000 fecal coliform bacteria / 100 ml water for unrestricted irrigation, a level unacceptable in the U.S. It is prudent for growers to acquire at least a basic understanding of microbiology as it relates to farming practices.
For drinking water, the maximum contaminant level (MCL) for total coliforms in water is zero, although EPA defines potable water in 40 CFR Part 141.63 as having <2 MPN generic E. coli / 100 ml water.

There is no existing MCL recognized for agricultural water. Some commodity groups have established specific recommendations for audit metrics that could eventually be a matter of law. It is useful to growers to keep abreast of developments in this area.

At the time of this writing, the California Leafy Greens industry has adopted for irrigation water the most restrictive level of the U.S. Environmental Protection Agency (EPA) guidelines for microbial quality of recreational water (intended for full body contact) as a standard (40 CFR Part 131.41c). The metric for indicator E. coli is 126 most probable number (MPN) / 100 ml water derived from a rolling average of five test results in a specified period. There is a contingency plan that requires additional testing in the event that a single test reveals counts that exceed a higher number, which varies depending on foliar or non-foliar contact. The important point for now is for growers to be aware that the global industry is moving from less specific voluntary GAPs programs to more prescriptive or mandatory requirements for some food safety program components, particularly for water use.

Other commodity groups are expected to adopt the leafy greens guideline. The California Tomato Farmers and the Florida Tomato Committee are two organizations that currently require members to conform to the leafy greens metric for irrigation water and to employ water testing to confirm compliance.

Frequency of testing is another issue that has been left to the interpretation of growers. Testing recommendations currently vary with the water source. For a closed system such as a deep well, one annual test at the beginning of the season should be sufficient. An uncovered well, open canal, reservoir or other surface water has a recommended testing frequency of every three months. A significant environmental event, such as flooding, is justification for additional testing. For public water systems, records from the municipality or district should be obtained at least annually. More frequent monitoring of test results is recommended to assess problems with the distribution systems and failures of backflow prevention.

Private third-party food safety auditing firms and representatives of regulatory agencies typically ask to review water test results. Prior to scheduling an audit, growers should be aware of the expectations of the auditing firm. The expectations of produce buyers, e.g. wholesalers, supermarket chains, re-packers, etc. also should be considered as these customers are commonly placing specific requirements on growers before they agree to purchase product. Growers who keep abreast of water quality requirements will be better prepared to respond to inquiries.

Water sample collection for testing is a scientific procedure that must be carried out correctly. If growers plan to collect their own samples, the testing laboratory will provide growers with a protocol and usually will offer training for taking the initial samples. Care must be taken in collecting and handling the sample to avoid contamination from any other source. Growers will be well served by seeking professional assistance in this important exercise.

**Remediation of Contaminated Water**

Several options for remediation are available to growers if they find that agricultural water is of poor or uncertain quality.

They first should attempt to identify the source of contamination and take steps to prevent the problem from occurring. This may not be feasible in the case of flowing surface water that becomes contaminated far from the production fields or if the source of contamination is beyond the grower’s control.

A second option is to make repairs to infrastructure that supports the water source. In the example presented earlier of a well that was potentially contaminated by surface water or by a nearby septic system, the first step would be to repair the well casing and ensure that all grouting is intact. It would then be necessary to remove the septic system, excavate contaminated soil and treat the well with appropriate sanitizers until tests verify that the water quality has been restored to an acceptable level.

Treatment of contaminated water with sanitizers also is an option. There are a number of ways to improve the microbial quality of water. This author is familiar with a system installed for the treatment of canal water that entailed four steps, or hurdles. First was filtration through sand to remove large particulate matter. The second step was additional filtration through material that removed smaller particulates. The filtered water then was passed through chambers of ultraviolet lamps. Finally the water...
was chlorinated. Weekly tests of the treated water were implemented to ensure that the water quality met or exceeded the EPA standard for potable water which allowed for the use of water for pesticide mixing. Chlorination and other water sanitation practices are discussed in detail in Section III of this Manual.

If remediation of a water source is not possible the grower may be forced to consider alternative water sources. For example, if available surface water cannot be treated effectively or if the treatment is too expensive, the installation of a well could be a viable alternative.

### Summary

Agricultural water uses include irrigation, pesticide and liquid fertilizer mixing and application, frost protection and evaporative cooling.

Workers in the field need potable water for drinking, hand washing and for cleaning of field equipment and sanitary facilities.

Water of poor quality can be a direct source of contamination to the crop. Water also is a vehicle for the spread of contamination.

Risks associated with agricultural water use are influenced by the way water is used, the type of crop, its stage of development, the time between water exposure and harvest, and possibly other factors.

Waterborne human pathogens have led to outbreaks of illness associated with the consumption of fresh fruits and vegetables. Some human pathogens can remain viable in water for long periods of time.

Agricultural water comes primarily from three sources: surface water, ground water and public water supplies. Although any of these sources can become contaminated, surface water generally is at greatest risk for contamination.

Wells must be properly designed to prevent the introduction of contamination. Growers must be aware of potential hazards associated with wells and other water sources and take steps to mitigate risk.

Hazards associated with the use of agricultural water must be identified and controlled in a way that mitigates risk.

Irrigation methods vary in the potential risk they present to the crop. Methods that involve direct contact between water and the edible portion of the plant present the highest risk for contamination.

There are no laws or regulations governing the microbial quality of water used for irrigation, however some commodity groups have adopted the guidelines for recreational water established by EPA as a standard for irrigation water.

Water used for mixing and application of pesticides must be of potable quality.

Backflow prevention is essential to ensure that water removed from its source cannot return to the source.

Microbiological testing of water is useful for tracking changes in water quality. Common tests for fecal indicators do not correlate with the presence of viruses or parasites.

Contaminated water can be treated to reduce or eliminate biological hazards.

If the source of contamination cannot be mitigated, growers should consider alternative sources.
Introduction
Fields used for agricultural production eventually require the addition of plant nutritional supplements (fertilizers) for soil enrichment in order to maintain the productivity of the land. Fertilizers are natural or synthetic substances added to the soil or in some cases, directly to the plant, to provide the nutrients necessary for plant development. Enhancement of soil fertility will enhance the quality and quantity of fruits and vegetables grown in it.

Fertilizers are divided into two large categories, inorganic and organic, depending on the source of the material. As a chemical definition, the term organic refers to chemicals containing carbon and inorganic refers to non-carbon containing materials. For the purpose of this manual, organic refers to naturally occurring substances such as manure, compost or cover crops, while inorganic refers to synthetic fertilizers.

In the context of food safety, organic fertilizers containing animal manure or animal components present the greatest number of hazards which are the subject of most of this Module. Inorganic fertilizers are discussed briefly.

Inorganic Fertilization
Inorganic fertilizers are, in most cases, salts that are produced on a very large scale through commercial chemical synthetic processes. In the developed world the large majority of fertilization is done with inorganic materials. The products themselves generally are not a source of microbiological contamination. However they can become contaminated through the use of unclean equipment for application or by the use of contaminated water for mixing. Those hazards and GAP for controlling them are discussed in various other parts of this Manual.

Organic Fertilization
Organic fertilizers are derived from plant material, animal manure, other animal wastes (fish emulsions, blood meal, bone meal, etc.) or from sludge (biosolids) collected from municipal sewage treatment systems.

Hazards Associated with Animal and Human Waste
The feces of animals and humans are rich in microbes, some of which can cause illness in humans. Strains of Salmonella, Shigella, Cryptosporidium, Enterococcus, E. coli and other bacteria have been isolated, as well as viruses such as Hepatitis. One of the most infectious microorganisms in animal manure is E. coli O157:H7 which resides in the intestinal tract of ruminant animals such as cows, sheep and deer.

Proper treatment of manure, usually by composting (discussed later), can inactivate bacterial pathogens. The survival of viruses and protozoa in compost has...
Other studies with E. coli survival in the soil have not yet yielded results that have been useful for management of manure. An example is found in the following graph depicting work that was reported from Canada. Liquid manure from a dairy cattle operation was applied to soil at two different times of year in either June or August. The application methods were broadcasting over the soil surface or by incorporation into the soil by plowing. At weekly intervals samples of soil were removed at a 5cm depth and the E. coli enumerated. Note that the bacteria survived from 8 to 20 weeks and there was no clear effect due to the method of application or the time of year that the manure was applied. Soil temperatures in Canada are typically cooler than in other farming regions and this may have obscured treatment differences.


Results of several additional studies are summarized on the following page that show the expectations for survival of either E. coli O157:H7 or Salmonella in soil, manure or other places in the environment.

The main point to be inferred from these studies is that survival of human pathogens in the environment is not been clearly determined. If composting or other treatments are inadequate, or if no treatment is used, the risk of contamination of fruits and vegetables can be extremely high.

Although raw manure is never recommended for use as fertilizer, in many parts of the world it is commonly applied. If it is used, it should be incorporated into the soil during preparation and significantly prior to planting. The population of pathogens in the soil will be reduced over time and the rate of reduction is influenced by a number of environmental and management factors to be discussed. In some studies pathogens have survived in the soil for as much as one year so the maximum amount of time should be allowed between manure application and planting. Raw manure should never be applied to produce intended for fresh consumption during the cultivation period. Continued application of untreated manure to land may increase pathogen populations and extends the time that pathogens are present.

Survival of microbes in the soil and their potential transfer to the edible portion of crops depends on the soil pH, water status, method of application of the organic material, effectiveness of composting or other inactivating treatments, presence of competing microbes and predators in the soil, tillage practices that allow for aeration and exposure to sunlight and probably other factors. Research studies have provided valuable insight into the persistence of pathogens in the soil but the results of those studies vary widely, making accurate farm-specific recommendations difficult.

The graphic below illustrates the influence of microbial competition in the soil on the survival of E. coli O157:H7 in manure applied to the soil. Low Microbial Competition indicates that the soil was autoclaved to kill competing microbes before application of the manure. High Microbial Competition indicates that soil was not autoclaved so that the natural flora in the soil was present at the time of manure application. Note that in autoclaved soil (Low Microbial Competition) the pathogen was recovered after 240 days. In soil with High Microbial Competition the population of E. coli O157:H7 decreased rapidly during the first 40 days and in general survived only half as long compared to treatment of the autoclaved soil. Management practices such as soil fumigation that reduce microbial competition may actually prolong the life of pathogens if manure is applied after fumigation.
most effectively if the compost pile is turned periodically to allow aeration (see active composting below). Anaerobic composting may generate compounds that are toxic to many seedling plants.

A temperature in the range of 130 to 150°F should be generated inside the compost pile. Heat energy accumulates as a result of microbial action. Thermophilic (heat loving) bacteria, which are particularly effective for composting, will thrive in this temperature range. Thus the heat produced by bacteria promotes their own growth which in turn speeds the composting process and reduces or eliminates human pathogens.

Composting treatments can be divided into two groups: passive and active.

Passive composting treatments require very little inputs. Organic waste is simply held under natural conditions. The piles are not turned and oxygen is depleted, resulting in anaerobic conditions that slow the composting process. Given enough time, environmental factors, i.e. temperature, ultraviolet radiation and humidity, inhibit the growth of pathogens and eventually kills them.

The disadvantage of passive composting is that much time is required and it is difficult to know when the pathogens are finally killed. The amount of time needed depends upon the climate, region and season, as well as the type of manure or waste being used. Because of these many uncertainties passive composting treatments are not recommended.

Active composting treatments are those in which the compost pile is managed to create conditions that speed the process of decomposing waste. This is an artificial process in the sense that environmental conditions are controlled. Active composting is the most widely used treatment in agricultural industries.

<table>
<thead>
<tr>
<th>Soil</th>
<th>Manure</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 to 150 days</td>
<td>5°C – 70 days</td>
<td>Water: 222 to 257 days $E. coli$ O157:H7 found to persist for 120 days in water trough sediments</td>
</tr>
<tr>
<td>or more</td>
<td>22°C – 56 days</td>
<td>Feed: $E. coli$ O157:H7 has been shown to proliferate in moist feeds</td>
</tr>
<tr>
<td></td>
<td>37°C – 49 days</td>
<td>Surface or incorporated – 300 days or more</td>
</tr>
<tr>
<td></td>
<td>Slurry: 21 to &gt;</td>
<td>Feces of carrier cows – 159 days</td>
</tr>
<tr>
<td></td>
<td>70 days</td>
<td>Slurry 10°C 132 days 20°C 57 days 30°C 13 days</td>
</tr>
<tr>
<td></td>
<td>Feces: &gt; 90 days</td>
<td>Pasture 91 to 231 days</td>
</tr>
</tbody>
</table>

Treatments to Reduce Microbiological Risks in Organic Fertilizers

Composting

Composting can be one of the most effective and economical methods of converting plant material and animal or human waste into organic fertilizer or soil amendments. It is a natural process in which bacteria and fungi break down organic matter into stable humus that can be utilized by plants. The fermentation that occurs during composting generates heat and various chemicals which, if properly managed, can reduce or eliminate biological hazards.

The principles of composting are quite simple. Naturally occurring microorganisms in the organic matter are provided with a balanced diet, water and oxygen to sustain their growth and promote their action upon organic materials. A small amount of nitrogen fertilizer may be added to the compost pile to supplement the nutritional requirements of the composting microbes. Ideally a C:N ratio of 25-30:1 optimizes the composting process.

The microorganisms need a moist, but not saturated, environment. A moisture range of 40 to 60 % in the pile is ideal. Excess water will cause the pile to become anaerobic and too little water slows microbial growth. Aerobic microbes, which are more effective for fast composting than anaerobic microbes, utilize oxygen and will function
Active treatment involves frequent turning of the material to maintain adequate oxygen levels within the pile. Moisture levels are monitored and water is added when necessary to maintain levels within the optimum range. Nutrients may be added to obtain the ideal C:N ratio, mentioned earlier, for microbial activity. Temperature also is monitored and when the pile stops heating the composting process is complete. Carbon dioxide and ammonia levels may also be monitored to determine completeness and curing stability. Under ideal conditions the high temperatures generated will kill most of the pathogens in a relatively short time.

Microbial analysis of the compost may be performed to determine if the procedure was effective in the elimination of pathogens. The presence of *E. coli* and *Salmonella* are generally used as indicators. If these pathogens are present the compost should not be applied to crops without additional treatment. Composting is considered adequate if tests for fecal coliforms are <1,000 MPN/gram compost and *Salmonella* tests are < 3 MPN/4 grams compost. Some current GAP programs consider these standards too permissive and, in addition specify a larger sampling mass for pathogen analysis.

Guidance for the development and management of a composting facility is available from the USDA Natural Resources Conservation Service (NRCS), from FAO, and from the Cornell University GAP websites.

**Heat Treatments**

Pasteurization with steam or dry heat effectively disinfects compost. Clearly the cost would be substantial for the utilization of heat treatments on a large scale. However, some industries have developed cost effective strategies. One example is the use of heat treated, pelletized poultry manure by the organic leafy greens industry.

**Fumigation**

Various fumigants or other volatiles (such as ammonia) can effectively kill pathogens. Fumigation presents occupational hazards which are discussed later in Section IV on the handling of pesticides.

**GAP for the Manufacture, Storage and Application of Compost**

To assure that pathogenic microorganisms do not contaminate fruits and vegetables and, ultimately, the consumers, it is necessary to implement a GAP program for the manufacture, storage and application of compost.

Manure should be isolated for treatment. The location for raw manure storage should be a reasonable distance from areas of treatment, finished compost, and production areas. Scientists have not identified with certainty what this distance should be, but the elevation of the facility relative to surrounding areas, run-off, the prevailing wind direction and the potential for farm traffic that might carry contaminant to the crop fields all are considerations for choosing a location. Barriers or some type of physical containment will help reduce risk. Composting can be achieved in an open area but managers must give special consideration to potential spread of contamination by wind or rain. Also consider the potential for re-contamination of the area by wildlife, birds or rodents, or by the introduction of fresh uncomposted material to the piles.

Contamination of water sources near the composting area is a concern. Ideally, treatments would be conducted on a concrete floor to reduce the risk of leaching into groundwater. Piles would be covered either by a roof or with sheets of plastic to reduce the risk of recontamination by wildlife and dispersal by wind. These practices also reduce risk of run-off into sources of surface water or onto surrounding fields.

Equipment used to handle raw manure should be thoroughly cleaned before it is used with finished compost or in a production field. Pressure washing and the use of an appropriate sanitizer is recommended. Likewise, personnel who handle manure or compost should not enter fields or be involved in harvesting or packing operations until proper attention has been given to clothing, footwear, protective gear and personal hygiene.

Compost should be applied prior to planting or in the early stages of growth. Ideally it would be incorporated into the soil. It should not be applied when the fruits or vegetables are near maturity or at harvest time. Always maximize the time between application and harvest. It is a violation of GAP to apply compost in a way that allows direct contact with the edible portion of the plant.

Consider the type of crop being produced. Crops grown at ground level, such as leafy greens or cantaloupe melons, would be at greater risk than fruit growing on a tree. Growers must exercise good judgment and common sense in the application of organic fertilizers.
The feces of animals and humans may contain pathogens that pose significant food safety risks that must be controlled through appropriate treatments.

The survival of pathogens in soil or in compost are influenced by temperature, pH, water status, effectiveness of composting or other inactivating treatments, methods of application and tillage, type of crop and time.

Composting is a natural process in which bacteria or fungi decompose organic matter into stable humus than can be utilized by the plant.

Passive composting relies on natural conditions to gradually break down organic matter which requires a relatively long period of time.

Active composting involves the active manipulation of the environment to control and speed the composting process.

Safety of compost may be further enhanced by heat sterilization or by fumigation.

Microbiological analysis of compost is recommended to ensure that the process has been effective for the inactivation of microbes.

The accepted standard for microbial quality is to reduce the population of fecal coliforms to <1,000 MPN / gram and Salmonella to <3 MPN / 4 grams.

A detailed GAP program should be implemented for the manufacture, storage and application of compost.

GAPs should include steps to ensure that contamination from compost is not transferred to sources of water or to production fields.

SSOPs should be developed for compost manufacture and handling. Record keeping of all steps in compost operations is an essential component of SSOPs.

SSOP and Record Keeping

Individuals or companies that practice composting should have detailed SSOP for each part of the process. Record keeping is a critical component of the SSOP. Following are a few examples of essential records. Depending on the specific operation additional records may be required.

The origin, composition and amount of organic material must be noted. If different types or sources of waste are utilized all of these data must be recorded. The specific method of treatment must be identified along with the location of the facility and dates that the treatment was initiated and terminated. If an active composting treatment is used the dates of turning the material are recorded. Times and temperatures are logged periodically throughout the process. Any unusual event occurring during treatment or storage, such as flooding, must be recorded. Results of microbiological analyses and the service laboratory providing the results should be available. Finally, the person managing the operation and contact information for the responsible individual should be stated on all record sheets.

If purchasing compost from a supplier, all of the above record-keeping should be presented in a Certificate of Analysis (COA) provided at the time of delivery and copies maintained by the grower for at least three years.

Summary

Fertilizers are natural or synthetic substances that provide nutrients that are necessary for plant growth and development.

Inorganic fertilizers are, in most cases, salts that are produced by commercial synthetic processes and pose relatively low food safety risks to crops.

Organic fertilizers are naturally occurring substances derived from manure, compost, cover crops, biosolids or waste from packing or processing operations.

Organic fertilizers offer many advantages when properly treated to reduce or eliminate food safety risks.

The use of manure and compost teas, although discouraged, is popular with some organic and conventional producers. The same precautions that exist for dry compost application should be exercised with even more stringency for the application of teas.
Introduction

In fresh produce operations the term “pest” applies to all organisms that negatively impact the quality and safety of produce, directly or indirectly. Animal pests that present food safety hazards during crop production are the primary concern for this Module. Pest control for postharvest facilities is covered in Section III.

All animals including mammals, birds, reptiles, amphibians and invertebrates (insects, slugs, snails, etc.) are considered potential sources or vehicles for contamination of fresh produce with pathogens. Their surfaces, e.g. hair, feathers, skin, and mouthparts can harbor large numbers of pathogens, which may also reside internally in their respiratory and gastrointestinal systems. Exclusion of animals from production areas is the only effective means of eliminating these hazards but this is not a realistic expectation. Minimizing risk by limiting intrusion is a practical goal but still difficult to achieve consistently.

Non-crop vegetation and dense weeds may also represent a hazard as they provide habitat and likely harbor insects, birds and vermin. Farmers deal with these pests more in the context of the limitations they place on productivity and quality rather than as food safety hazards. Chemical controls (pesticides) are addressed in Section IV.

Hazards Commonly Associated with Animals

Feces are considered the major source of pathogenic microorganisms from animals. Microbiological hazards associated with feces are discussed in detail in various Sections throughout this manual.

Some bacteria are commonly associated with animal skin. These include Salmonella, Staphylococcus and Streptococcus. Chickens and other domestic birds may harbor these pathogens on their feathers. Wild birds, reptiles and amphibians are common carriers of Salmonella, which has been isolated from these animals in numerous scientific investigations. Animals also can carry more opportunistic pathogens (typically not as serious as E. coli O157:H7, Shigella and Salmonella) and spoilage microorganisms. These reduce the quality and shelf life of fresh produce by causing decay.

Workers who handle animals must practice personal hygiene and clean their clothes and footwear before they work in fruit and vegetable fields or in packinghouses to avoid contaminating the product. It also is important to recognize that animal handlers are at direct risk of contaminating themselves. In commercial animal production some diseases have been identified as occupational illnesses because of the exposure that workers have on a daily basis. Illnesses have occurred in people who touch animals in petting zoos or other settings and then touch their food or mouths without washing their hands properly.

Physical damage inflicted by animals to the surface of fruits and vegetables immediately reduces quality. The damage also serves as a point of entry for human pathogens and spoilage microorganisms which multiply readily on the nutrients available from within the product. It is clear that GAP for the production and handling of fresh produce must include steps for the exclusion of animals from the environment.

Entry and Distribution of Pathogens in the Food Supply

This graphic illustrates several ways that contamination from the feces of animals can reach food and then be spread though the food handling system (modified from Beuchat, 1996).

[Diagram showing the entry and distribution of pathogens from animals to humans, including pathways through feces, insects, soil, water, plants, and feed to humans through meat, milk, and eggs.]
Feces from humans and domestic or wild animals can contaminate the soil, water or be carried by insects. These are indirect routes to the contamination of produce. Insect vectors and birds are a special concern because of their mobility. They may feed on feces, animal feed stockpiles, or on contaminated produce and carry pathogens to any point in the harvesting, handling or processing environment.

A direct route also exists from feces to produce if the feces are deposited directly on the product by wild animals or birds in the field. There has been at least one suspected case of wild hogs having directly or indirectly acquiring *E. coli* O157:H7 from close interactions with cattle. This in turn contaminated the feces of the hogs before they deposited their own feces in produce fields. Another example is rodents that carry zoonotic pathogens from chicken houses to adjacent crops.

In a food preparation context, cross contamination of produce can occur with improper handling of meat, milk or eggs. Outbreaks of illness have been associated with this type of cross contamination occurring in restaurants, as well as with wholesale distributors that improperly store or co-mingle food products.

Ultimately, if the contaminated produce is eaten by humans, an outbreak of illness can be the result. Other scenarios for the spread of contamination certainly exist, but this graphic is a clear depiction of known risks associated with indirect or direct contact between animals and food.

The most critical principle of GAP is clearly illustrated in the above discussion. Prevention of contamination is essential for the assurance of food safety. Once pathogens have entered the food handling chain there is little that can be done, short of cooking, to eliminate the risk.

**Classification of Animal Hazards**

Some animals pose greater risks than others. Formal risk analysis is beyond the scope of this Module, but we can make some classification of animals based on their potential for being reservoirs or carriers or pathogens, as follows:

**Primary reservoirs** include cattle, deer, and pigs. Animals in this group have a very high likelihood of carrying pathogens of high concern internally and special effort should be made to exclude them from fruit and vegetable production areas. Calves in particular are known to shed pathogens with their feces at a relatively high rate.

**Secondary reservoirs** include horses, goats, sheep, cats, dogs, rabbits, rats, gulls, geese and other birds. Animals in this group perhaps pose less risk than the primary reservoirs. Larger domestic animals can be excluded and the smaller ones should be excluded from fields to the extent possible.

**Transient carriers** are those animals that do not have resident populations of a pathogen and are not commonly infected but may carry a pathogen in or on their bodies. Almost any animal, including humans, can be considered a transient carrier.

**Mechanical vectors** are animals that seldom are infected with pathogens but if exposed to contamination they can physically move it to another host. Slugs, nematodes, insects and Canada geese are examples of demonstrated mechanical vectors.

**Animal Control and Exclusion**

There are several methods for controlling animal and other pest incursions. None of them are completely effective but they all decrease the risk to varying degrees.

The direct control of animal populations by depredation (killing) is an option in some specific cases. Controlled hunting of hogs, deer and other wild animals may be permitted in some locations. The use of chemical controls such as baits or poisons may also be an option, but be aware that some animals, particularly rodents, can carry poison baits to fields or packing areas, potentially exposing produce to the chemical hazard. Growers must be aware of local regulations governing the elimination of animals before exercising any of these methods. Dispose of dead or trapped animals promptly to avoid attracting other animals to the area.

Fields and surrounding areas should be kept clean and free of garbage that will attract any type of animal pest in the area. Workers who eat near fields must be provided a means for disposal of food garbage and they must be trained to follow company protocols for taking breaks and disposing of garbage. Do not leave unused equipment, trailers, etc. around fields so that animals can seek shelter under such items.

Evaluation of the need to remove harborage areas around fields is recommended. The environmental impact of such measures should be considered as it influences run-off, etc. Many crops are grown in close proximity to wildlife habitat. Buffer zones around the field from which
Vegetation is removed can help discourage animals from making a home next door to the field. The effectiveness and necessity of this practice or the extent of vegetation removal is highly dependent on the type and natural behavior of animals in the area. Recent research is beginning to bring the practice of wide plant-free buffer zones into question. For example, some rodents don’t venture into crops in close proximity to their natural habitat and others are not deterred from crop intrusion by plant-free zones. Small isolated fields, shown below, may be at greater risk for animal incursion than other areas because there might be less human and machine traffic that would discourage animal entry. In addition, as represented in the graphic, fields that are positioned between habitat and a water source may become a corridor for animal traffic.

Deterrent devices are available commercially and some can be constructed by the grower. Propane cannons can be set to automatically discharge at a particular frequency to scare birds. Farmers are creative in the construction of scarecrows to mimic the presence of a person in the field. Unfortunately these methods lose their effectiveness after birds or other animals become accustomed to the noise or the presence of a scarecrow that cannot move about the field.

Some growers utilize domestic animals (dogs) to deter wild animals. Though this may be effective, most third-party auditing services will consider the presence of a domestic animal an immediate food safety risk and use that as a basis for a failure of the audit. Inspectors from regulatory agencies also view this as a serious violation of GAP. It is recommended not to allow domestic animals in fields.

Animal exclusion is one of the most difficult tasks facing growers in their GAP programs. There is no easy solution because practically all control measures are temporary, primarily cosmetic, and may create other concerns such as with the use of poison bait stations. All animal control methods employed should be stated in the SSOP for the farm’s food safety program and must be documented.

Field Inspections

Frequent inspections of production areas are required to determine if exclusion methods are effective. Check the condition of fences, traps and bait stations. Non-poison bait (feeding) stations such as attractant-impregnated wax blocks may be used to monitor rodent presence and pattern of intrusions. Test deterrent devices to determine if they are working properly. Look for the presence of feces and for injury to the crop caused by feeding animals. Record the time and dates of inspections and keep these records in an appropriate location.
Summary

All animals are considered sources or vehicles for the contamination of fresh fruits and vegetables with pathogens.

Feces are considered the major source of pathogens associated with animals.

Workers who come in contact with animals must give special attention to personal hygiene before they work in fresh produce fields or handling facilities.

Animals are sources of spoilage microorganisms as well as human pathogens. Physical injury of products caused by animals is a point of entry for these microbes.

Once microbiological contamination has entered the food production or handling environment, it can be transmitted to humans in many different ways.

Prevention of this contamination is the key to an effective GAP program.

Different types of animals differ in the degree of risk they pose to fresh produce. However all animals should be excluded from the production and handling environment as much as reasonably possible.

Animal and pest incursion may be controlled by various methods, including elimination, trapping, baiting, poisoning, by the construction of fences and barriers or by the use of deterrent devices.

Growers must be aware of local regulations governing animal control practices before implementing any method.

Fields and surrounding areas should be clean and free of food waste. Harborage areas should be reduced to the extent possible without causing environmental concerns.

Domestic animals should not be permitted in production and handling areas.

Frequent inspections of fields should be conducted and records kept of the inspections.
Introduction

The responsibility for reducing or avoiding contamination during primary production falls heavily on agricultural workers. Healthy people are more productive than those that are ill and are less likely to contaminate food and fellow workers. Numerous food safety hazards are identified throughout this manual, but ultimately it is the people who work with food that are the key to the assurance of food safety. This Module focuses on personnel and their role in the prevention of illness.

Hazards Associated with Personnel Practices

There are numerous routes for the transmission of disease. Sick or infected people can infect other persons directly through personal contact. They may also contaminate objects with their hands, such as a doorknob or money, which are then touched by others who become infected. When infected or ill persons touch food or food contact surfaces, the risk of causing illness in consumers is dramatically increased. Outbreak investigations have shown that just one identified infected person handling food has caused regional and multi-illnesses due to distribution and consumption of the contaminated product.

People themselves can be hazards. There are several pathogens for which humans are the only reservoir. Categories of biological hazards identified in Section I included bacteria, viruses and parasites. Each of these groups contains pathogens that reside, only infect, or must reproduce in people. Bacterial pathogens specific to humans include Shigella and Salmonella typhi. Viral pathogens include hepatitis virus A and Norovirus. One parasite, Cyclospora, is believed to be sourced from humans although the research is still preliminary. Any pathogen from any source may potentially be transmitted by people once contact is made.

Employees who feel sick should be trained and encouraged to report their condition to their supervisor. Workers may be reluctant to report illness because if they are not working they may not be paid. Managers should be trained to recognize the obvious symptoms of illness and they must be vigilant in the detection of employees who may be ill. Workers who are experiencing diarrhea, vomiting, dizziness, abdominal cramps, jaundice or who have open or exposed wounds or sores should not be allowed to perform tasks in which they contact food or food-contact surfaces. Employees who make frequent trips to the toilet or exhibit any other behavior indicative of illness should be questioned about their health. Frequent absenteeism may also be an indicator of illness. Detection of ill workers is an extremely important component of a GAP program.

Some pathogens can infect people without causing illness. These carriers of the pathogen who do not show symptoms (asymptomatic) may still have the capacity to shed the microorganisms that directly or indirectly find their way onto food. Controlling the spread from asymptomatic carriers is very difficult because even they do not know they are infected.

There are two specific considerations for personal hygiene that are of critical importance. First, the fecal-oral route of transmission of pathogens must be interrupted. Second, proper handwashing is essential in order to prevent the transfer of pathogens. All other components of GAP are important, but food industries cannot achieve the goal of food safety assurance if they fail to focus adequate attention on these two concerns. The health and hygiene of workers is critical for success.

Health Care for Workers

Ideally agricultural workers should have access to a preventative health care system. Once an employee is diagnosed with illness, he or she should not be allowed to return to work until they have clearance from a licensed healthcare worker. Unfortunately we do not live in an ideal world and the exclusion of sick employees from the workplace remains a significant challenge for managers.

A first aid kit with supplies for treating injuries should be readily available at the work site. The kit should contain at a minimum, adhesive bandages for small injuries, other larger bandaging supplies, hydrogen peroxide and disposable gloves. The simple procedures for cleaning,
something other than their assigned tasks, handwashing is required.

Visitors to the fields or handling facilities, including produce inspectors or buyers, should follow the established hygiene and safety practices. Managers in particular should follow all practices to set an appropriate example for the workers. Signs describing appropriate handwashing procedures, using clear graphic icons to accommodate language or literacy issues, should be placed in strategic locations such as near toilets or at the entrance to a restricted work area as a reminder to everyone.

In order to facilitate proper handwashing, potable water, soap and single-use paper towels must be provided for all employees and visitors. Stand-alone handwashing stations located in convenient areas in the fields and packinghouses will encourage use. Handwashing policies are useless without the resources to implement the practices.

In addition to handwashing workers should bathe regularly, wear clean clothes, keep their fingernails short and clean, and use hairnets if the company policy requires them. In the same way that dirty hands can result in product contamination, so can dirty clothes and an unclean body.

Several tools are available to trainers to demonstrate the consequences of poor personal hygiene. The Glow-Germ demonstration is recommended for the classroom because it is simple and provides a quick result for the class to see. This involves placing a harmless powder or lotion on the hands and asking the participants to rinse or wash for varying lengths of time. The material that is not removed is visible under the “black light”. Residue on doorknobs or clothing can also be observed.

Gloves

Glove use generally is not mandatory or necessarily better than bare hands in agricultural production operations. If a company determines that gloves should be used by some specific workers, it should specify the policy in the SSOP and take steps to ensure compliance. If the company has a policy and the practice is not implemented, auditors and inspectors will note this as a serious deficiency in the GAP program.

Gloves are not a substitute for proper hand washing and other hygienic practices. This must be clearly understood by workers and supervisors. Hands should be thoroughly washed before putting on gloves. When properly used, gloves are an effective means of preventing contamination
of food and protecting employees. However gloves can be a means of spreading contamination if they are not changed or disinfected after a potential contamination.

If gloves are used, the disposable kind (plastic, latex, etc.) are better than multiple use gloves since frequent replacement of gloves can help assure cleanliness and reduce the potential for growth of microorganisms on wet or dirty gloves. Gloves should be changed any time that bare hands would be washed. This includes after using the restroom, smoking or eating, taking a break, covering coughs or sneezes, touching skin or wounds, touching floors or other dirty surfaces or equipment, or handling cleaning materials or agricultural chemicals.

**Sanitary Field Stations**

Historically agricultural field workers did not have access to toilet facilities. They simply had to find a location within or near the fields, perhaps with some privacy or perhaps not. Obviously if there were no toilets there also were no handwashing facilities.

Today in practically all developed countries there are laws that require that toilets be made available to workers. The number of toilets must be adequate for the number of workers in the field. Generally the rule is that there must be at least one toilet for each 20 workers of the same sex. If male and female workers are present in the same work area toilets should be designated by gender.

Toilets must be accessible to personnel, within 400 meters (1,300 feet) or less than a 5 minute walk from the work site. The more accessible the toilets are, the more likely that workers will use them. Access should be permitted at any time a worker needs to use them, not just during break periods.

Toilets should not be positioned within the production area. Although there are no laws stating the distance from the production field, some third-party auditing firms stipulate that the distance must be at least 50 feet from cultivated plants.

Toilets should be cleaned regularly and be supplied with hygienic (toilet) paper. Workers should be trained to deposit used paper inside the toilet and not on the floor where it might be inadvertently transferred into the field. Records of cleaning and replenishment of toilet supplies must be kept. Workers are more likely to use a facility that has been serviced than one that is dirty. All workers should be trained to report dirty facilities to the person in charge of having them cleaned.

Most audit guidelines stipulate that the presence of toilet paper or human feces in or around a production field results in an automatic failure of the audit. Inspectors from regulatory agencies also view this as a serious violation of GAP. Managers must inspect fields and the perimeter for signs of non-compliance with these rules. Evidence of non-compliance should be cause for an immediate training session for the workers.

Toilets should be constructed in a manner that does not pose a risk for contamination of the field or nearby water supplies. It is recommended that they be positioned not less than 400 meters (1,300 feet) from sources of agricultural water, e.g. wells, canals, reservoirs, etc. This is a particularly difficult recommendation to comply with when fields are relatively small and surrounded by canals for furrow irrigation.

Portable toilets should be positioned so that trucks that service the units have easy access and present low risk for contaminating the crop. Ideally the servicing of portable units would be conducted away from the fields to reduce the risk of contaminating soil, water or workers in the event of spillage. Training for procedures employed for responding to accidental spills, including the company policy for limiting contact with impacted areas, should be stated in the SSOP. All training must be documented.

Permanent toilets should be connected to suitable septic drainage system, discussed earlier in Module 2 on Agricultural Water.

Toilets should be accompanied by hand wash stations. These should be supplied as described earlier. Water used for handwashing (gray water) should be captured and disposed of away from the production area. Tanker trucks or other containers used to transport water to the field station should be emptied periodically, preferably daily, and cleaned and disinfected to reduce the possibility for the formation of biofilms on the interior surfaces of water tanks or the plumbing system.

Appropriate signage instructing workers on proper sanitation in the field should be placed in strategic locations to remind personnel of these important practices. The signs on the following page were developed by the National GAPs Program in the U.S. In addition to signage and frequent training, many companies have found it useful to station full time workers near the sanitary facilities.
All three groups of microbiological hazards discussed earlier (bacteria, viruses and parasites) have been associated with contaminated water. Bacterial pathogens have included E. coli O157:H7, other pathogenic or toxigenic E. coli, Salmonella, Listeria, Campylobacter and Shigella species. Viruses have included Hepatitis virus A and norovirus. Parasites include Giardia lamblia, Cryptosporidium and Cyclospora cayetanensis. The presence of any of these microorganisms, with the exception of Listeria, generally is an indication that fecal contamination has occurred.

The three most common sources of drinking water in descending order of risk are: treated surface water that comes from rivers, canals, lakes reservoirs, etc.; ground water from below the surface, including wells that require pumping or springs from which water flows naturally to the surface, and; municipal water from a city water treatment facility. Municipal water is preferred over other sources, but water from practically any source can be treated to make it potable.

It is beyond the scope of this Manual to discuss all of the treatment strategies to make potable water. Various methods are available to remove organic and inorganic contaminants but filtration followed by disinfection are perhaps the most common practices. Filtration media include sand, diatomaceous earth, and membranes of various designs. Disinfection methods include chlorine, chlorine dioxide, ozone and ultraviolet light. Each of the methods listed has some limitations. For example, generally acceptable levels of chlorine disinfectants are not effective

to replenish supplies throughout the day and to remind workers that they must comply with GAP.

**Drinking Water**

Companies have a moral, ethical, and in most countries, a legal obligation to provide workers with a safe supply of drinking water. Workers with access to water are less likely to suffer heat exhaustion or develop other illnesses that could lead to contamination of fresh produce.

Water for human consumption must be potable, i.e. free of microorganisms or chemical contaminants that can jeopardize the health of the person drinking the water. Standards for potable water quality have been established in most countries. The microbiological standard is that a test of 100 ml of water must confirm that no fecal coliforms or E. coli are present. Chemical standards vary with location and typically a maximum allowable limit is set for specific chemicals.

Coliform bacteria are present in the environment and are not normally harmful. However, if a total coliform test reveals that one or more coliforms are present in 100 ml of drinking water, additional testing should be conducted to determine the source of the contamination and the effectiveness of the treatment process to purify the water for human consumption. A thorough inspection of the water source, treatment method and distribution system should be conducted periodically to identify potential sources of contamination with documentation of the inspection.
against *Cryptosporidium* which has been implicated in some outbreaks of illness associated with the consumption of fresh produce. Ozone is very effective against *Cryptosporidium* but has no residual effectiveness in a water distribution system. Boiling is an effective method for killing microorganisms but it may not have an effect on chemical contaminants.

Ideally, drinking water would be treated immediately before consumption. There are different systems available that employ chlorine or ozone injection, ultraviolet light or micro filtration. In a field setting it may not be practical to utilize equipment of this nature.

The efficacy of any method or combination of methods must be verified by microbiological testing before the water is made available for human consumption.

Once water has been treated and the potable quality has been verified, additional precautions must be taken to ensure that re-contamination does not occur. Frequent monitoring is required to verify that the water supply, treatment processes and distribution systems are in good working order and functioning properly. Water storage or transport tanks or other containers should be cleaned and sanitized frequently, ideally on a daily basis. They should be closed at all times and stored out of the sunlight or excessive heat. Disposable cups should be provided and each worker should use a different cup.

Records must be kept of microbiological or physical evaluations of drinking water. Simple sensory evaluations (color, odor and taste) should be conducted on a daily basis. Any unusual observation requires that water be discarded and replaced with a suitable supply. If the water is sourced from a municipal supply, authorities should be notified of the irregularity.

**Worker Hygiene Training Program**

Employers can provide training and other resources to educate workers, but in the end, the effectiveness of the program relies on the workers’ understanding and implementation of personal hygiene and safety practices. The quality of the overall food safety program is related directly to the quality of the worker training program and the value that workers place on the training provided.

Management must provide workers with information about acceptable practices, ensure that the information is understood and set an example for workers to follow so the importance of the practices is clear for all personnel. An SSOP should be developed for worker training that includes a detailed description of the behavior that is expected of all employees and the benefit to them personally.

All employees including supervisors and full-time, part-time and temporary personnel should participate in the training program. Commitment of managers and other company administrators to GAPs is essential in order for employees to fully understand the importance and participate willingly in the GAP program.

The level of knowledge required should be set according to the type of operation, responsibilities and type of activities in which the employee participates. Demonstrations of procedures are usually more effective than verbal instructions. Pictorial training for critical steps may be essential where language is a barrier.

Training should be in the language or dialect of the employees to ensure comprehension. Trainers should be sensitive to cultural aversions and ingrained practices when planning and delivering a training session and find an appropriate way to overcome these obstacles. Worker training is a challenging exercise but it is essential to an effective GAP program.

Training should be reinforced on a regular basis. Managers must be observant of the day to day practices of workers and conduct refresher trainings any time the need arises. Such training may be directed to an individual or to a group of workers who have similar responsibilities.

Records of all training activities should be kept. Workers who participate in training should sign a dated record sheet that is kept in an appropriate location. Third party auditors and representatives of regulatory agencies routinely ask to inspect training records.

**Summary**

The health and hygienic practices of employees is one of the most critical components of GAP because of the capacity for workers to transmit pathogens to other workers.

Proper handwashing must be practiced by all employees in a fresh produce operation.

Workers who are ill should be excluded from tasks that require them to touch food or food contact surfaces.

Workers who are ill should report their condition to their supervisor. Managers should be familiar with the obvious
If necessary, full time workers may be stationed near field sanitation units to ensure that workers comply with company policy for personal hygiene.

Companies are obligated to provide workers with an adequate supply of potable water for drinking.

The microbiological quality of drinking water should be verified by testing.

The possibility of produce contamination is related directly to the quality of the worker training program, the availability of resources to practice proper hygiene, and the employees’ acceptance of the importance of their actions.

An SSOP should be developed for worker training that includes a detailed description of proper hygienic practices.

Symptoms of illness and question workers who exhibit symptoms.

Ideally agricultural workers should have access to a health care system, should be familiar with first aid for minor injuries and should have access to first aid kits.

Every company should establish a glove use policy in their SSOP and take steps to ensure compliance with the policy.

Gloves and hand sanitizers are not substitutes for proper handwashing practice.

Workers should bathe regularly, wear clean clothes, correctly use toilet facilities, keep their fingernails short and clean, and use hairnets if the company policy requires them.

Training in the above practices should be conducted at the time of hire and frequent reinforcement training conducted thereafter.

Records of training and other critical health and hygiene practices must be kept.

In general, any time workers use their hands for something other than their assigned tasks they should wash their hands.

Visual aids and demonstrations are more effective training tools than simple explanations.

Managers and visitors to fields and facilities must practice the same personal hygiene steps that are expected of workers.

Workers must use sanitary field stations. The presence of human feces in or near a production field is reason for failure of a third-party audit and is viewed by regulatory inspectors as a serious violation of GAP.

Toilets must be conveniently accessible to workers. Toilets must be clean and supplied with hygienic (toilet) paper.

Hand wash stations must be near toilet facilities and must be supplied with potable water, soap, paper towels and a receptacle for disposal of towels.

Portable toilets must be cleaned and handled in a manner that does not pose a risk for contamination of the crop, field or workers. Permanent toilets must be connected to a proper septic system.

Signage for toilet use and handwashing policy should be strategically located.
Good Manufacturing Practices for Harvesting and Handling Fresh Produce

Module 1  Harvesting
Module 2  Cooling
Module 3  Produce Cleaning and Water Treatment
Module 4  Packing and Storage
Module 5  Transportation
Module 6  Facilities and Equipment Cleaning and Sanitation
Module 7  Development of Sanitation Standard Operating Procedures
Introduction

Harvesting of fresh produce represents the transition from GAP to GMP. At the moment when a fruit or vegetable is detached from the plant, production has been completed and the manufacture of the finished product has begun. The finished product may simply be a packed carton or it may consist of any number of handling, trimming, bunching, and postharvest or packaging treatments to complete an item that is ready for shipping.

For clarification, the USDA and some commodity groups have developed harvesting and handling food safety guidelines that are entitled Good Handling Practices (GHP). These are largely based upon the GMP criteria defined by the FDA and others with some modification to apply to fresh produce. For the sake of simplicity, the term GMP is used here with the understanding that GHP is an equally valid and perhaps more appropriate term for some postharvest practices.

Microbiological contamination can occur during the harvest operation. Contamination may be introduced by workers, from the soil, from harvest equipment such as knives or clippers, from field containers or harvest-aid surfaces, during field-side accumulation or staging, or from transport vehicles. The first step in developing a food safety program for harvest operations is to review the process and identify potential safety hazards.

The principle of preventing contamination is the key to minimizing food safety risk. It should not be expected that remedial actions such as washing will eliminate contamination that may occur at harvest. A comprehensive set of Sanitation Standard Operating Procedures (SSOP) must be developed that are specific to the harvest operation. Effective training of all personnel involved in harvesting is essential. The development of SSOP is discussed in Module 7 of this Section.

Worker Health and Hygiene

Good worker hygiene is critical to a food safety program for harvest operations, especially for products that are harvested manually, because every fruit or vegetable is touched by human hands. The specifics of personal hygiene are discussed in detail elsewhere in this manual. It is important to re-emphasize the importance here and to restate that personnel practices should be thoroughly addressed in the SSOP for harvest operations. Here is a review of some essential points, as well as some harvest-specific practices.

Toilets and handwashing facilities must be provided in a manner that meets or exceeds relevant laws. Even if no laws exist, they must be provided as part of any effective food safety program. Eating, drinking beverages other than water, smoking, spitting, etc., must not be allowed in the workplace. Worker training that addresses proper behavior is essential and periodic reinforcement training is necessary. Training must be documented. If gloves are used, there must be a formal written policy. Workers who are required to stand inside bins or gondolas should wear appropriate disposable shoe coverings or dedicated footwear (rubber boots) that is cleaned and sanitized regularly.

Children under the age of 13 are not permitted in fields under any circumstances. The presence of any child in diapers compromises the rule of absolutely no human feces in the field. Further, a worker who changes the child’s diaper will have a high probability of contaminated hands. Most third-party auditing companies will give an automatic failure to an operation if a young child is present in the field.

Worker health can be critical to the safety of the product. Managers must be vigilant in observing the work force and taking note if someone has a chronic cough or is visiting the toilet frequently. Any worker who appears to have an illness or injury that could lead to contamination of the product should not be allowed to perform a task that requires them to have direct contact with the product or any food-contact surface, including packaging materials.

Harvest Methods

Generally there are two methods of harvesting: manual and mechanical. The choice of harvesting method depends largely upon the characteristics of the commodity and the market. The general principles of GMP, often modified for
raw agricultural commodities in the form of GHP, apply to any method but there will be some unique requirements for food safety depending on the method.

Manual harvesting simply means that the product is separated from the plant or removed from the growth media (soil) by the hands of a harvest worker. This technique is employed for delicate commodities such as strawberries or grapes and for commodities that may naturally separate from the plant at maturity, such as most cantaloupes. For these products there is no substitute for human hands and eyes for the selection and careful handling that is required. Many fruits and vegetables are harvested by hand but with the use of an implement such as a knife, clippers or prong.

There is an adage that the hands of the harvest worker are the most important hands that ever touch the product. In the second that it takes a harvest worker to drop product on the ground or throw it roughly into a field container, all of the investment in farming has been lost. Proper training of harvest workers to protect the integrity of product is essential to the profitability of a company and to the safety of the product.

Mechanical harvesting means that a machine is utilized to detach the fruit or vegetable from the plant. In general, mechanical harvesters are more likely to cause injuries to a product than manual harvesting. Products that can withstand some rough handling, such as carrots, potatoes or radishes, are best suited for mechanical harvest. More recently, mechanical harvesters have been developed for blueberries and citrus. Mechanical harvest aids also may be employed to perform specific tasks in the operation. There are numerous examples of products that may be harvested either manually or mechanically, such as leafy greens, celery, and blueberries. Typically, products that are harvested mechanically are further handled by machines so that there may be little or no contact between the product and the hands of workers.

Mechanical harvesting has its own set of GMP considerations. The SSOP for mechanical harvesting must include a rigorous program for the cleaning and sanitation of the harvest machine. Once a machine becomes contaminated it can spread the contamination throughout the field and onto the harvested product.

Field Packing

Some produce is packed in the field directly into the final shipping unit. This may be done with or without some form of washing or other cleaning step. This practice is called field packing. In field packing, the finished product may be manufactured directly by the harvest worker at the ground level as is often the case with strawberries. In a typical strawberry operation, the harvest worker picks the fruit and places them in a small basket or clam shell container that is intended for retail sale. These retail containers are positioned in cartons, which are ready to be palletized. The worker harvests, selects for quality and packs in a single operation. When this process is complete the fruit will receive no further contact with human hands. Other workers on a truck or trailer may palletize the cartons.

In other field packing operations, such as for melons, broccoli, celery or cauliflower, workers walking through the field pull the melons from the vine or cut the other products from the plant with knives. Commodities typically are placed on some type of machine that is passing through the field with the harvest crew. The packing process is conducted by workers on this field pack machine. The fruit or vegetable might be packed in a carton naked or it might receive a plastic over-wrap prior to being place-packed in a carton. The finished carton typically is palletized in the field.

A final example of field packing involves products that are harvested, tossed into trailers or wagons, and transported to an area near the field where they may be further handled and packed. Cabbage is a good example. Workers cut the heads with knives, trim the soiled outer leaves and toss the heads into a trailer. At the packing station, cabbage heads are unloaded from the trailer, outer leaves are further trimmed, heads are sorted for size and quality, and place-packed into cartons for palletizing.

There is debate within the produce industries and public agencies about the relative safety of field packing versus the use of a packinghouse where sanitizing treatments may be applied. An example of this is the tomato industry in the State of Florida, where field packing is now specifically prohibited unless a sanitizing step is included in the field operation. All tomatoes must be taken to a packinghouse and washed or rinsed with water containing an approved sanitizer. The relative risks are not clear regarding the exposure of tomatoes to water versus packing the product dry and relying on consumers to wash the tomatoes at the point of use. Risks associated with water are addressed later in Module III of this Section.
Risk Factors in Harvest Operations

Methods employed in the harvest process vary widely and food safety risks are present in all systems. All of the previous examples of harvest operations have common issues for food safety that must be properly addressed in their specific SSOP following a thorough evaluation to identify unique hazards. It is impossible to cover every scenario, but several common harvest elements are highlighted below.

Equipment sanitation is sometimes overlooked in harvest operations. There must be a well-defined process and schedule (SSOP) for cleaning and sanitizing all field equipment, including but not limited to cutting tools, buckets, bins, trailers, field pack machinery and any other harvest aid or accessory. All food contact surfaces should be clean and free of visible soil, oil, grease or chemical contaminants. Some traditional food contact surfaces are very hard to clean. Sanitation verification methods are discussed in Module 6 of this Section.

Microbes have the capacity to attach themselves to surfaces through the production of certain chemicals, resulting in the formation of biofilms. In very simple terms, biofilms might be considered analogous to biological “glue” that holds a pathogen on the surface and interferes with the cleaning and disinfection of the product surface. Biofilms are discussed further in Module 6.

Field sanitation should be reviewed frequently. Prior to the initiation of harvest, a manager should inspect the fields for the presence of animals or indications that animals have been present. The presence of animal tracks, feces or indications that animals have fed on the crop requires that this area of the field be clearly marked and that workers be instructed not to enter the marked area. Obviously no product should be harvested from the area. Domestic animals are not permitted in fields. Garbage or any debris that might attract or harbor animal pests should be removed.

Contact with the soil can directly transfer soilborne microorganisms to the product or to equipment surfaces. Avoid direct contact of finished product containers, cartons, bins, reusable plastic containers (RPC), etc., with the soil. Harvested products that are dropped onto the soil should not be picked up and packed. This requirement is rather difficult to enforce and requires emphasis during worker training. Since many products grow in contact with the soil (melons, cucumbers) and others do not (staked tomatoes, tree fruits), workers may find it difficult to understand why the requirement exists.

Field transportation is another risk factor. Field vehicles, including trucks, tractors, trailers and gondolas, used for fruits and vegetables should never be used for the transport of animals or animal products, manure in particular. This could lead to cross contamination of the produce. If a farm has animal production in addition to fresh produce production, trucks and tractors that are used in animal enclosures may transfer contamination to the produce field. There should be a SSOP for the cleaning and sanitizing of field vehicles.

Temporary storage areas often are needed near the field for harvest containers, RPC, cartons and other harvest materials. The storage area should be clean and free of any materials that are not needed for the harvest operation. An appropriate pest control program should be in place to deter entry of animals, insects, etc.

Decayed or damaged product poses an increased risk for the growth of human pathogens. Research has demonstrated relationships between some plant pathogens and human pathogens. A fruit or vegetable that has been exposed to a plant pathogen may be more susceptible to subsequent infection by a human pathogen, which can grow more readily in conjunction with the decay-causing microorganism. A specific example of this relationship is found with species of *Pseudomonas*, a decay-causing microbe, and *Salmonella*, a human pathogen. Additional work has shown that the presence of *Erwinia* decay can increase the likelihood that *Salmonella* will be present.

Harvest workers should avoid handling product with decay, especially fruit, and leave any rotten or damaged product in the field. They also should take care not to inflict rough handling injury to the produce. Bruises, fingernail punctures, cuts and scrapes create a point of entry for human pathogens and for decay-causing microorganisms. Further, damaged produce has increased rates of respiration and ethylene production that shortens its quality shelf-life.

In the instant that it takes a harvest worker to damage the product, all of the investment in production is lost. All of the above examples reinforce the basic concept that prevention of contamination is favored over the expectation that remedial cleaning or washing treatments can remove contamination. Harvest workers often are working in a hot, unpleasant environment and may be paid for piece work rather than hourly. They are motivated to move quickly to increase their earnings so proper training of workers...
and vigilance of field managers is necessary to ensure that workers are adhering to the food safety program. Quality inspections of product in the field or at the packing facility should be communicated back to the harvest foreman and reinforcement training of workers should be conducted as needed.

**Conclusion**

In general, harvest practices that enhance the safety of the product will also enhance the product quality and thus increase profitability. During training of workers and managers, it is appropriate to emphasize that food safety is good for business. A safe, high quality product requires attention to all harvest details and implementation of food safety practices at each step.

**Summary**

Conduct a review of harvest operations to identify potential risk factors.

Develop and implement detailed SSOP specific to those processes that can increase risk.

Emphasize worker health and hygiene. Conduct a comprehensive training program for new employees and conduct frequent refresher trainings to re-emphasize concepts.

Inspect fields for potential sources of contamination and correct any deficiencies.

Clean and sanitize all tools, equipment and vehicles.

Keep records of all activities specified by the SSOP.
Introduction

Cooling is an essential process for almost all fruits and vegetables unless they are intended for marketing directly from the field in local markets. It offers a number of benefits for perishable commodities. Cooling improves the shelf life and helps preserve quality by reducing the rates of respiration, ethylene production, water loss and spoilage caused by plant pathogens. It also limits the growth of some human pathogens, thus proper cooling is a strategy for helping to ensure the safety and quality of fresh produce.

Pre-Cooling

Pre-cooling is a term used to describe the rapid removal of field heat from produce soon after harvest. At the time of harvest, the temperature of the product usually is near or slightly above the ambient temperature in the field. Once the product is detached from the plant, water movement from the plant through the fruit or vegetable ceases and heat energy begins to accumulate as a result of exposure to the sun as well as from the heat of respiration in the living tissues. Rapid cooling usually enhances quality and safety both. There are exceptions, such as some varieties of apples or onions, which may have better storage and shipping characteristics if they are allowed to lose some water. The target temperature for pre-cooling depends upon the type of commodity and its specific temperature requirements. A number of different methods are utilized for cooling. It is important to describe these in order to identify the food safety practices that apply to each.

Cooling Methods

Room Cooling

This is the simplest and slowest of all methods. Produce is simply placed in a cold chamber and heat energy from within the product is transferred to surrounding air. The rate of cooling can be increased by increasing the flow of air around the product. Various types of air jets and fan configurations have been employed to facilitate increased air movement. Apples are typically cooled in this manner since rapid cooling is not critical for this fruit. A drawback to this method is that during busy shipping times the product may not have cooled sufficiently for loading into trucks. The risk of loading and shipping warm product is discussed in Module 6 on Transportation.

Forced-Air Cooling

This method also requires that product be placed in a cold chamber, but fans, tarpaulins and a system of air ducts serve to force the cold air directly through the containers of produce. The moving air causes the rapid transfer of heat energy from the product into the air stream. Heat is then removed from the air by the refrigeration system. A well designed forced-air unit might cool strawberries from the field temperature to 4°C in as little as 45 minutes compared to 12 hours or more in a passive room cooling situation. Forced-air cooling is especially suited to products that should not be exposed to water, such as berries or grapes. Common cold rooms can be adapted to forced-air cooling relatively inexpensively by constructing a duct or baffle system with a fan to pull air through a stack of product that is partially covered with a tarpaulin or other material to direct the air flow.

Vacuum Cooling

A sturdy airtight chamber is utilized to hold the product. The atmospheric pressure within the chamber is reduced by vacuum pumps, which causes the water inside the product to vaporize. As the water vapor is lost from the product surface evaporative cooling occurs. The technique is most effective for products that have a high surface to volume ratio such as leafy greens. The disadvantage for vacuum cooling is that with each decrease of 5-6°C in product temperature there is a loss of approximately 1% of the product weight, which is mostly water. Vacuum coolers can be very large in order to accommodate a rail-car load of product, but more commonly they are portable enough to be moved to different locations as needed.

Hydro-Vac Cooling

A standard vacuum cooling chamber is equipped with a system to deliver a fine mist of water onto the product. This offers two distinct advantages. The mist on the product surface contributes to the evaporative cooling effect and the amount of water lost from the product itself is reduced.
The water applied should be of potable quality and an appropriate sanitizer may be included.

**Hydro-Cooling**

Water is used as the medium to rapidly absorb heat energy from the product. Containers filled with produce may be placed on a conveyor in a flow-through system or simply placed in a batch type chamber. A large volume of cold water is pumped over the product to remove heat energy. The process is effective because a given weight (e.g., kilogram) of water can absorb more heat than an equal weight of air. This process is commonly employed for peaches, nectarines, asparagus, sweet corn and other commodities. Alternatively, commodities may be placed directly into a tank of cold water. Usually the water is pumped so that there is a flow toward a conveyor on the opposing side to remove product from the tank. This system has been employed for melons. It is an effective cooling method, but there are risks for food safety and strict adherence to water sanitation procedures are discussed in Module 3.

**Icing**

Ice may be applied directly to a product. Broccoli, sweet corn and green onions are examples of products that often are treated with slurry of ice and water pumped directly into the carton, which is made of wax-coated paper so that it does not break with the exposure to water. This is called package-icing. The penetration of ice into the carton of product is extensive so that cooling is rapid and thorough. Additionally, ice may be blown onto the top of pallets after they are loaded into a truck. This is called top-icing. Cooling facility operators are able to calculate the amount of ice needed for a given amount of product based on the product temperature. Ice should be made from potable water.

**Risk Factors in Cooling**

In all of the cooling methods noted, the two media that absorb heat energy from the product are air and water. Each of these presents specific concerns for food safety.

In the methods that utilize air (room cooling and forced-air cooling), the risk of microbiological contamination is relatively low. Obviously, air quality is of concern. Microorganisms can be present in the air on dust particles and in water droplets, which become vehicles for the transfer of microbes onto the produce. Ideally, the air should be clean and free of pathogens. Animals, compost storage and potential chemical contaminants should not be located near the air intake of cooling chambers. The chambers themselves should be subjected to a rigorous cleaning and sanitizing program and SSOP (see Module 7) should be developed for this process.

Water as a cooling medium is of much greater concern than air. Water represents the single critical point capable of amplifying an error in sanitation practices that may have occurred during production, harvesting or in subsequent handling steps. A small microbiological risk introduced into recirculated water can become a very large problem because the microbes can be dispersed throughout the total amount of product in contact with the water.

Water-related risks can be reduced by subjecting equipment to thorough cleaning and sanitizing, using potable water to fill the reservoir, and the proper use of water sanitizers. Ice should be manufactured with potable water and ice should be properly stored and handled to prevent contamination. Cooling facility operators should monitor water quality, pH, temperature and the concentration of sanitizers.

The purpose of water disinfection is to prevent cross contamination of the produce, particularly in systems where water is recirculated. Water sanitizers should not be expected to disinfect the product, especially if the product has a rough surface as with cantaloupes. Water can be internalized (infiltration) into the product and if living microbes are present they can be internalized as well. Internalization is discussed in Module 3.

**Summary**

Cooling is the primary tool that is available to postharvest managers for extending the quality shelf life of perishable commodities and for reducing the rate of growth of plant and human pathogens.

Several cooling methods are available and each presents its own special challenges for food safety management.

The use of water in any form presents overriding concerns for food safety.

Postharvest managers must have a clear understanding of the principles of water quality management.

SSOP must be developed for every aspect of cooling.

Appropriate record keeping must be implemented for all cooling methods.

Proper water quality management requires monitoring water temperature, pH and levels of sanitizers.
Introduction
Microorganisms are everywhere in the production environment for fresh fruits and vegetables. All products have naturally occurring microbiota on the surface, most of which are harmless to people. Pathogens that are carried to the surface by contaminated irrigation water, organic fertilizer, splashing soil, wild animal feces, etc., can coexist with the natural flora in many cases or simply survive and have no interaction. This is especially relevant for parasitic spores and enteric viruses. Cleaning can dramatically reduce this microbiological load. It also removes soil, some pesticide residues, sooty mold and other materials that are unattractive to consumers. After harvest, cleaning is often the first step in preparing a product for market.

It also is important to remind the reader that human pathogens do not occur naturally on fresh fruit and vegetables. They are present on the product only if contamination occurs. There are some exceptions in the diverse category of fresh produce, most notably sprouted seeds and mini-greens. Contamination “naturally” present inside the seed has been shown in model system research to result from internalized cells passed seed generation to seed generation. Bacteria that can infect plants, insects and humans, termed cross-over or cross-host pathogens, are known to be part of the normal plant colonizers. This does not truly alter the principle that human pathogens of greatest concern are invariably brought to the plant.

Many of the principles discussed in this Module are intended primarily to assist handlers with the prevention of cross contamination from a source of pathogens onto product that is not contaminated. Remember the basic principle that prevention of contamination is favored over reliance on remedial action to remove or inactivate the pathogen.

Cleaning
There are a few examples of products that are not cleaned at all prior to the immediate steps to consumption, such as grapes, strawberries, raspberries, blackberries and head lettuce. These items are delicate and exposure to water, even if the water is heavily sanitized, can lead to rapid decay.

Other products may be dry cleaned by simple brushing, either by hand or on a machine, to remove excess soil. Examples of this are fresh garlic, onions or even cantaloupes. High velocity air blowers or vacuums might be used to assist with the removal of dust or, in the case of bulb onions, the dried outer scales.

The large majority of fruits and vegetables are exposed to water in some manner to facilitate cleaning. It is critically important that handlers understand the concept of water quality and methods for managing the microbial levels in water.

Handlers of fresh fruits and vegetables sometimes have the misconception that cleaning and treatment with sanitized water is a sterilization step. This is not true. Sterilization is the complete inactivation of any microorganisms. Pasteurization is intended to eliminate all human pathogens. This is accomplished only by cooking or an equivalent thermal or nonthermal process such as ultra high pressure, special frequency radio waves or irradiation.

Sanitizing is simply the reduction of the microbial load to an acceptable level through chemical treatment. In most postharvest operations the produce itself is not sanitized. Rather, the use of sanitizers is for the benefit of water, food contact surfaces, etc., discussed later.

Water Quality at the Source
Water is categorized based upon its microbiological quality. Potable water would be water of quality that is safe to drink, which means that it is free of any human pathogen, essentially free of coliform bacteria and free of unacceptable levels of a long list of chemicals and heavy metals. Microbiologically potable water should be the starting point for source water used in postharvest operations or for spray application of agricultural chemicals, even though the addition of relatively large amounts of any sanitizer or antimicrobial would render the water unfit to drink.
Another category would be agricultural water for use in irrigation. Traditionally there was not a microbial standard for agricultural water, but recently some industries have adopted the level of 126 colony forming units (CFU) of indicator *E. coli* 100 ml water. This is the most stringent level established by the U.S. Environmental Protection Agency (EPA) as the standard for full body contact with recreational water as noted in Section II on GAP.

Water may be contaminated at the source and thus can be inherently bad. Utilization of this type of water for any purpose that exposes it to the edible portion of the product is not acceptable. Further, water can serve as the vehicle for spreading contamination from one place to another. The role of sanitizers in water is to help prevent the spread of contamination from any source within or among lots of fruits and vegetables during washing or other aqueous postharvest treatments. Water sanitation helps prevent a localized problem from becoming a very widely dispersed problem. For all of the following discussion on postharvest practices, we will assume that we are starting with water of potable quality.

**Water Uses in Postharvest Operations**

Water is used in many ways for the preparation of fresh produce for market. Many uses are discussed in this Section. Any use which may have been inadvertently omitted still has the same concerns for water quality management. Management concerns are introduced in this discussion and are addressed in detail throughout the Module.

Dump tanks are reservoirs or tanks of water into which products are emptied from field containers to facilitate movement onto a packing line. Tomatoes, mangoes and many other products often are handled in this manner. For many commodities, dump tank water should be heated to a temperature that is approximately 6°C higher than the pulp temperature of the product. If warm product is submerged into cold water, the intercellular space inside the product will contract as it cools and draw minute amounts of water through the stem scar or other natural openings or points of detachment. Water congestion can also occur through small cuts or abrasions to the interior of the product. If human pathogens or decay-causing microorganisms are present at these openings or wound sites, or in the dump tank water, they can more easily infiltrate the product and may begin to multiply. Outbreaks of illness as well as high rates of decay have been associated with such infiltration. The SSOP for dump tank water management should address initial water quality, sanitizer use, water heating and verification monitoring.

Water commonly is used as a spray rinse as part of a packing line. Typically the product would be treated with water as it passes over a bed of revolving brushes to clean the surfaces. A relatively low level of sanitizer such as chlorine, chlorine dioxide, ozone or peroxycetic acid might be utilized in spray water.

Water can be used as a means of conveyance. Apples, cherries, citrus, chopped lettuce and other small leafy greens often are transported in a water flume. This involves a relatively large amount of water that may be recirculated and used for an extended period of time, thus the maintenance of appropriate sanitizing conditions is critical since any contamination can quickly spread to a large volume of product.

Bananas are typically placed in large tanks of water immediately after the hands of bananas are cut from the stalk. This allows latex to exude from the stems into the water and avoids the occurrence of latex stains on the fingers, which is unattractive to consumers. Although large tanks of water may be used for extended periods, the risk of infiltration is minimal because the bananas have positive internal pressure that forces the latex from the cut stems. Human illness has not been associated with consumption of fresh bananas. Even so, water quality management in banana operations should be addressed in a SSOP.

Waxes or fungicide solutions, commonly used for mangoes, peaches and other fruits, may be formulated from water. Sanitizers generally are not compatible with the wax or fungicide. For example, the addition of chlorine to a fungicide mix might result in binding and inactivation of the fungicide. This situation demands that potable water be used for preparation of wax and fungicide solutions and that all mixing and storage containers are thoroughly sanitized and protected from contamination during use.

Finally, water is used for cooling either as liquid (hydro-cooling) or in the form of ice (icing). This was discussed in Module 2.

It is clear from the above examples that the use of contaminated water, or the introduction of any amount of microbial contamination into water, can lead to the spread of the contamination throughout the product that comes in contact with the water. Every operation that involves the use of water has unique requirements for the management.
of water quality. Remember that sanitizers for the treatment of water are intended to prevent cross contamination. They are not intended to sanitize the produce.

**Water Sanitizing Agents**

There are a number of sanitizing agents and processes available to treat water. These include various halogens, “active” oxygen, ultraviolet light, copper ionization and combinations of treatments in a process described as “hurdle” technology. All of these have specific management considerations.

**Halogens**

The halogens include chlorine, fluorine, bromine and iodine. Although there have been attempts to commercialize water sanitizing products with all of the halogens, chlorine is the only one of major importance today and is the focus of the following discussion.

Chlorine is by far the most widely used sanitizer for water due to the number of benefits that it offers. It is relatively inexpensive and effectively reduces pathogens, including many key human pathogens as well as decay-causing plant pathogens and spoilage microorganisms. Proper dosing reduces the transfer of pathogens from contaminated product to noncontaminated product, and can kill some pathogens on the product, depending on the nature of the surface.

Chlorine compounds that are utilized for sanitizers are in two categories: those that result in the formation of hypochlorite in water and those that lead to the formation of chlorine dioxide.

Three chemicals that form hypochlorite in solution are approved for use as a water sanitizer in fresh produce applications. These are liquid sodium hypochlorite (NaOCl), solid calcium hypochlorite (CaOCl₂) and gaseous chlorine (Cl₂).

Liquid sodium hypochlorite is the formulation available as bleach in the local supermarket, but these products are not approved for agricultural food contact uses. This form typically is 5.0 to 6.0% active ingredient. Industrial forms of bleach may be as high as 12.0 to 15.0% active ingredient. Either formulation of the liquid material must be diluted to provide the desired level of sanitizer for fresh produce. Only formulations specifically labeled for contact with fresh produce should be used.

Calcium hypochlorite in the form of granular material or compressed tablets is widely used for treating swimming pool water. This is a concentrated material with a content of active ingredient of approximately 65%. It is important to note that not all swimming pool chlorine is acceptable for fresh produce applications. In swimming pools, cyanuric acid may be used as a chlorine stabilizer and in some formulations the cyanuric acid may be combined directly with the calcium hypochlorite. Cyanuric acid is not approved for food contact. It is critically important that the user study the label to know if the calcium hypochlorite formulation contains cyanuric acid and if the material is approved for food contact.

Gaseous chlorine is available from industrial sources. This is the most concentrated of any of the chlorinating materials. Usually chlorine gas is the least expensive form of chlorine, but it is extremely dangerous and must be handled with care. The use and placement of chlorine gas tanks and injection engineering is generally regulated by government authorities for worker protection as well as general public safety.

Chlorine exists in water in several forms. It is important to review some of the basic chemistry in order to understand how to manage chlorine effectively as a sanitizer. It also is important to understand the distinction between free, bound and total chlorine.

Chlorine in solution that is available to function as a sanitizer is called free chlorine. During the processing of fruits and vegetables, organic matter may accumulate in the water. Some of the free chlorine will bind to the organic matter to form certain amines or other compounds. This is described as bound chlorine. Bound chlorine is not available to serve as a sanitizer since it is inactivated once it becomes bound. Total chlorine is the combination of free active chlorine plus any bound inactive chlorine. The significance of this will become obvious in the following discussion.

The rate of sanitizing capacity of chlorine is affected by pH. Sodium and calcium hypochlorite as well as chlorine gas all dissolve in water to establish a balance of hypochlorous acid and hypochlorite ion.

\[
\text{HOCl} \rightleftharpoons \text{H}^+ + \text{OCl}^- 
\]

At a pH below neutral (<7.0), the equilibrium shifts toward hypochlorous acid. This is the form of chlorine that functions best as a sanitizer where short contact times are
Note that temperature has minimal impact on the relationship between pH and chlorine availability. This indicates that pH management practices will be identical for cold water in hydro-coolers or for warm water in dump tanks.

Managers must consider the impact of chlorinating materials on the quality of the produce. Some commodities, such as peaches, can be irreversibly discolored if exposed to either low or high pH so the management of pH is a concern for product quality as well as food safety.

Safety of the work environment also must be considered when handling chlorine. In situations where wash water may be unusually soiled, especially with organic matter, the use of large amounts of chlorine can create odors that are irritating and possibly detrimental to workers’ health. The use of concentrated chlorine gas is particularly dangerous if leaks occur. Finally, the over-addition of acid with a rapid reduction in pH can cause off-gassing of chlorine into the air. Adequate ventilation of packinghouses is necessary and attention to appropriate safety precautions is absolutely essential.

Relatively low amounts of chlorine can kill many pathogens, but higher concentrations are typically used so that during periods of exposure to high amounts of organic matter the level of sanitizer remains high enough to be effective. A general recommendation is to maintain 100 to 150 ppm free chlorine, but this may vary depending upon the specific use of the water. Dump tank water, which typically becomes heavily soiled, may require more chlorine than a cleaner procedure such as a flume for pre-washed product. Managers should consider the specific application when choosing the level of chlorine to be maintained.

In addition to maintaining a suitable chlorine concentration, managers should maintain pH in the range of 6.5 to 7.5 as noted earlier.

Tanks and flumes should be drained often, cleaned and refilled with potable water. The frequency of draining and cleaning depends upon the specific process and how quickly the water becomes soiled. If water is recirculated, it may be filtered through screens, sand filters or other suitable devices to help remove soil and organic matter.

This will help reduce the demand for chlorine, improve the efficacy of sanitizing and reduce costs. Pumping water to a sedimentation sump, often with the addition of small amounts of a flocculation agent, is also useful in combination with mechanical filtration.
A means for the accurate measurement of chlorine is essential. Various types of test kits are commercially available, as well as paper test strips and titration methods. Any of these manual testing procedures are acceptable if calibrated to the performance of the system. Paper test strips are the least accurate but can be used effectively. An indirect estimation of chlorine can be accomplished electronically with an instrument that measures the oxidation-reduction potential (ORP) of water.

Chlorine concentrations and pH may be maintained manually or automatically with suitable equipment. Manual adjustment requires frequent measurements and addition of appropriate chemicals. It is generally better to have a slow constant feed of chemicals with periodic verification that the system is operating at the desired conditions than to monitor at set times and add large amounts if the levels dropped too low. Automated systems employ electrodes that continuously monitor ORP and pH. When water conditions need adjustment, a controller activates pumps that inject the chemicals until the electrodes sense that conditions are within the set range. If an automated system is used, its operation should be verified periodically with a manual test.

Keep accurate records of all water management activities. Managers should record the date, time, water conditions and actions taken to make adjustments as needed. A detailed SSOP must be developed for any procedure that involves water.

Refer to Demonstration P-9. This exercise shows the method for calculation of the amount of chlorine needed to give a desired concentration and the effects of pH and organic matter on free chlorine levels.

Chlorine dioxide (ClO₂) has become a widely accepted alternative to the use of hypochlorite for water sanitation because of the numerous advantages it offers. It is effective against many bacteria, fungi and virus and has good biofilm penetration. It is readily soluble in water, even at low temperatures, and does not break down in the same manner as other chlorine compounds. The water pH has a low impact upon its efficacy as a sanitizer. In most applications it has lower off-gassing and is less corrosive to equipment than hypochlorite materials.

Chlorine dioxide also presents challenges that must be managed. In concentrated form, it is unstable and should not be shipped. It is explosive in concentrations above approximately 10%. A number of companies have developed methods for on-site generation that are convenient and affordable. No attempt is made here to discuss commercial products, but a simple search online will reveal an abundance of technical information about chlorine dioxide and its applications.

Managers should follow manufacturer’s label requirements for the use of chlorine dioxide. In all cases, potable water is used for preparing the formulation. Relatively low rates are adequate for misting produce on a retail display and for a clean water rinse, spray or flume in a packinghouse. For biofilm penetration and sanitizing flumes and packing line equipment, up to 100 ppm is used. For storage room walls and floors, up to 200 ppm has been recommended. At the higher concentrations protective masks and clothing are recommended. Safety and health of workers always must be a priority concern.

Chlorine dioxide can be measured reasonably accurately with simple test strips but an electronic sensor or handheld meter is preferred. The frequency of measurement will depend upon the specific application, e.g., single use in a spray versus repeated use in a flume. All management practices should be defined in the corresponding SSOP.

**Active Oxygen Materials**

Active oxygen materials are effective water sanitizers. Included in this category are hydrogen peroxide (H₂O₂), peroxycetic acid (CH₃CO₃H) and ozone (O₃). These are more powerful oxidizers than any of the chlorinating materials previously discussed.

Peroxycetic acid is a mixture of acetic acid and hydrogen peroxide. There is only moderate impact of pH on efficacy and the presence of organic matter in the water does not inactivate the materials. The reaction products are water, acetic acid and oxygen, which are safe for workers and are of less concern for environmental discharge than residues and reaction byproducts of chlorination. Follow manufacturer’s recommendations for the concentrations and methods of monitoring the concentration.

Ozone can be a very effective alternative to chlorine for water sanitation in closed system applications. It is a strong oxidizer that kills pathogens rapidly with no harmful residues. There are disadvantages. Ozone presents inhalation health risks for workers and state laws in the U.S. vary regarding the methods for protecting workers. The start-up cost is quite expensive relative to other water treatments discussed and there is a high electrical cost as ozone generation must be done onsite. It cannot be manufactured and transported due to its high instability.
Light Irradiation

Ultraviolet (UV) light illumination is effective in clear water, but as the water gains suspended solids and the light tubes become soiled the light penetration is dramatically reduced. Wavelengths in the range of 235-285 nm have peak germicidal efficacy. Commercial systems usually are designed so that water circulates around self-cleaning tubes with an ultraviolet lamp in a closed system to give maximum exposure of the light to the water and to protect workers from harmful UV irradiation. Systems are available in small and large capacity at reasonable cost.

Copper Ionization

Copper ionization has been promoted as a means of sanitizing water, but research information on its effectiveness is limited. There are reports from industry that this method is best used in combination with chlorine systems.

Water is passed through a small chamber with two electrodes that have low voltage applied. Positively charged copper and silver ions are released into the water stream. These ions kill bacteria by attacking their outer membranes. Copper ionization works best in applications with long contact times, generally much longer than typical postharvest washing and cooling systems. Growers have installed copper ionization generators to inject into well water as it is pumped for packinghouse operations. However, levels that can be used (0.5–1.0 ppm) without unsightly residues are not effective for rapid inactivation of *E. coli* and *Salmonella* and at least 5 ppm chlorine should be maintained in conjunction with the copper treatment.

Hurdle Technology

Hurdle technology employs a combination of any number of treatments to create multiple steps for disinfection. As each “hurdle” is cleared, the safety of the product is further enhanced.

A hypothetical case of hurdle technology could be the following. Hypochlorite could be used at high concentration in a dump tank. The product would be rinsed and then pass on to a bed of brushes and sprayed with a relatively low concentration of chlorine dioxide or peroxyacetic acid. After the product has been graded by workers, it might pass under UV light on active rollers that would turn the commodity for maximum exposure of the product surface to the light. At this point the product would be packaged and would not be touched again by workers or machinery.

Caution

Managers should always read the label and follow manufacturer’s guidelines for any chemical that is used for postharvest treatment. All federal, state and local laws pertaining to sanitizer use should be followed.

Summary

Cleaning procedures for fresh fruits and vegetables are commodity specific.

Pre-clean very dirty commodities prior to other post harvest operations.

Choose a water sanitizing method that is appropriate for the application.

Sanitizers are used to treat the water. They cannot be expected to serve as a “kill step” for pathogens on the surface of produce.

Check the levels of any sanitizer frequently.

Always use potable water to start a post harvest process and change the water as often as necessary to maintain sanitary conditions.

Consider the risk of infiltration in dump tank systems and monitor product pulp and water temperatures.

Use screens or filters in processes involving recycled water. Investing in filtration reduces chemical costs and is essential in ozonation systems.

If hypochlorite is used, there must be a program for managing water pH.

Design equipment for easy access and thorough cleaning and sanitizing.

Use all chemicals according to the manufacturer’s label specifications.

Develop an appropriate SSOP and keep records of all cleaning and sanitizing operations.
Introduction

The condition of packing and storage facilities is one of the most obvious indicators of a company’s commitment to a Good Manufacturing Practices (GMP) program. Failure to give attention to the general maintenance and cleaning and sanitation (C&S) of facilities will be apparent to any visitor. This Module covers general facilities management. The specific practices for C&S are covered in Module 5.

Physical Condition of the Facility

First and foremost, packing and storage facilities should be in good repair. They should be inspected regularly for damage to the roof, walls, floors, windows, doors and door seals, lighting, structural support and any other part of the physical plant. Repairs and maintenance should always be completed in an effective and timely manner. Records of inspections and maintenance activity should be a part of a SSOP.

Facilities should be designed so that they are easy to clean and sanitize. Workers are not as likely to give attention to areas that are difficult to access, are poorly drained or have any other design flaw that would impede the C&S processes.

Floors should have an adequate number of drains that are properly distributed throughout the facility. This will facilitate easier cleaning and removal of water that may be spilled during normal operation of the facility. The drains themselves should be inspected regularly to ensure that they are not blocked and they must be cleaned regularly.

All lighting should be properly protected to help prevent breakage and to avoid the scatter of glass or brittle plastic in the event that breakage does occur. Trash containers should be covered and should be emptied daily or more often if conditions warrant.

Surrounding Environment

Areas surrounding the facility should also be inspected to identify and remove potential risks. Hazardous waste, fuel, pesticides or other chemical contaminants should never be stored in or near a packing and/or storage operation.

Garbage cans and dumpsters should be covered so they do not attract insects, birds, rodents or other pests. This is especially important if they contain any food waste, which can be a source of microbiological contamination. Dumpsters and other trash containers should be emptied daily or more often if necessary.

Animal production near a fruit and vegetable handling facility presents a significant risk of microbiological contamination. Pathogens may be transferred to the facility by the wind, runoff from heavy rain, vehicles or people.

Pest Control

Pest control is an issue that impacts every single area of packing and storage facilities. There are three basic requirements for a pest control program. These are to eliminate any habitat for pests, take steps to exclude pests from within the facility and surrounding areas, and finally to implement a program for eliminating (trapping) pests that do find a way to enter. Domestic animals are absolutely prohibited from food handling areas at all times.

Birds are a problem for fresh produce operations throughout the world. The large majority of packing facilities are not fully enclosed and birds may be able to move practically unrestricted throughout. Once inside an enclosure, birds may roost in hard to reach areas. There is a trend in the fresh produce industry to fully enclose all buildings where fruit and vegetables are handled, but many companies have not reached this goal.

Many species of birds are carriers of Salmonella and other human pathogens. When they are allowed to nest or if they move freely they may leave fecal contamination on walls, floors, packing machinery, packaging materials or on the product itself. Cleaning is quite difficult because the contamination may be splattered by the water used for washing equipment, walls or floors. Bird droppings in processing water, e.g., dump tanks, hydrocoolers, etc., present a special concern because the water may spread the contamination as discussed in the previous module.

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Managers should adhere to the basic requirements for effective pest control as stated above. Remove habitats, in this case birds’ nests and roosting platforms, from within the facility and from outside areas in proximity to the facility. Take steps to block entry points. Windows should be screened properly. Louvered windows are particularly attractive as a nesting location. Netting is available to cover beams or other structural areas that house pipes, cables, etc., that are attractive roosting areas for birds. Netting can be customized with openings to allow for changing light bulbs or performing other routine maintenance.

Bird deterrent devices, such as those with spikes extending outward, can be installed on surfaces where birds might roost. Auditory devices are available that emit recorded sounds of birds of prey, which may help discourage smaller birds from the area. Exclusion and deterrence are the primary options for dealing with birds because they are so hard to trap once they have entered a facility. Local housing or health codes may not permit birds to be killed at the site.

Rodents also are problematic pests because they can be carriers of human pathogens. Rats and mice are able to move through very small openings and they will nest in almost any place where they can isolate themselves from human traffic.

The basic rules for pest control apply to rodents as well. Eliminate habitats. Clean and organize storerooms so that they are not cluttered with items that are not needed for the work activities within the facility. Store packaging materials and other supplies away from direct contact with walls so it will easier to see if rodents are present. Cartons and other containers that are intended specifically to contain produce should not be used for general storage or for any other purpose.

During routine inspections of the facility pay special attention to areas that are dark and not frequently traveled by workers. Rodents are not as likely to nest in well-lit areas.

Restrict access points for rodents to enter the facility. Make sure that door and window seals are in good repair and there are no holes in walls, especially near the ground. Do not leave doors open longer than necessary.

Implement a trapping program inside and outside the facility. Sticky traps are effective for small mice but larger rats may escape from the sticky traps. Specially designed box traps, sometimes called “tin cats,” should be placed at appropriate intervals. These traps must be inspected frequently. Dead rodents must be removed and the numbers recorded. Poison baits are not allowed inside a food handling facility of any kind.

Food scientists have long studied the behavior of rodents around food processing and handling facilities. Pest pressure may come from landscape installations or neighboring property and entry may be facilitated by people, trucks or anything else that moves into or out of the facility. Long-term studies with traps have shown that the most rodents are caught near doors.

Insect pests, especially cockroaches, are potential carriers of human pathogens. Flies also can transmit pathogens from bathrooms into the handling and storage facilities or directly onto the product. Toilets should be cleaned and workers should be instructed to place used toilet paper directly into the toilet. Incidents of illness caused by Shigella, a pathogen that is found only in humans and not other animals, have been linked to the transmission of the bacteria from dirty toilets to the product by flies.

Storage areas for packaging materials seem to be especially attractive for all types of pests. Since the packaging materials will contain food, it is important that C&S of these areas be thorough and that they are well illuminated to discourage pests. The presence of pests or fecal matter on packaging material is reason for automatic failure of any GMP inspection. Many inspectors will request that the review of a facility begin in the packaging storage area, or they may seek out areas where workers do not like to clean, because these are places where problems are most likely to exist.

Potential Sources of Contamination from Outside the Facility

Contamination can enter a facility in many ways, so daily operation should be assessed to identify potential contamination routes. Bins or other field containers that have been in contact with the soil, mud, fecal matter or compost should never be taken inside a facility. C&S of field containers after each use is highly recommended.

Ideally, trucks or trailers used to haul bins of produce from the field would not enter the facility to off-load. This would be done in an adjacent area. The parking or staging area should be kept free of debris and should be washed periodically. Vehicles that have been used inside an animal
production area should not be allowed to enter areas where produce is off-loaded.

Employees should wear clean clothes to work. Placement of foot baths at entrances can help reduce the likelihood of workers bringing in contamination on their shoes.

**Packing Machinery and Sanitary Design**

Inspect the packing equipment frequently to make sure that it does not have loose parts, flaking paint, rust, excess lubricants or any other potential hazard that might contaminate food. Motors should have catch pans installed underneath so that excess lubricants do not drip onto the product. Only food grade lubricants should be used.

If purchasing new equipment or building a new facility, you should evaluate the sanitary design. Buildings and machinery can be designed in a way that facilitates easy C&S, making the programs more effective and less expensive due to reduction in chemical costs and personnel time required to complete assigned tasks.

**Conclusion**

Keeping packing and storage facilities clean and well maintained is critical to fresh produce safety. Internal and external factors both can impact safety in addition to anything that enters the facility, including workers. A comprehensive C&S program defined in SSOP must be implemented for all areas. C&S is discussed in Module 5 and SSOP development is discussed in Module 7.

**Summary**

- Packing and storage facilities must be clean and in good repair.
- Assess surrounding areas to identify and remove external risks.
- Remove garbage and other waste from the facility and surrounding areas.
- Never store hazardous chemicals in or near the facility.
- Pest control programs are essential for food safety.
- Pay special attention to packaging material storage areas.
- Develop comprehensive SSOP and keep records of all GMP activities.
Introduction

Transportation provides a number of links in the chain of movement of fresh fruits and vegetables from the field to the consumer. A typical transportation scheme might include hauling from the field to the packinghouse, from the packer’s shipping department to a repacker who might regrade and add value by applying a particular packaging treatment, from the repacker to distribution center (DC), from the DC to supermarkets, and finally from the market to the consumer’s home. Any number of variations might exist in this pattern of movement, but regardless of the logistics, it is clear that there are numerous potential food safety risks and numerous opportunities for quality deterioration during transport. Thus it is critical that a comprehensive food safety and quality program give adequate attention to the management of the transportation environment.

Methods of Transportation

In the United States, the introduction of transportation by rail in refrigerated cars was a turning point in the commercial distribution of perishable produce. Western production locations, especially in California, were provided a link by rail to the large population centers in the east. Although railroads are still important in commerce in numerous countries, such as for the transport of bananas across Russia, they have yielded to refrigerated trucks, which today transport the vast majority of our perishable products. Air transport is utilized most commonly for products that are highly perishable, have high value and must be delivered to distant markets. The following food safety considerations apply to all modes of transportation.

Transportation Unit Inspection

Prior to loading a container or trailer, which will hereafter be referred to as a unit, a thorough inspection should be performed. Often an inspection sheet has two categories, one for the functionality of the unit and the second for food safety concerns. The functionality is simply the ability of the unit to serve its transportation role effectively. Food safety concerns are linked to the unit’s functionality, since safety of the product can depend directly on the operation of the unit.

The shipping manager or a designated employee with training for unit inspections should perform a thorough evaluation. Food safety risks include visible filth, bad smells, or wet areas that are indications that something has been hauled previously that would be inconsistent with the food safety requirements for fresh produce. The driver or transportation manager should be asked for a history of previous loads. If the unit has been used for chemicals, fish, meat, chicken, eggs or any other animal product, there should be a record of C&S of the unit. Ideally, the transportation company would be able to provide a copy of its SSOP for C&S. Even if the unit has been cleaned, the presence of objectionable odors would indicate that the procedure was not thorough and should be repeated.

The physical condition of the unit is an indication of its functionality. If a trailer or container has a cooling system that delivers cold air from the top of the unit, inspect the air delivery chute to make sure that it is not torn or otherwise damaged. If the chute is damaged the cold air may “short cycle”, or find a path back to the cooling coils without actually passing through the load of produce. Likewise the front bulkhead should be examined for damage that might allow short cycling. If the refrigeration system delivers cold air to the bottom of the load, be sure that the floor channels are open and there are no obstructions to air flow. This will be less of a concern if the cargo is palletized.

Hermetic seals should be in good condition. Inspect all seals around doors. If there is a side door, be sure to open it and inspect those seals as well. Door seals that leak and allow cold air to escape may prevent the unit from maintaining the desired temperature. Floor drains should have a plug that can be removed for cleaning. Sometimes these plugs are lost or are not properly installed, allowing cold air to escape. Inspectors should note the presence and condition of these plugs. A note of caution: tightly sealed transport units in long-haul distribution could have insufficient air exchange, allowing oxygen to be depleted and humidity to increase due to product respiration. This could promote off-odors, superficial mold growth and accelerated decay.
Note any physical damage to the walls or doors. If the integrity of the wall or door covering is broken, the insulation can become wet. This negates the insulating properties and the damp area is a haven for growth of microorganisms that could lead to product contamination.

The refrigeration system should be tested to ensure that it is working properly. Temperature is critical to product safety and quality. When products are stored at their optimum temperature there will be less decay and shelf life is extended. Refrigeration also reduces the growth of some human pathogens.

In general, excessively high temperature promotes product decay and growth of human pathogens. Very low temperature can damage sensitive products and in the extreme can freeze the product. The optimum temperature is specific to the fruit or vegetable being transported. In the fresh produce industry loads may be mixed, or contain multiple products that may not have the same temperature requirements. If temperature must be compromised, it typically is set to give the best possible conditions for the portion of the load having the highest value.

In trailers and containers, product must be stowed in a manner that allows good air circulation throughout the cargo. Air will follow the path of least resistance. This is most likely to be a problem with produce that is not palletized and is solid-stacked. If conditioned air cannot pass easily through or around the packed boxes, heat of respiration will accumulate and temperature will increase during shipping. Excellent transportation handbooks are available from the University of California at Davis that give guidance for all important aspects of loading cargo.

**Cold Chain Management**

Maintenance of the cold chain is critical. This simply means that once the product is cooled to its optimum temperature it should be maintained at or near that temperature throughout all handling steps.

Loading is a step where the cold chain is easily broken. Never load cooled product into a hot truck or vice versa. Refrigerated highway trailers are not designed to rapidly or significantly cool packed product. The truck should be pre-cooled and as soon as the load is placed the doors should be closed and the refrigeration unit activated. Ideally, product would be loaded from an enclosed refrigerated dock. The dock doors should be designed so that when the unit is positioned for loading it is sealed to the dock space. This helps to ensure that the cold chain is preserved and pests are excluded.

A temperature monitoring device (recording thermometer or temperature data logger) should be properly installed in the load of product. It should be tamper proof and should have sufficient battery or be otherwise designed so that it operates for the duration of the trip. Placement in 2-3 locations is ideal but typically one device is placed at the rear of the load near the end of the air-chute or below the load line for bottom air units. Temperature records from certified thermometers are admissible in legal proceedings in which temperature management is a concern for quality and safety.

The loading pattern for the product in the unit is important for maintaining proper transit temperatures. Product should be placed so that air moves as uniformly as possible throughout the load. When air channels are blocked, the heat of respiration can accumulate in dead zones and raise temperatures to undesirable levels. In most palletized loads, the air can only circulate around the product and not through it. Optimal pre-cooling prior to loading is important for cold chain control.

The containers used for air transport are not typically equipped with mechanical refrigeration systems but other temperature management strategies are available. Styrofoam or other packaging material with good insulating properties may be used to help prevent the absorption of heat energy by the product. Dry ice or liquid nitrogen both have been used to help maintain the cold environment. Managers should be sure that product is cold when it is loaded, minimize the staging time so that the product is exposed to high temperatures as little as possible, and when the product arrives to its destination, quickly move it in to a refrigerated environment. Containers that are left on the tarmac prior to loading or upon arrival will warm quickly. Air containers sometimes are placed directly into refrigerated rooms until the product can be unloaded. Recooling by commodity brokers at destination is often practiced; asparagus is a good example.

**SSOP**

There must be a SSOP for inspection and for C&S of all types of transportation units. These are discussed in detail in the next Modules.
Summary

Transportation units should be cleaned, sanitized and in good repair.

Conduct a thorough inspection of the unit before loading. Look for factors affecting the functionality of the unit as well as food safety hazards.

Refrigeration systems and all related components should be functioning properly.

Precool the product prior to loading and precool the unit. Never load cold product into a hot unit or vice versa. Loading hot product into a cold unit can result in excessive condensation.

Stow the cargo in a manner that allows proper air circulation.

Implement a program for cold chain management and use temperature recorders during transit.

Develop appropriate SSOP for transportation and keep records.
Introduction

It is important to implement cleaning and sanitation (C&S) procedures at every step from “farm to fork” to help prevent the transmission of human diseases in foods. Food residues serve as substrate for the growth of human pathogens and can attract and support all types of pests that transmit those pathogens. Further, C&S can help improve the shelf life and quality of perishable commodities because it reduces the load of decay-causing microorganisms.

The development of effective C&S protocols is a complex process. In the fruit and vegetable industry there are many different surfaces that require C&S on a regular basis. This Module addresses many of the technical aspects of C&S but managers are urged to obtain assistance from professionals who understand the concepts and can assist with the numerous decisions that are involved.

C&S is implemented in two distinct steps: clean first and then sanitize.

Cleaning

Cleaning is simply the complete removal of unwanted matter (soil) by using appropriate detergent chemicals and scrubbing in the proper manner. Managers first must identify areas and items to be cleaned and choose the appropriate tools, chemicals and application methods for each area. Always follow label instructions for cleaning agents.

What Do I Clean? Literally everything must be subjected to C&S. All surfaces that contact fruits and vegetables directly must be given special attention. This includes, but is not limited to, hands, gloves, utensils, knives and other cutting tools, harvest containers, cutting boards, tables, conveyors, ice makers, ice storage bins and aprons. Surfaces that are not in direct contact with food also must be cleaned, including walls, ceilings, floors, light fixtures, fans and drains.

What Should I Know About Cleaning Tools? The cleaning tools themselves can be a major source of microbial cross contamination if they are not cleaned, sanitized and properly stored after use. These include brooms, mops, squeegees, buckets, sponges, scrapers, foaming equipment, pressure washers, water guns and any other cleaning tool. Once they are cleaned, they should be dried and stored in a dry secure location.

Tools should be properly identified for the locations in which they are used and should only be used in these locations. For example, tools that are used to clean toilet facilities might be labeled with red paint or tape. These should be used solely for that purpose. Tools that are used to clean walls and floors might be labeled with a yellow color and those used for packing machinery might be blue. Workers should understand the meaning of the coding system and take care to keep tools in their proper locations.

Minimize the use of wood for any purpose. Common wooden handles on tools can absorb water and harbor microorganisms. Plastic or metal tools are more appropriate because they can be cleaned more thoroughly. Tables in food handling areas should not be constructed of wood, even if the wood is coated with food-grade paint. The paint can chip and exposed wood can harbor microorganisms.

What are the Types of Soils? Once the areas to be cleaned and the proper tools have been identified, the types of soils that must be removed are assessed. Different soils require different detergents. Personnel need to have a clear understanding of the types of substances they are cleaning and the basic chemistry of removal. In a fresh fruit and vegetable operation we can identify four general types of soils:

1. Those that dissolve in water include simple carbohydrates, or sugars, complex carbohydrates such as starch, and simple salts.

2. Those that dissolve in alkali include proteins, starches that are bound to proteins or fats, and bacterial films known as biofilms. Biofilms are discussed in more detail later.

3. Those that dissolve in acid include salts associated with hard water that may contain calcium, magnesium
or other minerals. More complex mineral films may contain iron and manganese.

4. Those that dissolve with surfactants include fats, oils, grease, many food residues, inert soils such as sand or clay, fine metal films and some biofilms.

The type of cleanser used must be suited for the type of soil and the surface to be cleaned, discussed in more detail later.

What are biofilms? Biofilms are a collection of microorganisms, mainly bacteria, growing together in a matrix of polymers (glue-like material) secreted by the microorganisms themselves. Biofilms are formed by the attachment of bacteria to a surface, colonization on the surface and subsequent rapid growth to form the film. Biofilms can accumulate on almost any surface, but generally are most problematic on packing line machinery, floors and in pipes.

Once microorganisms grow into biofilms, C&S becomes more difficult because the microbes continue to secrete adhesives that make them more difficult to remove. They have resistance to biocides because even if a layer or two of microorganisms are removed the biofilm structure protects other microbial cells. If the biofilm is not completely removed during C&S it remains a continual source of microbes that may cause spoilage of food or illness in humans.

Why is Water Important? Water is a critical factor in the cleaning process. Surface cleaners consist primarily of water and detergent. Water is the universal solvent and is the basis for all surface cleaners. Cleaning with water alone is the yardstick with which we measure the effect of cleaning chemicals that are added to water. It comprises approximately 95-99% of cleaning solutions and has many functions in the cleaning process. It is used as a prerinse to remove gross amounts of soil. It softens soils left on the surface, carries detergent to the surface to be cleaned, carries wastes away from the surface being cleaned and rinses detergent off the surface. Water quality, particularly its mineral hardness, can drastically alter the effectiveness of a detergent. This is why knowledge of the cleaning water quality is important before it is used in the C&S process.

### Application of Cleaners

Having completed the decisions regarding what is to be cleaned and the type of chemicals that will be used, we are ready to consider the manner in which cleaning will be accomplished.

There are three general methods for the application of cleaners:

1. Manual cleaning, in which equipment is manually disassembled for hand scrubbing and washing;
may vary with different types of equipment, but in general a pressure of <15 bar is considered low, 15 to 30 bar is considered medium and 30 to 150 bar is considered high pressure. The recommended pressure for cleaning in food handling settings is <45 bar. At higher pressure, spray can form aerosol mist from irritating chemicals and atomization of water can spread soil and microorganisms.

Foam cleaning is useful for hard to clean surfaces. Foaming adds to the retention time of the detergent on the surface, especially for vertical surfaces from which water drains away quickly. Foam is generated by the addition of detergent to water with the application of compressed air. This causes the formation of tiny bubbles that release detergent slowly over time.

A typical foaming technique would be to pre-rinse to remove loose soil and residue. Work in small sections and foam from the bottom up before rinsing from the top down. Foam that is too wet will run off the surface too quickly. Allow the foam to remain on the surface for 10 to 15 minutes, being aware of surfaces that are susceptible to corrosion if exposure to detergent is excessive. There usually is no advantage to foaming hot solutions. Workers should wear protective equipment, e.g., goggles, gloves, suit and boots.

Automated Cleaning
This is sometimes referred to as clean-in-place (CIP) and is the cleaning of production equipment without disassembly. Examples of surfaces for which CIP is utilized include tanks, heat exchangers, pumps, valves, pipelines and any other enclosed surface. Cleaning solutions contact the surface by any combination of pumping, circulating or automatic spraying. Contrary to manual cleaning, CIP may involve high chemical concentrations and high temperatures.

The effective use of CIP involves turbulent flow in order to have good scrubbing action. Product pumps are designed for smooth laminar flow, which is not a good characteristic for CIP. Specially designed CIP pumps work with high volume at high velocity. Pipes run completely full with no headspace and the flow is chaotic and turbulent.

Sanitizing
Sanitizing is a procedure for treating food contact surfaces that destroys most disease-producing bacteria and viruses, substantially reduces the number of other undesirable
microorganisms and does not adversely affect the product or its safety for the consumer.

Surfaces must be properly prepared for sanitizing. First and foremost, the surface must be physically clean. One cannot sanitize a dirty surface because organic soils will consume the sanitizer or form a protective barrier over contamination. Detergent residues must be rinsed well because they will neutralize many sanitizers. Many detergents are alkaline with a negative charge while many sanitizers are acidic with a positive charge. Sanitizing can be done with either heat or chemicals.

**Thermal Sanitizing**

This can be done with dry heat, but most often involves the use of hot water or steam. The exposure to heat should be for a specific time at a specific temperature. Steam and hot water both are effective, but both are expensive and present a physical hazard to workers. Worker safety should be the first priority. Steam has limited application because it is difficult to regulate and difficult to monitor contact time and temperature. Hot water (80-85°C) for >30 second exposure time is an effective method of sanitizing most surfaces and it is noncorrosive and easier to apply than steam.

Following outbreaks of *Salmonella*-related illnesses associated with the consumption of fresh mangoes from Brazil, packinghouse operators in Brazil implemented a system of hot water treatment of recyclable plastic containers that were used for harvesting the fruit. This proved to be quite effective. In general, thermal sanitizing has had limited application in fresh fruit and vegetable handling facilities.

**Chemical Sanitizing**

Chemical sanitizers are a group of compounds that have dramatically different properties, yet they all achieve a common purpose. Some are chlorine or iodine based. Quaternary ammonium compounds (quats) have become widely used in recent years. There also are acid-anionic sanitizers, such as peroxide and peroxyacetic acid.

Several factors must be considered in the selection of a chemical sanitizer: the type of equipment and kind of surface to be sanitized, water hardness, the microorganisms likely to be associated with the product or the processing environment, and the sanitizer’s effectiveness under practical conditions that include temperature, contact time and corrosion potential.

Choose the appropriate method for applying sanitizers. The method might be as simple as spraying the sanitizer onto the surface. It might also be the immersion of disassembled equipment in sanitizer solution. Fumigating, or fogging, the chemical agent into the air is sometimes used. Finally, CIP may be the method of choice for surfaces that are not easily accessible.

Chlorine-based sanitizers are the most commonly used sanitizers in food applications. All forms of chlorine are broad spectrum germicides. They act on microbial membranes, enzymes and other proteins, and deoxyribonucleic acid (DNA). Management of chlorine was discussed earlier under water treatment.

The use of iodine-based sanitizers dates back to the 1800s. They have a broad spectrum of activity as antimicrobial agents. They are powerful in acidic aqueous solutions and are generally used in the range of 12.5 to 25 ppm available iodine. They can cause permanent staining on some surfaces, especially plastics.

Quats are cationic surfactants with fair wetting properties. They react strongly with the cell membranes of certain microorganisms. They are more effective than chlorine against yeasts, molds and gram-positive microorganisms like *Listeria monocytogenes*. They are less effective against gram-negative bacteria such as *Salmonella*, *E. coli* and coliforms in general.

There are a number of considerations for the effectiveness of quats. They are cationic and thus are incompatible with most soaps and anionic detergents, so surfaces must be thoroughly rinsed between the cleaning and sanitation steps. They are excellent environmental sanitizers for floors, walls, drains and equipment, are noncorrosive to metals and are stable at high temperature. Their effectiveness is severely limited by high water hardness.

Workers should follow the label recommendations for the use of quats and all other chemicals, but some typical recommended use levels for quats are as follows: equipment sanitizing 200 ppm; floors and drains 800 ppm; floor mats 1,800 ppm; foot baths 2,400 ppm, and walls and ceilings for mold 2,000-5,000 ppm. Quats may be used at <200 ppm without a rinse step. Take care to use quats in a manner that does not cross contaminate fresh produce.

Acid-anionic sanitizers are surface-active sanitizers that are negatively charged. They serve the dual function of providing an acid rinse and sanitizing in one step. They must be used at low pH since activity above about pH 3.5
The details of C&S methods should be written in a single document that is called the Sanitation Standard Operating Procedure (SSOP). Considerations for the development of a SSOP are discussed in the final Module of this Section.

**Summary**

Cleaning and sanitizing (C&S) are two distinct procedures. You must clean first and then sanitize. All surfaces in a food production and handling system must be subjected to C&S. Choose the correct tools, processes and chemicals for C&S. Solicit advice from a trained professional. Workers should be trained to understand the C&S process and must know how to handle chemicals safely. Develop a SSOP for each individual C&S operation. Keep records of what you do.

**Verification of Sanitation**

Take steps to verify that the C&S program is effective. Many food processors routinely use an ATP (adenosine triphosphate) analysis to detect unwanted residues of organic matter on surfaces that have been subjected to C&S. This method gives immediate feedback on the cleanliness of the surface and corrective actions can be taken, if needed, prior to start-up.

Surfaces may also be swabbed and the swabs cultured to detect the presence of specific microorganisms. This method is always retrospective as results are not generally known for 24-36 hours. During this time the equipment may have been in use.

If surfaces are still contaminated following C&S, managers should analyze all steps to determine the weakness in the C&S procedure. Perform C&S on a regular schedule. When there is any unusual circumstance that may cause contamination, implement the process again.

Hydrogen peroxide has a long history of use as a sanitizer. It has largely been replaced by peroxyacetic acid (PAA), discussed earlier in Module 3, which is an equilibrium mixture of acetic acid and hydrogen peroxide in an aqueous solution. It is a strong oxidizing agent with a stronger oxidizing potential than chlorine. The pungent acetic acid odor may be objectionable to workers. It is used to control odor and remove biofilms from food contact surfaces and is a versatile agent for sanitizing floors, walls and indoor processing and packaging facilities.

The advantages of PAA are that it is nonfoaming, is effective at relatively low temperatures (5 to 40°C) and is environmentally safe since it breaks down to oxygen, carbon dioxide and water. The disadvantages are that it is corrosive to soft metals, its concentration is difficult to monitor and it is rapidly decomposed by organic matter.

When working with concentrated chemicals, follow the label instructions carefully. Handlers must always store concentrated chemicals in the original container. Work with proper dilutions and wear protective equipment recommended by the manufacturer.

is minimal. Their acidity, detergency, stability and non-corrosiveness make them highly effective against a broad spectrum of bacteria and viruses but they are not very effective against yeasts and molds.
Introduction
Sanitation Standard Operating Procedures (SSOP) are defined by the USDA-FSIS as a description of all procedures an official establishment will conduct at specified intervals, before and during operations, sufficient to prevent direct contamination or adulteration of product(s). Traditionally, SSOP were associated with the manufacturing of food and were focused specifically on cleaning and sanitation practices. For the fruit and vegetable industries, SSOP are more broadly defined to cover procedures defined by GAP as well as GMP, thus farming practices are included. Any procedure with potential impact on the safety of fresh produce should be covered by a SSOP.

Purpose of the SSOP
SSOP are useful for many reasons. In addition to describing the basic sanitary practices, they provide a schedule for key activities and serve as the basis for training all employees in food safety principles. This helps to ensure that every employee, from production workers to management, has an understanding of acceptable behavior in the company.

SSOP provide the foundation to support a routine testing or monitoring program. The records from this program can help to identify trends and prevent recurring problems, which in turn encourages planning to correct deficiencies that can be anticipated. All of this leads to overall improvement of the food safety program. Finally, buyers and inspectors are afforded a perspective of the commitment that the company has to food safety.

Development of the SSOP
A SSOP is a written plan. It must be signed and dated by an official of the company when it is initiated and again when there is any revision to the original document.

Typically, preoperational activities are defined separately from those activities that are conducted during the operation of a facility. For example, a major preoperational cleaning and sanitation of a packing facility would be described apart from the routine cleaning of a restroom or break room that must be conducted periodically throughout the day.

A SSOP should identify the individuals, either by name or by title, responsible for the implementation of the procedures described in the document. The company must maintain records that demonstrate that the SSOP is being executed and that corrective actions are taken when there is a deficiency in the process. Managers have considerable flexibility in the way that records are kept. They may be paper copies or may be computerized. Any functional format is acceptable as long as it accurately describes the process in a clear and concise manner and allows for documenting the implementation and monitoring of the SSOP.

A SSOP is specific to a process in the company. There is not necessarily a right or wrong way to write a SSOP as long as it accurately describes the points that are made above. Companies that must develop a series of SSOP, which would be the case for any fruit or vegetable operation, are best served by developing a standard format. Each new SSOP is numbered or otherwise identified and placed in a book for easy reference. Inspectors and auditors will appreciate the fact that the SSOP is well organized and information is easily accessible.

A typical SSOP would have a title followed by a statement of purpose, objective or relevance. The scope of work would be described and the individual responsible would be identified. A list of materials, equipment or tools needed to carry out the task would be included, as well as procedures for storing, mixing and measuring the concentration of chemicals.

The actual procedure is described and the frequency of the activity is noted. Appropriate record sheets are included that have a signature line for the responsible individual to affirm that the work has been done. An additional signature might be required from a supervisor or manager to indicate that the work is acceptable to the company. Clearly the format of the SSOP could vary considerably.
First, conduct a thorough inspection to identify any areas that could harbor microorganisms. These areas will require more meticulous C&S than the larger surfaces, e.g., ceilings, walls and floors. Problem areas in a cold room might include drains, cracked hoses, hollow framework, open bearings, filters, areas of standing water, condensate on walls or pipes, porous surfaces such as wood, insulation, or door seals, and light switches. Determine how these problem areas will be replaced, repaired or simply meticulously cleaned. Make note of this in the SSOP.

Define a C&S schedule. At least once per season remove equipment from the coolers and thoroughly clean and sanitize all surfaces from the top down. Walls might be cleaned and sanitized monthly while floors and drains could be treated weekly. Dry cleaning, or sweeping, might be done daily depending upon the nature of the product being stored. Note that these are merely examples of scheduling and are not intended to be specific recommendations.

After setting a schedule, note the types of surfaces and choose appropriate cleansers and sanitizers. Reputable suppliers of chemicals can assist with this decision. Quaternary ammonium compounds (quats) often are used in cold storage areas because they are effective against *Listeria monocytogenes*, which is a serious microbial concern in a cold environment.

Describe the C&S process. This typically will entail steps for pre-rinsing, cleaning, rinsing, sanitizing and possibly rinsing again. Ceilings, walls and floors are cleaned from the top downward. Surfaces are brushed to remove gross contamination before cleaners are applied, followed by scrubbing and rinsing. Clean drains with brushes small enough to reach all areas. Pay special attention to the problem areas that were identified initially. After cleaning, apply a high level sanitizer (800 ppm quat), let stand for 20 minutes, rinse, apply low level sanitizer (200 ppm quat), rinse again and allow all surfaces to dry. Clean all tools and store in an appropriate manner.

Be aware of special risks associated with cold storage facilities. Contamination can be brought into a room on the bottoms of pallets or on the wheels of forklifts.

Other areas within the operation may be more complex. Transportation units provide an excellent example of a situation that may have numerous types of surfaces. There can be wood, aluminum, steel, rubber seals and the refrigeration coils that may require dry or gaseous cleaning and sanitizing steps. Each of these might require different

### Verification of a SSOP

Verification that a SSOP is effective is critical to its purpose. In the case of cleaning and sanitation (C&S), a visual inspection is the easiest way to verify a process. One might use a flashlight and a scraper to help see and smell a surface. A worker who is a good observer and uses common sense usually will be able to determine if a C&S process has been conducted effectively.

In many instances the existence of records are sufficient for an inspector or auditor to be assured that the objectives of the SSOP have been fulfilled. For example, purchase orders for cleaners and sanitizers and a well-maintained inventory of their use would normally be adequate verification that a SSOP is being implemented.

In some cases a more sophisticated test may be required to support common sense observations. For example, swabs of an equipment surface can be used to take samples for microbiological analysis, which could include an evaluation of indicator organisms or specific human pathogens. Obviously this requires laboratory capability and results will not be available immediately. Another technique involves bioluminescence monitoring. A swab is analyzed for the presence of adenosine triphosphate (ATP), which is an indicator that organic matter is present. A limitation of the technique is that it does not identify the origin of the organic material, which might be microbial or simply food residue. Results from ATP testing are immediately available. These were discussed in the C&S verification component of the previous Module.

If testing indicates that a cleaning and sanitizing program has not been effective, it will be necessary to review the process and validate all parameters. It is important to confirm that the right chemicals were used at the right concentrations for the appropriate application time and temperature. Review the amount of mechanical force (scrubbing) that was performed, or if pressure washing was used verify that the pressure setting was appropriate. A thorough evaluation will identify deficiencies that can be corrected before repeating the process.

### Examples of SSOP Considerations

Following is a discussion to guide the development of a SSOP for cleaning and sanitizing cold storage facilities. Note that this is only a general discussion. A real SSOP would be specific to the location.
C&S tools, chemicals and processes, all of which would be described in the SSOP.

As mentioned, SSOP applies to farming operations as well as packing facilities. Recall that SSOP are intended to prevent direct contamination of foods. On farms, this might occur with contaminated irrigation water, inadequate toilet facilities, workers who do not practice good hygiene, unclean harvest equipment, etc. A SSOP should be developed to address each of these potential hazards.

**Summary**

Repeated, systematic application of GAP and GMP as defined in SSOP is an essential step in the assurance of the safety of the product.

The purpose of a SSOP is to describe procedures that prevent direct contamination or adulteration of a food product.

A SSOP is a written plan. Employee training is a critical part of the plan.

Each risk area at every step of harvesting and subsequent handling of fruit and vegetables should have a SSOP that addresses a method for risk reduction.

Keep records of all activities specified in the SSOP.
Section V

Food Safety and Quality Assurance Issues

Module 1  Safety and Quality Assurance
Module 2  Quality Attributes, Grades and Standards
Module 3  Quality Attributes and Spoilage
Module 4  Utilization of HACCP Principles for GAP and GMP Development
**Introduction**

Fresh fruit and vegetable growers, packers, shippers, retailers and consumers all have long recognized, at least intuitively, that product quality is the primary factor affecting profitable trade in the produce industry. Only in the past twenty years or so has food safety also become a driving force in conducting business. This has resulted in a plethora of opinions regarding the relationship of safety to quality. In commerce perhaps the safety factor is not often given greater importance than the overall quality, but when an outbreak of illness occurs, safety overrides all other quality considerations.

In this Module we will define quality and safety terms and discuss the ways in which the two concepts can be integrated to provide consumers an abundant supply of safe food with the best possible quality.

**Food Safety**

Food safety is defined by the World Health Organization (WHO) as the assurance that the food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use. Reasonable assurance of safe food requires the reduction of risks that may occur during production, handling, and preparation for consumption by the end-user.

It is beyond the scope of this Module to identify every microbiological, chemical or physical cause of human illness or injury, but many common risks will be discussed in this Section. Identifying risks is critical to food safety because it is difficult to control a hazard if it is not known to exist. The point of GAP and GMP is to reduce risks that occur during production and handling of fruits and vegetables in order to minimize the occurrence of illness or injury.

**Food Quality**

The International Organization for Standardization (ISO) defines quality as “the totality of features or characteristics of a product that bear on its ability to satisfy the stated or implied needs.” Webster defines quality more simply as the “degree of excellence.” There also is an adage of the farmer who stated that he could not really describe quality, but he knew it when he saw it.

Some aspects of quality can be measured, such as purity, color, maturity, ripeness, nutritional value, etc. Other characteristics are highly subjective, such as flavor, which can only be assessed by the person doing the tasting. Aroma, an important component of flavor and quality perception, can be measured for the presence of signature volatiles, but consumers vary in their sensitivity to these volatiles. In commerce, the “quality” of fresh produce as it applies to pricing is influenced strongly by supply and demand.

Understanding that quality is made up of many factors that are often subject to interpretation that varies from person to person highlights the complexity of defining quality.

**Safety is a Component of Quality**

Safety is a component of quality. It can be argued that safety is the most important component of quality since a failure to assure safety can cause serious injury or death to the consumer. It is difficult, usually impossible, to determine if a product is safe by simply looking at it.

**Figure 1. An illustration of a few of the components of quality, including safety.**

Note that each of the quality parameters in Figure 1 is unique in some way and may or may not be obvious to our senses. Obviously, we can see the appearance and smell...
the aroma. Flavor and texture can be assessed subjectively by eating or objectively by biochemical or mechanical techniques. Safety is seldom obvious. A product may have high appearance or flavor quality, but have poor safety quality due to contamination with pathogens or chemicals. Alternatively, a product might have poor market quality but still be safe to eat.

Obvious quality deficiencies such as bruising or other injuries typically lead to lower pricing, lower sales or outright rejection. In contrast, safety hazards might go undetected until the product is consumed. Safety assurance is vital to public health.

Although it is impossible with current technologies to eliminate all potential food safety hazards associated with consumption of raw produce, food safety programs should be the foundation upon which all other quality management programs are built.

**Safety and Quality Assurance Programs**

Managers of fresh produce operations are required to be focused on crop productivity, harvest efficiency, pack-out maximization, and dozens of other management criteria that are involved in the profitability of the enterprise. Quality assurance (QA), including safety assurance, is an ongoing process that must be a part of every agricultural practice from field selection through the ultimate consumption of the product.

Once quality is compromised it is virtually impossible to restore it. Thus managers must focus on the prevention of quality and safety problems rather than reliance on remedial action to correct management errors. It also is important to learn from mistakes that impact quality so that those can be avoided in the future.

A strong, semi-independent QA program is essential. For large companies, QA may be a discrete department within the company. Although the QA program may be managed independently of production management, there must be good communication and collaboration between QA managers and all other managers.

QA management requires many diverse technical and analytical skills. QA personnel continually monitor, or train other managers to monitor, inputs into production and the final product to ensure compliance with compositional standards, microbiological and other safety requirements, and various government regulations. All of this must conform to the expectations of the customer since profitability ultimately depends upon consumer acceptance. A QA manager may halt production, refuse acceptance of raw material, or stop the shipment of product if specifications are not met. They must have the trust and confidence of company owners since their decisions can impact profit.

Historically in fresh fruit and vegetable industries, safety assurance was not included in QA programs. Periodic outbreaks of illness with fresh produce during the past two decades have brought about change in the way that safety assurance is integrated into the overall QA program. Progressive companies will have periodic food safety training of managers from all divisions of the company so that those managers can in turn train the workers under their supervision.

A process analysis, in which each unit operation in the company is isolated and studied individually, will help identify the steps where contamination may occur. In some cases the control steps may be simple common sense practices that the industry may have followed for years. In others, the existing infrastructure and practices may need significant modification in order to reduce or prevent contamination.

Good Agricultural Practices (GAP, Section II), Good Manufacturing Practices (GMP, Section III), and Sanitation Standard Operating Procedures (SSOP, Section III, Module 7) all are based upon the principles of Hazard Analysis Critical Control Point (HACCP) programs used for processing industries. While HACCP is not specifically applicable to fresh produce operations, all of the practices covered in this manual are HACCP-like in the sense that management systematically applies principles of food safety in a stepwise fashion (Module 4).

In summary, the development of an effective QA program must include adoption of GAP and GMP, development of and adherence to SSOP, establishment of specifications for grades and standards (Module 2), defining quality and spoilage attributes, and attention to phytosanitary issues.

It is important to note that management practices that help maintain the highest level of product quality often help to assure its safety. During the process of risk assessment, these practices become more obvious and will serve as the backbone of the food safety program.
Rapid Detection and Remedial Actions

Methods for rapid detection of microbiological contamination are under development with considerable investment from the public and private sectors. Some of the methods that are reported to be most effective are proprietary. Detailed discussion of this topic is beyond the scope of this Module. Companies that seek to implement testing are likely to hire a professional service company to conduct the tests.

Remedial action, essentially a “kill step,” to eliminate microbiological hazards also is of great interest. The ultimate kill step is to cook the product, but obviously any such thermal treatment negates the whole concept of “fresh” fruit and vegetables. Nonthermal technologies that preserve freshness are under development. The technology that is most publicized is irradiation. Gamma irradiation and electron-beam irradiation have been tested for various food types but have not gained widespread consumer acceptance and for many products the techniques are too costly for implementation.

Summary

Food safety is the assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Quality is the degree of excellence of the food.

Safety is a component of quality.

Food safety is an absolute condition, while quality is subject to interpretation.

Food may appear to have high quality but be unsafe. Alternatively, food may appear to be of poor quality but be perfectly safe for consumption.

Companies must have quality assurance (QA) programs that place an emphasis on food safety.

Management practices that help maintain quality often help to reduce the risk of contamination and help to ensure safety.

QA programs must encompass all steps from field selection to final consumption of the product. This is particularly challenging at the consumer level where the grower and handler has no control.

Prevention of contamination is favored over any remedial action to try to restore quality and safety to a product.

In the future, we may expect that techniques will be developed for rapid detection of pathogens that will be useful for the assurance of safety.
**Introduction**

Quality entails some attributes that are subjective. For business purposes, e.g., for uniformity of produce quality in commerce, it is essential to have practical, objective grades and standards that define quality. In this Module we discuss the ways that quality is measured and the regulations that define quality for business practices.

**Quality Attributes Defined**

It is not possible to clearly differentiate each quality attribute from all others as they all relate to each other in some manner. However, experts have classified some quality characteristics for the purpose of evaluating them in the course of conducting business and for scientific studies. These fit into three general categories: external, internal and hidden attributes.

External attributes are the ones that are perceived immediately when the product is encountered. These are the ones that are seen and felt. Appearance quality includes color, size, shape, and the presence or absence of defects. Defects may be due to a myriad of causes such as insect injury, environmental factors (sunburn, splitting from excessive watering, etc.), handling injury (bruising, cuts, scrapes, etc.) or decay. Aroma may be sensed externally but is more commonly measured as an internal characteristic of the flesh. Collectively, the external attributes are the factors most likely to influence the consumer’s decision to purchase or reject a product.

Internal attributes typically are not obvious until the product is cut or bitten, although a trained evaluator may make an accurate prediction of internal quality based on external characteristics. For example, a watermelon might appear to be ripe to an average customer in the supermarket, but for a trained observer there may be external characteristics that indicate the fruit will not have good eating quality. Aroma, flavor, texture, color, turgidity and firmness are a few examples of internal quality characteristics.

The combination of internal and external characteristics will determine if the customer is likely to make a second purchase of the product. For some fruits and vegetables the appearance quality may still be good long after flavor and other sensory quality attributes have deteriorated, resulting in disappointment for the consumer and reluctance to purchase the product in the future.

Hidden attributes include wholesomeness, nutritional value, and safety. As the name implies, these are almost impossible for the average consumer to assess. However, the perception of the hidden attributes may play a large role in the customer’s decision to purchase. For example, wholesomeness and nutritional value are generally associated with an appearance of freshness. Items that are wilted or are not brightly colored may not be perceived to be wholesome and may be rejected at the point of sale. Information about nutritional value sometimes is posted at the point of sale.

Perception of safety is difficult. The media can have a strong influence on consumers’ perceptions of safety, especially during an outbreak of foodborne illness, when country or state of origin may influence consumers’ choices.

**Measurement of Quality**

Only a few quality attributes can be measured by purely objective methods. Any method for quality evaluation must somehow relate to the sensory evaluation that consumers make at the point of purchase. Quality measurement is critical because growers, packers, shippers, inspectors and scientists all need standards upon which to base the effectiveness of their own work and to be able to make legitimate comparisons of their work to that of others.

**External Attributes**

Size is easily measured and is used as a grade standard for almost all commodities. Numerous types of mechanical sizing methods are in use in the produce industry today. These usually function by measuring the physical dimensions or weight of the product. In small operations, sizing may be done manually and aids are available to assist workers with the evaluation.
Internal Attributes

Although appearance quality may be most important in the decision to purchase, flavor (taste) is perhaps the single most important quality attribute for the consumer for repeat purchases. Unfortunately, taste cannot be determined with certainty until the product has been purchased and eaten.

The four basic tastes are sweet, sour, bitter and astringent. Sweetness is related to sugars and the sugar to acid ratio. Soursness is caused by acids. Bitterness and astringency are related to a large number of different compounds. For practical purposes taste is best determined by a panel of people (trained or untrained) who are willing to do taste tests. In the laboratory there are numerous methods for quantifying the biochemical constituents that have flavor.

Aroma, odor and smell all refer to the sum of the volatile compounds sensed by the nose. They impact overall taste because of the sensory interactions in the mouth and nose. Fruits and vegetables are rich in aromatic compounds, many of which have not been characterized with biochemical analysis. While aroma can be an important quality criterion to the consumer, it is difficult to measure or even to describe in practical terms.

Texture is related to the structural elements of food. The most obvious element, firmness, might be described as the resistance felt when chewing. Other textural characteristics are collectively described as mouthfeel, i.e., the sensory impacts on the tongue, palate and teeth.

In fresh produce the common textural characteristics include tenderness, crispness, crunchiness, chewiness and fibrousness. It is difficult to write descriptors for most of these for a sensory panel. Objectively, texture is most often determined by applying force to the food and measuring the resistance to shearing or deformation.

Hidden Attributes

Wholesomeness was described earlier as the perception of freshness. It is relatively difficult to measure in any practical manner but it may be important for marketing and pricing at the point of sale. Discriminating customers are likely to reject products that do not appear wholesome. This attribute does involve a sanitary component in that the product must appear to be clean and free of foreign material or decay. Perception also can be influenced by production practices, i.e., some consumers view organically grown product as more wholesome than conventionally grown.

Shape is more difficult to characterize than size but for many products visual guides have been developed. A typical grade standard might use the descriptors “well formed” or “having a shape characteristic of the product,” but obviously these are subject to some degree of interpretation and may vary by variety within a commodity group.

Color is a complex attribute but it can be quantified. Color is caused by the number and type of pigments found in the commodity. Colorimeters have been developed for nondestructive measurement of external color. There are biochemical methods for specific pigment analysis. As a practical measure, the human eye is an excellent colorimeter. Visual aids have been developed to assist the eye with color evaluation. Changes in color often may be correlated with maturity, ripeness or freshness of a product.

Defects and their causes were mentioned earlier and their presence is an important quality criterion. In a packinghouse the personnel that grade products will evaluate defects visually and remove product of inferior quality. Visual aids have been created to assist workers with identifying and assessing the severity of some defects.

Optical equipment has been developed for use on packing lines to evaluate any or all of the preceding external quality attributes almost instantaneously, although limitations in their effectiveness do exist. Support equipment can receive a signal from the optical evaluation to direct the product to a specific path within the packinghouse. These optical graders are most often employed for fruit and fruit type vegetables that have smooth skin.

Firmness can be described as the degree of softness. It is related to the structural integrity of cell walls and membranes in the flesh of the product. Softening is part of the normal ripening process and can also be related to bruising. There are various mechanical means for firmness measurement that are used in laboratories. One that is employed in some fruit industries, e.g., peaches, apples and kiwifruit, is the measurement of puncture pressure. A probe is pushed into the tissue of the product and resistance to penetration is measured as pounds or kg force required for penetration. This is useful for a number of different fruit types but obviously it is a destructive test. Nondestructive methods measure resistance of the product to deformation when pressure is applied. To date there are no rapid, nondestructive methods available for large scale use in packinghouses. Consumers may conduct their own firmness test by squeezing the product at the point of purchase.
Nutritional value is related to the presence and amounts of constituents that support life. Fresh fruits and vegetables are recognized as good sources of vitamins, minerals and fiber. More recently researchers have identified that they are sources of antioxidants and other phytochemicals that have roles in preventing or controlling some diseases. The types, quality and quantity of these constituents that individuals consume can directly impact their health.

Safety, defined earlier, is the assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use. Detecting and monitoring safety risks are difficult. Microbiological techniques are used to determine the presence of pathogens. Chemical analysis is required to detect pesticides or other chemicals. Physical hazards may be found by x-ray or other imaging techniques. Some tests are destructive so not every piece of product can be tested. The implementation of an effective safety assurance program is essential in order for a test to reasonably predict the safety of the entire lot of product.

Quality Standards

Food standards consist of precise descriptors for the criteria that define the quality of the product. They provide common frames of reference that can be used as a basis for business transactions and for disputes to be settled by regulatory authorities.

It is critical for the business community to have these grades and standards that provide uniformity in the determination of the quality of fresh produce. When a sales person is speaking with a customer on the phone about the quality of the product offered for sale, usually neither of the parties is able to look at the product at that moment and they may be thousands of miles apart if the transaction is an international one. There must be a common language or terminology that both parties understand. This helps to establish market value and to prevent economic fraud. Without standards, the description of product quality could easily be misrepresented or misinterpreted. There are several types of standards in use today and all are based upon the various quality criteria discussed previously.

Official standards, discussed later in more detail, are those set by governments and their regulatory bodies. These usually are binding upon the produce industry as a matter of law and are used not only for the initiation of a business transaction but also for settlement of disputes if the transaction is not completed successfully. It is important to note that official standards still do not exist for every produce item. In these cases, disputes have to be resolved within the companies that conduct trade.

Industry standards may be set by commodity producer groups who typically wish to set a standard for their product that may be higher than the official standard. These may be voluntary for producers, but those producers who do not participate in the program may not receive certain benefits that are offered to members of the group. For example, at the present time there are programs under development by the leafy greens and tomato industries to set food safety standards that are expected to exceed the standards that are in place for other commodities. If and when these standards are accepted widely by a commodity group they may be adopted as law and thus become official standards.

Association standards, as the term implies, are those set by trade associations for their members. In the U.S. these standards may be binding upon members if they are based upon an official USDA Marketing Order. There are many examples, but one that is familiar to many customers in the U.S. is the Vidalia onion standard. This requires that only certain types of onions grown in specific locations within the State of Georgia may be labeled as Vidalia onions.

Buyer standards, or specifications, are those set by businesses who wish to establish their own standards to generate customer confidence and loyalty. Although these specifications are not necessarily based on law, they have become a powerful tool in trade. In the area of food safety in particular, many retailers have imposed specific requirements upon their suppliers for certain conditions to be met. These usually involve audits or inspections of farms and facilities to assure compliance with the buyer’s requirements, particularly food safety requirements.

Consumer standards are not written or formal, but they may be the most important of all standards. These are the criteria that the consumer will use at the point of purchase to decide if he/she will buy the product.

International Standards

For most countries, especially the U.S., the food supply is an international one. The National Geographic Society recognizes almost 200 independent countries and the U.S. imports food from approximately two-thirds of these countries. The products imported are regulated largely by the USDA and the FDA. There are many other regulating...
bodies that have set standards for international trade and it is useful to review a few of those here.

In conjunction with World Trade Organization (WTO) Agreements, the Codex Committee on Fresh Fruits and Vegetables has the responsibility for developing standards and codes of practice for fresh produce. A code of practice known as “Quality Inspection and Certification of Fresh Fruits and Vegetables” has been adopted by the Codex Alimentarius Commission. This code contains provisions for packing, shipping, control and inspection of fresh produce.

Codex standards are a combination of grading for quality and inspection for wholesomeness, safety and freedom from economic fraud. Inspection and certification are conducted at the point of origin by a national official or a recognized service person.

The objective of the Codex standards is to protect consumers’ health and ensure fair practices in the trade of food. The Codex Committee on Food Import and Export Inspections recommends that public health protection issues be given the highest priority when considering standards. There is no legal obligation for World Trade Organization (WTO) members to adopt Codex Standards into law. Individual countries establish their own standards for imported food. However, member countries must be prepared to justify to WTO any domestic standard that is more restrictive to trade than the Codex standard.

The International Organization for Standardization (ISO) is another well-known entity in many industries including food. ISO specifies requirements for food safety management systems and requires that they demonstrate the ability to control food safety hazards in order to ensure that food is safe at the time of consumption. ISO standards are applicable to all organizations regardless of size.

Phytosanitary issues are a concern for all importing countries. Domestic agencies are responsible for protecting their own food supplies from the import of exotic pests that may threaten domestic production. In the U.S., phytosanitary issues are addressed primarily by USDA Animal and Plant Health Inspection Service (APHIS), which has mandatory programs for inspection of imported food. At times, phytosanitary issues may overlap with human health issues, in which case the FDA or other agencies such as the Centers for Disease Control (CDC) may become involved.

Refer to Section VII of this Manual for a more detailed discussion of U.S. and international food laws.

**U.S. Domestic Standards**

The USDA Agricultural Marketing Service (AMS) has developed over 150 official grading standards for fruits, vegetables, tree nuts, peanuts and related commodities. These can be viewed at http://www.ams.usda.gov/standards. The viewer can print information for the commodities of interest.

In conjunction with the descriptions of grades, the USDA has developed a number of specific guidelines to ensure that the grades are applied uniformly. If the packer or shipper has requested an official grading based on U.S. standards, the shipping certificate will show which USDA grade the shipment has met.

It is important to note that the USDA-AMS grading process is for quality attributes other than safety.

**Inspection vs. Grading**

Inspection is usually a mandatory process done by a government agency to help ensure a product’s wholesomeness, safety or adherence to regulations. For example, products entering the U.S. may be sampled by FDA at the port of entry and analyzed for microbiological contamination or pesticide residue. This is a mandatory exercise.

Grading is a voluntary program of classification of a product based on certain quality characteristics. This gives those in the produce industry common language for buying and selling. Users of the USDA-AMS service have to pay a fee for the service. Grading may be mandatory for products that are subject to a marketing order, marketing agreement, or that are subject to import or export requirements.

Grading is most commonly conducted at the packing or shipping point but may also be implemented by the receiver to settle disputes about quality.

Grading also refers to the process conducted by company employees to remove inferior products prior to the manufacture of the package that will enter commerce. This is an essential step for quality assurance.
Summary

Quality attributes may be classified as external, internal or hidden.

External attributes are those that are obvious when the product is examined, such as size, shape, etc.

Internal attributes, such as flavor and texture, require that the product be cut or bitten.

Hidden attributes are those that usually require an analysis in a laboratory, such as safety and nutritional value.

Quality attributes may be measured by a variety of methods. Some of the attributes can be objectively quantified while others are completely subjective.

Quality standards are precisely defined descriptors for the criteria that define the quality of a specific product.

Standards are of critical importance to the business community because they provide common language to help ensure the uniformity of quality of the product.

Standards may be set by a variety of entities. Some are set by government or other agencies and are official. Others may be set by a specific commodity industry or trade association. Supermarket or restaurant chains may require their own standards. The ultimate standard is that of the consumer that makes the purchase.

International trade standards have been set by a number of different organizations. Probably the most widely known are the Codex Alimentarius Commission and the International Organization for Standardization.

Domestic standards are set by individual countries. In the U.S. this is USDA-AMS for quality attributes and USDA-APHIS for phytosanitary issues.

Inspection is usually a mandatory process done by government or other agencies.

Grading is a voluntary process that helps establish common quality criteria for buying and selling.
Introduction
Fresh fruits and vegetables are alive. At harvest they are removed from their source of water and nutrients and they begin to utilize the limited amounts of metabolites and water that are stored within to sustain life processes. In this Module the factors that influence spoilage and the relationship between spoilage and food safety are examined.

General Considerations for Spoilage and Quality Deterioration
An enormous amount of fresh fruits and vegetables is lost during production due to environmental stresses, poor production management or simply because the product fails to meet specified quality standards at the time it is harvested. Additional product is lost after harvest for a variety of reasons mentioned later.

Some experts estimate that less than half of the fresh commodities produced in the world actually is consumed. Fresh tomatoes in the U.S. are a good example. Approximately 25% of the fresh market tomatoes produced are left in the field at harvest because of problems with condition. For those that are harvested, an additional 25% are graded out and discarded in the packinghouse due to quality problems. For the remaining 50% that enter commercial channels, an unknown amount will decay before they can be consumed. These estimates are realistic and may well apply to other commodities. Clearly it is beneficial to business and to the security of our food supply to examine ways in which these losses can be reduced.

Depending on the commodity, stored reserves may be forms of carbohydrates, organic acids, fats, or proteins. Some commodities, such as strawberries, have very little stored reserves, while others such as potatoes are in fact storage organs. Quality deterioration and spoilage both are affected by the type of commodity, handling practices, the rate at which stored reserves are utilized, the rate of water loss and the level of infection by plant pathogens.

During production, unfavorable weather conditions account for the greatest loss of productivity. Drought, flooding, frost, wind damage, sunburn, etc., all contribute to losses. In some cases these factors can be mitigated with irrigation, frost protection, windbreaks, shading, and other management practices. In all cases, attempts to manipulate or control the production environment add cost to production.

In the postharvest sector, three management concerns account for most of the losses. Rough handling injury that results in bruises, cuts, scrapes, discoloration, etc., increases water loss and provides an entry for decay-causing pathogens as well as any human pathogens that may be present. Poor temperature management can cause chilling or freezing injury if the temperature is too low. When temperatures are too high, decay, excessive water loss, and undesirable physiological processes, discussed later as biological factors, can occur. Finally, poor sanitation practices, especially in operations involving the use of water, lead to decay and potential infection with human pathogens if they are present. Managers of postharvest operations must give priority to these issues at all steps in the handling system.

From the above discussion it can be concluded that water loss, mechanical injuries and temperature related disorders are common to all fresh commodity groups. It is useful to list the five commonly recognized categories of fruits and vegetables and mention additional special quality concerns for individual groups.

Root and tuber vegetables include carrots, beets, onions, garlic, potatoes, sweet potatoes, and numerous tropical root crops. Several of the commodities in this group actually benefit from controlled water loss, a process described as curing, which can extend the storage life. In storage, premature sprouting caused by high temperatures, light or excessive storage time is a quality limiting factor. Products of tropical origin are susceptible to chilling injury, which is a type of low temperature-induced physiological injury that occurs above the freezing point.

Leafy vegetables include lettuce, chard, spinach, cabbage, green onions, and a variety of leafy greens that are most
Microorganisms are the direct cause of decay in fruits and vegetables. Bacteria and fungi that have the capacity to grow in the tissues of the commodity eventually cause rot. Depending on the relationship between the type of microbe, the host and the environment, decay may take months or it may happen in a matter of days. The end result is that the quality of the product is reduced and it becomes unmarketable. Decay-causing organisms secrete enzymes that cause softening (degradation of cell walls) and allow penetration of the host cells. By this mechanism, decay can spread within a container from one fruit or vegetable to another, proving the adage ‘one bad apple can spoil the whole barrel’.

It is beyond the scope of this Module to list all of the decay-causing microorganisms that attack produce or to list the common names for the resulting types of decay. The key point is that decay control is an important area of production and postharvest science. Technologies for control of decay are constantly changing, albeit slowly, and managers must keep abreast of the current knowledge in order to optimize their decay-control practices.

Microorganisms also can cause human illness as is emphasized throughout this text. Some relationships between plant pathogens and human pathogens have been identified. For example, the presence of decay-causing Erwinia bacteria increases the risk that Salmonella may be present. Further, it is known that infection with the plant pathogen Pseudomonas facilitates the colonization of Salmonella on the product surface. There are a number of known interactions between certain fungi and E. coli and Salmonella. Scientists undoubtedly will identify other such relationships in the future.

Based on this discussion of microbiology, it is critically important to reemphasize that management practices that help reduce decay and preserve quality may also help assure the safety of the product. This is an invaluable message when training managers and employees who may not understand or do not fully accept the importance of GAP and GMP. Food safety is good for business.

Physiological factors also are important for quality and safety. We must first understand that death of a fruit or vegetable is inevitable. Senescence is the term to describe the natural aging and ultimate demise of the organ. Management practices employed to extend the postharvest life of the product are delaying the onset or prolonging the period of senescence. Several physiological processes are involved.

**Specific Processes Involved in Spoilage and Quality Deterioration**

**Biological Factors**

The presence of pests, specifically rodents, birds and insects and/or their droppings is cause for alarm because it represents an immediate food safety hazard. The damage that pests can cause to the surface of the commodity is an obvious quality issue, but this is secondary to the concern for food safety. Pest issues during field production were addressed in Section II and pest control during handling was covered in Section III.
Respiration is the process through which life is sustained. Storage reserves in the detached organ are metabolized to provide energy for cells to survive. During respiration oxygen is utilized, carbon dioxide is released and energy is provided. The following chemical equation is oversimplified but it summarizes the process.

\[ \text{Stored Reserves} + O_2 \rightarrow \text{Energy} + CO_2 + H_2O \]

Each component of this equation is important. As storage reserves are depleted the organ is racing toward death. The depletion of oxygen and release of carbon dioxide into the surrounding environment can impact the respiration rate and other metabolic processes that influence quality. A portion of the energy that is created is released as heat and the water is released as vapor. The fact that the commodity is affecting its storage environment is a concern for refrigeration and ventilation requirements.

The rate of respiration of fruits and vegetables usually is an indicator of their rate of deterioration postharvest. Management practices that can help reduce the respiration rate are refrigeration, minimizing handling injury and manipulation of oxygen and carbon dioxide in the storage environment or within the product with waxes, other coatings or with packaging materials.

Respiration rate can be measured and often is expressed as either ml or mg of carbon dioxide released per g or kg of product per hour. The relative rate of respiration is commodity-specific. Knowledge of respiration rates has been useful for the development of postharvest management practices to prolong the storage life of fresh produce.

The following Table contains a summary of approximate respiration rates of selected fruits and vegetables.

<table>
<thead>
<tr>
<th>Class</th>
<th>Range at 5°C (mg CO₂/Kg-hr)</th>
<th>Commodities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very low</td>
<td>&lt;5</td>
<td>Nuts, dates, dried fruits and vegetables</td>
</tr>
<tr>
<td>Low</td>
<td>5-10</td>
<td>Apple, citrus, grape, garlic, onion, potato, sweet potato</td>
</tr>
<tr>
<td>Moderate</td>
<td>10-20</td>
<td>Apricot, banana, cherry</td>
</tr>
<tr>
<td>High</td>
<td>20-40</td>
<td>Strawberry, blackberry, raspberry, cauliflower, lima bean, avocado</td>
</tr>
<tr>
<td>Very high</td>
<td>40-60</td>
<td>Artichoke, snap bean, brussel sprouts, cut flowers</td>
</tr>
<tr>
<td>Extremely high</td>
<td>&gt;60</td>
<td>Asparagus, broccoli, mushroom, spinach, pea, sweet corn</td>
</tr>
</tbody>
</table>

Another physiological process of importance to quality and safety is the product’s rate of ethylene production. Ethylene \((C_2H_4)\) is a naturally occurring plant growth regulator produced by all plants and plant parts. Although ethylene has many roles in plant growth and development, in postharvest science it is regarded as the initiator of ripening and a modulator of senescence.

Ethylene is active in cells at very low concentrations. As little as a few parts per billion is enough ethylene to influence some aspects of plant metabolism. For postharvest uses, much higher concentrations, e.g., 100 parts per million, are applied for initiation of ripening.

The rate of ethylene production and its activity is influenced by temperature, disease, injury to the product and environmental stress. Management strategies for reducing the effects of ethylene in the storage environment include reducing temperature, lowering the concentration of oxygen, and increasing the concentration of carbon dioxide. These strategies are highly commodity-specific and managers must understand the characteristics of the commodity before initiating such environmental modifications.

Fruits and fruit-type vegetables are categorized as either climacteric or non-climacteric based on their patterns of respiration and ethylene production. Knowledge of these fruit characteristics have enabled harvest managers to determine the optimum time for harvest. Further, postharvest managers better understand how to manipulate the storage environment, not only to provide better quality products to consumers, but to enhance the profitability of the business.

Climacteric fruit are those that exhibit auto-catalytic production of ethylene. As the rate of endogenous ethylene production increases there is a corresponding rapid rise in the rate of respiration. Climacteric fruit may be harvested when fully mature but before the onset of ripening, which can then be initiated with exogenous treatment with ethylene. This is common commercial practice with bananas and mature-green tomatoes. International trade in bananas has been possible because the fruit can be harvested green, shipped long distances and ripened with ethylene at the destination. If climacteric fruit are harvested too late, after the initiation of ripening on the mother plant, the postharvest life of the product is dramatically shortened because senescence follows ripening. Other examples of climacteric fruit include mango, papaya, apple, peach and others.
Nonclimacteric fruit do not exhibit a dramatic rise in respiration or ethylene production as they ripen. In fact there is no clear physiological demarcation between maturity and ripening. These fruit attain their best eating quality if they are allowed to ripen on the plant before harvest. Examples of nonclimacteric fruit include citrus, cherry, strawberry, grape, pineapple and others. With the exception of pineapple, these commodities do not become substantially sweeter or achieve better eating quality after harvest.

The following stylized graph depicts the climacteric curves for respiration and ethylene production. A nonclimacteric fruit would not exhibit these increases, e.g., the line would be flat.

**Biochemical Factors**

It is not possible to make a clear distinction between the biochemical and biological factors that influence fruit and vegetable quality and safety. However, there are some processes in plant science that can be isolated and examined in vitro. These tend to be discussed in chemical terms.

Enzymes are proteins that occur naturally in all forms of life. They catalyze a multitude of important chemical reactions. Many of these reactions are beneficial while others result in quality deterioration. For example, softening is primarily due to enzyme-mediated degradation of cell walls accompanied by changes in cell membranes. The modification of lipids and other constituents can result in off flavors or fermentation but can also provide aromas that are desirable.

Oxidative enzyme activity is of special interest. Undesirable browning or other color changes and reduction in nutritional quality are often associated with oxidative reactions. Oxidative processes have been researched extensively because of their involvement in senescence of plants as well as animals.

Managers of postharvest operations, who deal with practical matters, seldom think of their activities in terms of product chemistry. But all reactions in fruits and vegetables are chemical reactions.

**Physical Factors**

Loss of water from harvested product to the surrounding environment is largely a physical process. Prior to harvest, water lost through transpiration is replaced by water taken up through the roots, but once the commodity is detached.
from the plant this supply of water is lost. Excessive transpiration after harvest leads to shrinking, shriveling, wilting, softening and changes in crispiness, juiciness and nutritional quality. Water loss can be mediated to some extent by application of waxes, coatings, packaging, and control of humidity and rate of air circulation in the storage environment.

Physical injury to commodities causes many undesirable changes in quality, some of which have been mentioned previously. The high water content of fruits and vegetables and the corresponding turgidity of cells make them susceptible to physical forces. Such injuries are unsightly and cause accelerated water loss, provide points of entry for decay causing microorganisms or human pathogens and cause an increase in rates of respiration and ethylene production.

As stated earlier in Section III, the hands of the harvest worker may be the most important hands that touch the commodity because in the instant that physical injury is inflicted to the product all of the investment in production is lost. Workers can also transfer human and plant pathogens to the product. This, once again, highlights the importance of worker training programs.

**Time**

Time is a factor in every aspect of spoilage, quality deterioration and food safety. Business managers in the produce industry should take every practical measure to ensure that fresh produce is moved from the field to the consumer in a timely manner.

**Summary**

All fruits and vegetables are alive. Their primary constituent is water. They are susceptible to injuries and infection that lead to quality deterioration, spoilage and food safety risks.

After harvest, fresh commodities must survive with the stored reserves and water that are present at the time of harvest.

The principle objective of postharvest management practices is to maintain quality and safety and to extend the life of the product.

Factors that influence quality deterioration may be biological (microbiological) biochemical, physiological or physical.
Introduction

Hazard Analysis Critical Control Points (HACCP) is a food safety assurance program that was developed for the food processing industries. It is a systematic approach to the identification, evaluation and control of food safety hazards. The fresh produce industry does not “process” food in the manner of other industries, but the principles of HACCP have been invaluable in the development of GAP and GMP and these programs are referred to as HACCP-like.

The term HACCP has been widely misused in the fresh produce food safety literature. The terms GAP and GMP were not formally defined by FDA until 1998 with the publication of the “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.” Prior to this date, there was no terminology that accurately defined food safety programs in fresh produce that were the focus of many Extension and Research publications. HACCP was routinely used in a context that does not accurately reflect the work that was being done during those years.

The importance of HACCP should not be minimized, but it should be discussed in the proper context. It is important that progress in fresh produce safety not be slowed by a debate regarding terminology. Rather, focus should be placed on the goal of developing and implementing effective GAP and GMP programs that utilize aspects of HACCP such as hazard analysis.

Origin of HACCP

The origin of HACCP is traced to the beginning of manned space flight in 1959, when the National Aeronautics and Space Administration (NASA) worked with the Pillsbury Company to develop a system for processing foods in a manner that could assure the safety of food consumed during space travel. The program was effective. As it became more refined and widely utilized, the National Academy of Sciences (NAS) recommended in 1985 that the program be adopted by regulatory agencies and mandatory for all food processors.

Principles of HACCP

There are seven basic principles involved in a HACCP program. The underlying theme of all of these principles is that prevention of contamination of food is favored over remedial action to inactivate contamination.

1. Conduct a hazard analysis.
2. Determine the critical control points (CCP).
3. Establish critical limits.
4. Establish monitoring procedures.
5. Establish corrective actions.
6. Establish verification procedures.
7. Establish record-keeping and documentation procedures.

Application of HACCP Principles to GAP and GMP

The utility and limitations of HACCP in fresh produce food safety programs can best be identified by conducting a brief analysis of each principle in the context of the production and handling practices used for fresh produce. First we should review the definitions of hazard and risk stated in Section I.

A hazard is a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
**Risk** is the probability that illness or injury will actually occur following exposure to a hazard. We control hazards to minimize risk.

A hazard analysis is appropriate for any food industry, including fresh produce. This requires a step by step analysis of the production and handling system. In farming systems, the use of water and compost both are potential hazards. Other potential hazards involve the personal hygiene of workers, the presence of animals in fields and contamination of food contact surfaces. Some of the same hazards exist in postharvest systems, with water and worker hygiene being two important issues. GAP and GMP include steps to reduce risks associated with these and other potential hazards.

The principle of monitoring procedures applies to all food systems. The SSOP that are developed for GAP and GMP programs stipulate that monitoring must be done for the preventative measures to ensure proper and consistent implementation.

Corrective actions are an important part of GAP and GMP. As production and handling systems are monitored, appropriate action must be taken to correct any measure that is observed to be deficient. Since fruits and vegetables are to be consumed fresh, there are no corrective steps that can eliminate or reduce hazards to acceptable levels once contamination has occurred. This is another reason that HACCP is not mandated for fresh produce. Further, it emphasizes once again that prevention of contamination is key to produce safety.

Verification procedures in GAP and GMP are tenuous at best. Since there is no “kill step” to apply to fresh produce, testing the product for the presence of microbes is not feasible, although there is debate in the industry and scientific community about the value of testing. In contrast, an analysis for chemical residue might verify with some certainty if a pesticide has been misused. Likewise a metal detector can verify the absence of a metallic physical hazard in the final package. In GAP and GMP methods of control can be verified in some cases. For example, water quality management in packinghouses that utilize chlorine as a sanitizer may monitor oxidation-reduction potential (ORP) continuously and conduct a periodic verification of the chlorine level with a test strip or some other method.

The final HACCP principle, record keeping and documentation, is also an essential practice for GAP and GMP. The SSOP should state what should be done and how to do it. Each time a SSOP is completed the procedure should be documented by the individual completing the task. These records allow for monitoring of the SSOP implementation.

The following Table provides a few examples of hazard identification, preventative measures, and records that might be utilized for GAP and GMP programs. Note that it includes a number of the principles discussed above.

The preparation of a similar list or table of information is a prerequisite for the development and implementation of GAP and GMP. This Table is by no means comprehensive and is intended to serve only as an example for the reader.
**Conclusion**

HACCP, though not directly applicable to fresh produce production and handling systems, does have attributes that can be utilized in the development of GAP and GMP programs. Personnel in charge of food safety programs will find a thorough review of HACCP to be beneficial.

**Summary**

HACCP is a systematic approach to the identification, evaluation and control of food safety hazards.

The fresh produce industry does not “process” food in the manner of other industries, but the principles of HACCP have been invaluable in the development of GAP and GMP. These programs are referred to as HACCP-like.

Hazard analysis involves a detailed review of the process of growing and handling food.

When potential hazards have been identified, controls must be implemented to minimize risks associated with those hazards.

There is no “kill step” available to inactivate human pathogens if they are present on fresh produce. The underlying theme of all aspects of GAP and GMP programs is to prevent contamination from occurring.

Personnel in charge of food safety programs will find a thorough review of HACCP to be beneficial as they develop GAP and GMP for their companies.
Section IV

Pesticides and Food Safety

Module 1  General Considerations for Pesticide Use and Minimization of Residues
Module 2  Pesticide Movement and Degradation in the Environment
Module 3  Pesticide Movement and Degradation in the Plant
Module 4  Best Handling Practices for Pesticides
Module 5  Minimizing Human Exposure to Pesticides
Introduction

Pesticides and the handling that is required for their use are regulated in most developed countries. The goal of regulation is to protect human health and the environment. Protection is the key word.

If the regulatory system sets appropriate limits and pesticides are applied properly, consumers of fresh fruit and vegetables are protected from exposure to excessive pesticide residues on the product. Farm workers are protected from occupational exposure, people who are near farms are protected from incidental exposure and the environment is protected from pollution. This Module is an introduction to pesticides, their use and control of their residues.

Definitions

Formal definitions are provided for critical terms that will be used throughout this Section.

Pest

For the purpose of U.S. law and regulations, a pest is defined as any insect, rodent, nematode, fungus, weed, bacteria, virus, or other microorganism, or any form of terrestrial or aquatic plant that the U.S. Environmental Protection Agency (EPA) declares to be a pest under the law.

The EPA definition excludes microbes on or in a living human or other animal. Recall that in Section II on GAPs, these microorganisms were included because of their critical involvement in food safety. To meet the objectives of this manual, human pathogens, birds and all wild and domestic animals are included in the category of pests.

Pesticide

A pesticide is any algicide, antifouling agent, antimicrobial, attractant, disinfectant, fungicide, fumigant, herbicide, insecticide, miticide, pheromone, repellent, rodenticide, termite, or plant incorporated protectant.

The legal definition, for the purpose of U.S. law and regulations, includes the above categories but is written in a more general style. A pesticide is defined as any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pests or used as a plant growth regulator, defoliant or desiccant. This is found in the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.), which includes not only the pesticide active ingredient but any inert materials as well.

Pesticide Residue

Residue refers to the amount of a pesticide chemical or ingredients in the pesticide mixture found in or on a raw agricultural commodity or in a processed food. The definition also includes residue of degradation products of the pesticide chemical, whether those products are the result of plant metabolism or some other degrading process. Thus the residue of concern may be the parent compound, a metabolite of the parent compound or a combination of the two.

Pesticide Tolerance

Tolerance is the amount of residue legally allowed to remain on or in the commodity at harvest. For the establishment and regulation of tolerances, agencies must consider the range of crops the pesticide is registered on or could be registered on in the future. They also must consider additional sources of residues in meat, poultry, milk or other food products if the pesticide is carried forward into the food processing industries.

Pesticide Registration

Registration of a pesticide is a scientific, legal and administrative process to enable authorities to control quality, levels, labeling, packaging and advertising of the product. Pesticides used in the U.S. and those used for products imported into the U.S. must be registered with the U.S. Environmental Protection Agency (EPA).

Control Methods to Mitigate Crop Damage from Pests

Growers have a number of options for pest control that can help to reduce the requirement for chemical pesticide
has contributed to the interest in organic farming and other natural approaches to diet and lifestyle. The human element is discussed in considerable detail in Module 5.

A second hazard associated with pesticide use is potential economic damage to adjacent nontarget crops or harm to beneficial insects, wildlife and the environment. Run-off, percolation or drift into water is of special concern since the pesticide could damage wells or flora and fauna far from the point of application of the substance.

The final hazard concerns the health and safety of workers who handle pesticides. In the U.S. and many other countries there are Worker Protection Standards (WPS) that regulate employers’ responsibility to provide safety measures, including protective equipment, for handling practices as a matter of law. Some aspects of WPS are discussed in Modules 4 and 5. Despite legal requirements, there have been well documented and publicized abuses of the law that keep public concern heightened.

Legal Principles of Pesticide Residue Minimization

A goal of regulators and growers alike is to apply the minimum amount of pesticide that allows for adequate control of the pest. This in turn minimizes the amount of residue left on food. Legal requirements (the label) must be followed at all times. In addition to the label, each pesticide is accompanied by a Material Safety Data Sheet (MSDS) that must be made available to those who work with the material.

The pesticide must be legally allowed on the crop and the location to which it is applied. Environmentally sensitive areas, such as native wetlands, that surround or border a production area might be cause for placing a restriction on the pesticide use on that particular site.

As stated previously, the pesticide must be used according to label directions. These are based on extensive testing for potential adverse effects on humans, animals and the environment. The label directions include specific information on dose, timing of applications, etc. Additional sections of the label address personal safety requirements for handling the pesticide, protections for wildlife, storage and disposal instructions, and other requirements. Research trials provide results that can be used to develop models for the prediction of residue levels remaining on crops under specific sets of conditions, discussed in Module 3.

Following application of a pesticide, there is a minimum amount of time that must pass before anyone can reenter...
the field. Appropriate signage must be placed to alert workers of the danger of reentry.

A minimum interval must be allowed from the time of pesticide application to the time of harvest in order for the chemical to degrade to a level that is at or below the tolerance. This interval may be influenced by the crop site, weather and life cycle of the crop. All of these variables are considered in the development of a pesticide label.

There are three distinct periods in the life of a commodity during which pesticide residues are influenced by biological processes, the environment or other external factors, such as cultural practices. These periods are the time from application of the pesticide until absorption by the plant, the time from absorption until the product is harvested and the time that the product is held in the postharvest environment. Regulatory agencies require pesticide manufacturers to conduct adequate studies and submit data to determine the fate of pesticides during these periods and to predict residue levels. This allows regulatory agencies and growers to identify practices that minimize residues while allowing for the intended action of the pesticide.

Factors Affecting Pesticide Residues in Crops

There are a number of variables in the use of pesticides that can influence the amount of residue that will remain on the crop at harvest and beyond. Researchers and regulatory officials must consider as many of these as possible as they develop labels for pesticides. Growers may go a step further toward residue minimization if they tailor their production practices to limit the amount and improve the efficacy of any pesticides that they apply, taking care always to adhere to label requirements.

Answers to the following series of questions offer insight into the prediction of residue levels and identify some of the practices that growers may implement to minimize residues.

Where is the pesticide deposited in the field? This is determined largely by the method of application and the equipment used, both of which usually are crop specific. For example, a low-growing field of strawberries or leafy greens might be treated with a low-volume over-the-row precision applicator that places most of the pesticide directly onto the plants. In contrast, tree fruit may require an air blast applicator using a relatively large volume of spray material in order to reach the interior of the tree canopy. Overspray will be deposited on the soil and might be carried by wind into surrounding areas. The residue level in the crop depends largely on the amount of pesticide that is applied directly to the crop. An additional environmental concern is residue in the soil or nearby areas.

How much pesticide is applied? The maximum allowable application rate and number of applications are specified on the label. However, growers should not feel compelled to always use the maximum amount. The implementation of an Integrated Pest Management (IPM) program defined earlier, in which pesticides are applied only in response to pest pressure that is determined by professional scouts, is a way for growers to minimize chemical use and thereby residues.

How much unintended pesticide is deposited on or absorbed by the plant? Hopefully the answer to this question is zero. However, unintended exposure can occur when pesticides are carried by wind through the air (drift), by water that has been contaminated or by soil particles that are caught by the wind or suspended in water. It is the grower’s responsibility to handle pesticides in a manner that does not allow unintended exposure of a crop. This can be challenging if a third party is contracted to do the pesticide application as it requires monitoring of the practices of others.

How much pesticide will penetrate into the plant? This is determined largely by the chemical formulation and the plant characteristics. Liquid formulations are generally more easily absorbed than dry formulations, which may require watering in order to reach their target. Waxy or hairy leaves tend to repel pesticides more than smooth surfaced leaves, but arguably hairy leaves could better trap the particles of a dry formulation. These variables are considered by those responsible for developing the pesticide label, but growers also should be aware that plant characteristics affect absorption.

How will the pesticide be degraded by the plant? There are three considerations: pesticide chemistry, plant species and weather. Water soluble pesticides generally are metabolized more quickly and are less likely to accumulate in the plant than fat soluble compounds. Different plant species are known to detoxify pesticides at different rates, depending on the specific pesticide. Cooler temperatures tend to slow the degradation. This is addressed in Module 3.

Where will the pesticide and its breakdown products end up in the plant? Obviously, the plant part(s) in contact with the pesticide will be the first host for the chemical, however translocation of pesticides can occur. Tissues or organs where pesticides accumulate are sometimes referred to as storage “depots.” Older classes of pesticides are more
fat-soluble and more likely to be stored in parts of the plant with higher oil content. The newer, more water-soluble classes are more likely to be removed through transpiration. Storage in the plant also can be influenced by timing of application relative to the type and developmental stage of the crop. One should note if the plant is using or storing energy during the season in which a pesticide is applied. This may indicate whether the pesticide is moving into the leaves, fruit or down into the roots.

How much of the pesticide and its breakdown products will remain in the plant? Several factors are involved and the relationships between these factors are complex. Different plant parts may absorb pesticides and facilitate their translocation within the plant at different rates. Once the pesticide has entered plant cells, biotransformation reactions can occur to degrade the pesticide. These are discussed in more detail in Module 3. Finally, the time that elapses between pesticide application and harvest is a factor. If this interval is increased it allows more time for biotransformation or other degrading processes to reduce residues to the tolerance, or preferably, below the tolerance.

Can a plant metabolize more than one pesticide at a time? If multiple pesticides are mixed and applied in one treatment, or if some residue(s) remains in a plant when the next application is made, the plant will need to detoxify more than one pesticide at a time. In this case pesticides may be competing for the same biotransformation enzymes and degradation may be slower.

What happens after the crop is harvested? Recall that the legal tolerance for residue is set for the time of harvest, but postharvest procedures can impact the residue level. Washing fruits and vegetables helps to remove surface residues. Processing, depending on the specific process, may either reduce or concentrate residues. Cooking almost always reduces residues. Peeling fruits and vegetables effectively removes surface residues, but also alters the nutritive value, as it removes vitamins and nutrients contained in the skin.

What happens to pesticides in animal feed, forage or pasture? Animals, including humans, have their own biotransformation processes. The important point to emphasize is that pesticides for plant production must be used in strict accordance with the label in order to minimize the amount of residue that animals ingest.

Interaction of the individual factors affecting pesticide residue levels is complex. Large research trials conducted over long periods of time are required in order to answer the questions presented here. All pesticides, including new chemical formulations, must be evaluated for the intended crops. This is a costly process but a necessary one in order to assure the safety of consumers, pesticide handlers and the environment.

Summary

The goal of pesticide regulation is to protect human health and the environment.

For regulatory purposes, the definition of pests includes certain animals, microorganisms and plants. For food safety purposes, human pathogens, birds, and wild and domestic animals are included in the definition.

A pesticide is defined as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pests or used as a plant growth regulator, defoliant or desiccant.

Residue refers to the amount of pesticide, its degradation products, or ingredients in the mixture found in or on a raw agricultural commodity or in processed food.

Tolerance is the amount of residue legally allowed to remain in or on the commodity at harvest.

Pest damage may be mitigated by a number of methods, including biological control, plant resistance, cultural practices, mechanical and physical methods, and chemical applications.

IPM includes consideration of all possible methods and judicious use of the best methods for a given crop/pest/environment situation.

Potential hazards associated with pesticide use include contamination of food, damage to the environment, negative health effects in workers who handle pest control substances, as well as workers’ families, and consumers of foods treated with pesticides.

The likelihood of adverse effects on human health and the environment is sharply reduced when proper pesticide handling and application methods are utilized.

Pesticide residues can best be minimized by strictly following the label requirements for the use of the material. The label is the law.

Many environmental and biological factors influence the amount of residue that is left on food. Interactions of these factors are complex and can be identified only through exhaustive research.
Introduction

Once a pesticide has been applied to a crop its fate is determined by a myriad of biological and environmental factors. In an ideal situation, pesticides would take action upon the intended pest and then rapidly be degraded to less toxic compounds. This is seldom the case. The fate of the pesticide must be determined in order to establish guidelines for the safe use of the product. This Module focuses on the interaction between environment and pesticides.

Factors Influencing Pesticide Movement

When analyzing the fate of pesticides, it is important for scientists to identify the specific locations in the environment where pesticides can occur. These locations are above ground, at ground level and below ground. Wherever the pesticides tend to end up, they may be degraded by different processes that are addressed later in this Section. The time required for degradation can be relatively short (a few hours) to extremely long (many years). It is important to understand where pesticides may accumulate and the time required for degradation in that location.

A pesticide application may be directed at the plant, the soil, or both. Pesticides that reach the plant may penetrate the plant, adhere to the plant surface or drip off on to the soil. The anatomical characteristics of the plant, such as the presence of a waxy cuticle, the chemical characteristics of the applied substance, and the weather all impact where the pesticide eventually resides.

Liquid formulations may “pool” on the plant surface due to surface tension. These may dry on the plant, volatilize into the atmosphere or drain off on to the soil. Volatilization is the conversion of a solid or liquid to a gaseous state and is affected by temperature and the vapor pressure of the pesticide. Knowledge of the fate of the material helps to determine its persistence in the above-ground environment.

Pesticides that reach the ground level have similar fates as described above, e.g., they adsorb to the soil surface, penetrate through the soil or are volatilized from the soil surface. They may also move off-site through drift, run-off or leaching.

Run-off is a major concern. This is the movement of the pesticide off-site laterally in water, which can occur after rain or irrigation. Run-off can result in the contamination of surface water or poorly constructed wells and endanger humans, domestic animals and wildlife. Run-off is affected by the slope of the land, with steeper slopes increasing the likelihood of run-off. Barriers or terraces may be needed to reduce run-off. If these are not effective, retention ponds may be constructed to capture the water.

Soil type strongly influences the likelihood of run-off. Clay soils contain many binding sites that can retain pesticides in their matrices. Sandy soils have less capacity for retaining pesticides. However, clay is not as easily penetrated as sand and heavy rainfall or irrigation may carry pesticides away from clay very rapidly. Strips of vegetation, particularly grass, that are strategically located around fields can deter run-off because the pesticide can be taken up by the vegetation, making it unavailable to be moved off-site in water. Frequent tillage, on the other hand, tends to promote soil erosion and increase run-off.

Pesticides that move below ground may adsorb to roots, penetrate the roots, adsorb to soil particles or leach out of the root zone. Adsorption to soil is influenced by soil texture, permeability, pH, temperature and organic matter content. These factors also influence leaching. Leaching is the downward movement of pesticides in water, which can result in the contamination of groundwater. The properties of the pesticide, particularly its solubility and how strongly it tends to adsorb to roots, influence its persistence in the root zone. In addition to factors mentioned above, leaching also is affected by the pesticide application method and rate, amount of rainfall or irrigation and tillage practices.

The Figure on the following page summarizes the fate of pesticides in various locations. Growers must consider many factors as they develop their management strategies for pesticide use. Practices that increase the efficacy of pesticide applications will usually protect the environment and reduce costs.
Microbial Degradation
Microbes in the soil secrete enzymes that can degrade pesticides. Soil conditions that influence the rate of microbial degradation include moisture content, temperature, organic matter, aeration and pH.

The repeated use of a specific pesticide on a site can create conditions that are favorable for an increase in the population of microorganisms that metabolize the substance. These are classified as aggressive soils. Aggressive soils have been a problem with certain herbicides in the U.S. where the microbial population has become so high that the herbicide is degraded before it can have its full effect on weed control. Microbial activity is generally highest in the root zone, with moderate activity in the subsoil and minimal activity in groundwater. Pesticides that leach into groundwater or enter via a poorly constructed well may persist there for many years.

Photodegradation
Photodegradation, as the name implies, is caused by ultraviolet light striking the pesticide molecule. Warmer temperatures work in combination with ultraviolet light to speed the process. The following map of the U.S. shows that soil surface temperatures in the southern states and along the eastern seaboard are substantially higher than the rest of the country. Generally, pesticides would be expected to degrade faster in these warm areas. Day length also is a factor in photodegradation. Tropical regions, especially near the equator where there is little change in climate or day length throughout the year, may be more predictable with regard to pesticide persistence in the environment.

Pesticide Degradation
Understanding pesticide degradation is important, both to reduce residues and to protect the environment. A few pesticides have as their active ingredient relatively small molecules containing mineral elements such as copper, zinc or manganese. These minerals tend to remain in the soil. Most pesticides are either large organic molecules or biological agents that are subject to degradation processes in the environment. Those that are not readily degraded are generally considered to be undesirable because of environmental concerns. DDT is one such pesticide that was used on a very large scale decades ago but has been disapproved in most countries because of its persistence in the environment and concerns about wildlife, such as reduction of bird populations due to eggshell thinning.

Three types of pesticide degradation will be discussed: chemical, microbial and photodegradation. Combinations of these processes are usually involved.

Chemical Degradation
Chemical degradation takes place naturally over a period of time. The period can be quite long unless aided by other processes. Each pesticide has its own specific half-life, which is the period of time necessary for half of the amount of pesticide to be degraded by chemical processes under a particular set of environmental conditions. Warmer temperatures and alkaline pH typically increase the rate of degradation reactions.
**Crop Removal**

Pesticide residues remaining in the crop at harvest are removed from the site. This eliminates one source for pesticide residue buildup in the soil. It also is the compelling reason that pesticide use must be managed appropriately to ensure that residues in the edible product are below tolerance and do not cause harm to consumers.

**Summary**

To establish effective regulations for the use of pesticides, scientists must understand the fate of the substance once it has entered the environment.

In an ideal situation, pesticides would take action upon the intended pest and then rapidly be degraded to less toxic compounds.

Scientists who study the fate of pesticides tend to focus on three locations in the field environment: above ground, ground level and below ground.

Pesticides may volatilize from the plant or soil and escape into the air.

Movement of pesticides into surface water by run-off, or into groundwater by leaching or via a poorly constructed well, is a concern for the safety of humans, domestic animals and wildlife.

Pesticide run-off and leaching is influenced by field topography and soil characteristics.

Pesticides may be degraded by the action of light, heat, chemicals or microbes.

Pesticide-degrading microbes in the soil may multiply into high populations and break down the pesticide before it can take action against the pest. These are termed aggressive soils.

Some pesticides are removed from the field on the harvested crop. This is a compelling reason for the management of residue levels to avoid causing harm to consumers of the product.
Introduction

The application of a pesticide will result in some amount of the material entering the plant. The fate of the pesticide within the plant is extremely important for the prediction of residue levels at harvest.

Internalization of Pesticides into Plants

The first step of internalization requires that the pesticide gain entry into the plant tissues. This can occur through either passive or active mechanisms, or both. All of the plant organs, e.g., leaves, flowers, stems, fruits, roots and tubers have potential entry sites.

Plants have a number of natural openings, such as stomata and lenticels, through which pesticides may enter passively. Damage to plants, such as tears, bruises, scrapes and scratches also provide a point of entry. The damage caused by sand or debris carried by the wind can be significant, as can the injury caused by equipment moving through the field. Any type of opening in the tissue is a potential point of passive entry.

Active entry of pesticides is a more complex biological process and not all pesticides penetrate in this fashion. Systemic pesticides are, by definition, designed to be carried inside the plant tissues. The binding and transport mechanisms for the translocation of pesticides at the cell level are well beyond the scope of this discussion, but would be classified as active entry.

Passive and active entry both are influenced by the pesticide formulation, weather conditions, particularly temperature and humidity, and plant morphology. Waxy leaves may repel the formulation while hairy surfaces tend to retain the applied material. Warm temperatures and high humidity can encourage entry by increasing the rate of metabolic activity of the plant and by causing the pesticide to persist on the plant surface for a longer period of time.

Distribution of Pesticides in the Plant

The movement and redistribution of pesticides within plants can be a critical factor in the activity of the applied substance. Some pesticides are applied to the soil, absorbed by the roots and translocated to aboveground parts where they have activity against pests feeding on leaves. Understanding the mechanism(s) of movement may provide insight into pesticide distribution within the plant.

There are two general “zones” for pesticide movement within plants. The apoplastic zone has been characterized by some as nonliving tissues. This includes the xylem and cell wall space. Cell wall chemists and physiologists take issue with the idea that the apoplast is dead space since there is enzyme activity and other metabolic processes that occur within the xylem and cell walls. For this discussion, the important point is that water moves relatively freely in the apoplast. Water-soluble and weakly lipophilic (fat-soluble) compounds are more likely to be transported through the system with the movement of water.

In contrast the symplastic zone, which includes the phloem, is very much alive. More lipophilic substances are moved in the symplast by active transport, which involves chemical “pumps” that move substances from cell to cell across membranes. Enzymes, co-factors and a myriad of metabolic processes are involved in active transport. A pesticide molecule that is designed to be transported in this manner must have a structure that will withstand the chemical rigors of the process. Movement to centers of metabolic activity, such as the tips of roots and shoots, occurs via active transport in the phloem. Cell to cell diffusion is a passive process occurring in the symplastic system.

The movement of some chemicals is restricted to one of these two routes, while other chemicals are able to move throughout both systems.
Often there is more than one pathway by which an organism (plant, animal or microbe) degrades a chemical and all of these processes will be taking place at the same time. Having multiple reactions and multiple pathways acts as a backup system to help protect all organisms and to degrade chemicals as rapidly as possible. The rate of biotransformation within the plant parts may vary even for the same pesticide. This is influenced by environmental factors such as temperature and humidity, the time of year and the overall health of the plant. Three phases of biotransformation have been identified: transformation, conjugation and sequestration.

Phase I (transformation) occurs in various ways and depends upon the chemistry of the pesticide ingredients, the formulation and the concentration of the applied product. Numerous enzymes are involved, including esterases, lipases and proteases. Cytochrome P450 enzymes are of particular importance. The results of Phase I are that reactive intermediates are formed with the degradation of the primary molecule. Reactive intermediates are chemicals with exposed sites that can be acted upon by other processes in the next phase of biotransformation.

Phase II (conjugation) is the binding of the reactive intermediates from Phase I to naturally occurring plant constituents such as carbohydrates or amino acids. Glutathione S-transferase is an important enzyme in Phase II reactions. The conjugated products are soluble and may be either less toxic or more toxic than the parent compound.

Phase III (sequestration) occurs when the conjugates from Phase II reactions become bound to insoluble structures within the plant. This non-extractable bound residue has restricted mobility in the symplast. Sequestered toxic substances are less available to the plant to cause adverse physiological effects.

There are three major sequestration pathways. Substances may be transported into the cell vacuoles, which act as “holding tanks” for the molecules. They may also be exported into the extracellular space and remain soluble. Finally, they may bind to lignin or other cell wall components. Bound residues in plants may or may not be bioavailable to predators.

The older generation of pesticides included compounds such as DDT, which was broad spectrum in its activity, lipophilic and persistent in the environment. The newer generation of pesticides includes materials that are more specific in their activity, are water soluble and have a half-life of hours to weeks. They are less likely to be sequestered.
and more likely to be degraded. These newer chemicals are generally considered to be more environmentally friendly than the older generation.

Plants are very efficient at recycling some pesticides. Plant cells use the breakdown products to synthesize chemicals for their own use. This has become an important emerging area of research. The National Center for Environmental Research sponsors studies on the use of plants to remediate contaminated sites.

**Postharvest Factors and Residues**

Once the edible portion of the plant has been harvested, degradation of pesticide residues may continue postharvest. Washing may remove some residues if they are on the product surface but systemic pesticide residues are not significantly reduced. Depending on the commodity, transportation, storage and marketing may require from days to months after harvest. It is important to characterize the persistence of residues during this period, even though tolerances are set based on the time of harvest.

As noted in Module 1, processing can either concentrate or degrade residues depending on the nature of the process, e.g., if it involves heat or chemical treatments. The focus of this discussion is on fresh produce that will be consumed raw.

In the U.S., the Environmental Protection Agency (EPA) has the responsibility for oversight of pesticide registration, which requires extensive studies on the toxicology and the development of risk profiles. Most residue data are available only through formal requests made under the Freedom of Information Act.

Prior to the approval of a pesticide, the EPA requires that residue studies be conducted on at least one root crop, one leafy vegetable and one fruit or fruiting vegetable. Collectively, these studies for pesticide registration and for other purposes have identified different fates, depending on the properties of the pesticide and of the plant in question. In some cases residues have been shown to remain mostly as the parent compound, indicating that the plant does not substantially degrade the pesticide. For other plant/pesticide combinations, residues appear mostly as metabolites, indicating substantial degradation by the plant. Studies also have shown that the final location of the residues vary widely. Depending on the combination of pesticide and plant, residues (either as parent compounds or as metabolites) may show up primarily in the leaves, fruits, seeds, tubers, roots, vines or stems.

**Biotransformation**

Biotransformation of pesticides in plants is a highly complex group of processes. Studies of the mechanisms involved in biotransformation are costly but are necessary to determine if pesticides can be used without adverse effects on humans or the environment. Crops with residues exceeding tolerance, or having residue for which no tolerance exists, can be confiscated.

**Summary**

The application of a pesticide will result in some amount of the material entering the plant.

Entry into the plant may occur actively or passively, or by both mechanisms.

The movement and redistribution of pesticides in plants can be critical to its mode of action.

Biotransformation is the modification of a pesticide through biological processes that yield degradation products.

Detoxification is the modification of the pesticide molecule to a point at which there is little or no remaining toxicity.

The three phases of biotransformation are transformation, conjugation and sequestration.

Degradation of pesticides continues after the commodity is harvested. Residue studies are required to determine if pesticides can be used safely.

The EPA is the regulatory agency for pesticides in the U.S.
Introduction

Growers should be aware of handling practices that provide the best efficacy for the product while avoiding injury to people, animals or the environment. Many of the land-grant universities in the U.S. have Best Practices manuals and other publications available online at no cost. This Module is an overview of the principles that would be covered in detail in a manual. Some of the points made in this Module are discussed elsewhere in this Section.

Sources of Excess or Unregistered Pesticide Residues

The intentional misuse of a pesticide is illegal and punishable by law.

The presence of unregistered pesticide residues, i.e., not registered for use on the specific crop, or an excess of a registered pesticide, both render the crop unmarketable. If either of these problems occurs, growers must analyze every aspect of their pest control program to determine the cause of the problem and to identify a strategy to prevent the problem from occurring again.

Illegal substance(s) may be present or legal residue(s) may be above tolerance for a number of reasons. There could have been overspray from careless application to a neighboring site or there could have been accidental drift from other application sites. A registered material may have been applied at too high a rate or it may have been applied too frequently. This could result in residue of an unapproved pesticide on the crop, or of approved pesticide but at too high a level.

Residues can accumulate in soil from previous applications to the site, from drift onto the site, run-off, leaching, irrigation water overspray, or from the deposition of contaminated soil particles carried by wind or water.

Producers of minor crops are at a distinct disadvantage because pesticides may not be registered for their particular crop. As discussed elsewhere, the cost of registering pesticides is very high. If manufacturers do not see an opportunity to recover this investment through sales, they may not choose to register a material for a minor crop for which sales of the product would be low. Growers of minor crops may not understand that a pesticide is not allowed on a minor crop when they use the same material on other crops on their farm. Nevertheless, the label is the law and growers must follow label directions at all times. In the U.S., funding is provided to IR-4 for research on minor crops so that pesticides can be registered for use.

Essential Records

There are a number of useful computer programs available to growers to help keep track of all pesticide applications. Pesticide label information is written in to the program. When growers enter information about an application, the program will alert them of any problems that may preclude them from making the specific application. The programs offer the additional advantage of preserving pesticide use records, which is required by law in most locations.

By U.S. federal law, record keeping is required for pesticides classified as Restricted Use Pesticides (RUP). Many states have additional requirements that exceed the federal law. They may require that records be kept for additional (not just RUP) products. Growers should check with the regulating agency within their state for specific information on what data are required. Recommendations below include the minimum requirements to meet the federal standard as well as best practices. They should be applied to all pesticides used, regardless of whether they are RUP.

Records must include the brand and product name; the EPA registration number; the total amount applied; size of the treated area; the crop, commodity, stored product or site to which the application was made; location of the application; month, day and year of the application; and the applicator’s name and certification. A pesticide application record sheet also should contain crop data including the variety, planting date, product traceback code, etc. Weather conditions at the treatment site and date of the last equipment calibration should be noted.

Worker training also must be documented. Training records should include the name(s) of the individual(s) trained,
their hire dates, date of training, the job title or description of duties, training topics and the institution responsible for conducting the training. A certificate signed by the trainer should be issued and kept on record.

**Protection of Water Sources**

Water issues were introduced in Module 2. Protection of water sources is an extremely important concern that producers must consider as they develop their pest control programs.

Growers should identify all conditions on their farm that might make a water source vulnerable to contamination. Selection of pesticides should be postponed until a risk analysis has been conducted for the site. Such areas would include sandy soils, presence of sinkholes, wells, shallow groundwater or nearby surface waters that could be contaminated by run-off.

Management of run-off was addressed in Module 2. Unless the label directs you to do so, do not apply pesticides to bare ground and do not apply before a rain event. Both practices can lead to contamination of surface water and/or water used for irrigation. The use of contaminated water for irrigation or for mixing pesticides can lead to illegal residues.

The following graphic shows several of the factors that contribute to the risk for leaching of pesticides into groundwater. If several of these conditions exist in the field and the grower concludes that the site is vulnerable to leaching it would be prudent to consider products and methods of application that would reduce this risk.

**Pesticide Carryover and Resistance**

Pesticide carryover simply means that some amount of pesticide remains on the site after the crop cycle is completed. If the same crop is planted continuously and if the same pesticides are used repeatedly, residues may eventually build up in the soil. These residues can be absorbed by the crop and the additive effect of applying additional pesticide can result in residues in the plant that are over the tolerance level.

Rotational crops may not have a tolerance for the pesticide(s) used for previous crops. To avoid illegal residues, growers should check the label for restrictions against planting certain crops into previously treated soil. Wait the proper length of time, as specified on the label, before planting rotational crops if a risk of contamination exists.

Pesticide resistance can occur when a pest population has been repeatedly exposed to the same pesticide. Sensitive individual pests are killed by each subsequent application of the pesticide, leaving only individuals with behavioral or physiological resistance to the material. These resistant pests reproduce and pass the resistant genes to the next generation. Over a period of time the pesticide loses its effectiveness for pest control.

Once resistance has begun to develop, it takes more and more of the pesticide to achieve the same level of control. In response, growers may raise the application rate or increase the number of applications. Either of these choices can result in the presence of residues above tolerance.

Integrated Pest Management (IPM) programs were discussed earlier and are strongly recommended. Under IPM, crops are evaluated by the knowledgeable grower or professional scouts who determine the population of pests and make recommendations for pesticide application based on pest pressure, as opposed to the arbitrary application of pesticides on a calendar schedule. Non-chemical control measures also may be appropriate. IPM can help growers reduce costs and residues, and avoid the development of resistance.

**Pre-harvest Interval (PHI)**

The time that passes between a pesticide application and harvest is known as the pre-harvest interval (PHI). Pesticide labels usually are quite specific about the PHI requirement. A PHI is necessary to allow time for biotransformation processes within the plant to reduce pesticide levels to within tolerance.

The PHI varies depending on the crop, the portion of the crop that is consumed (root, fruit, etc.), the intended use of the crop (human food vs. animal food), the application rate, soil type and climate. The important point for the grower to...
remember is to follow the label directions because all of these factors were taken into account when the label was written.

**Drift**

Drift refers to pesticide movement in the air. Vapor drift occurs with some products that volatilize during warm conditions (typically above 85°F) and are carried off-site by the air flow. If a product is known to volatilize, the label will specify a cutoff temperature above which the product should not be applied.

The more common type of drift is when very fine particles of liquid spray material are carried by the wind. Drift of some pesticides, such as herbicides, can seriously damage nearby crops. Drift of pesticides with high toxicity to humans may pose health risks to field workers as well as to those in nearby residential areas. Although it is thought that most drift incidents do not generally pose a threat of chronic health effects, it may occasionally be a valid concern. Schools, hospitals and nursing homes are particularly sensitive areas. In any case, drift of any material does present the risk of illegal residues on nearby crops.

Pesticide applicators should be aware of wind speed and direction. Wind gauges are relatively inexpensive and are very useful for measuring conditions at the field site if the applicator has any doubts about the risk of drift. Wind may also carry soil particles to which the pesticide is adsorbed. If there is any doubt about the risk of wind drift, then spraying should be postponed until conditions improve.

The viscosity, or “thickness,” of the formulation affects its ability to drift. Invert emulsions are thick and present low risk of drift. Water-based formulations are affected not only by wind, but by temperature and humidity, which influence the rate of evaporation that can occur.

Droplet size at the nozzle discharge highly influences the potential for drift. Larger droplets are less likely to drift than smaller droplets so nozzles with larger orifices are preferred. It is prudent for growers to determine the largest droplet size that still gives good pest control. Apply at the lowest possible pressure and lower the boom to reduce the distance that the droplet must fall before striking the target. Equipment manufacturers have charts available that show droplet size based on nozzle orifice and pressure. Check the pesticide label for any specific restrictions regarding volume requirements and concerns for aerial application.

Weather also is a factor. At higher temperatures large droplets evaporate quickly to smaller droplets. This process is slowed by higher humidity.

Temperature inversions can result in long distance drift. An inversion forms when air at the ground level has cooled and warmer air holding the pesticide has risen above the field as indicated in the photo. Inversions usually develop at dusk and can continue through the night. The warm air layer can drift for a long distance before the inversion ceases when the ground warms in the morning, depositing the pesticide on a distant location.

Growers should consider the use of a drift control adjuvant. Adjuvants change the viscosity of the spray mix so that it is less likely to drift. There is some disagreement among experts about the effectiveness of adjuvant and if the products function well. Growers should ask advice from a nonbiased source, such as an Extension Specialist, and conduct their own evaluation.

**Mixing Pesticides**

The four major concerns for mixing pesticides are protection of the crop, the water source, the soil and the workers. Always mix pesticides to the concentration specified by the label for the crop. Do not mix and load pesticides near surface water, wells or drains. Do not mix at the same location each time unless you have a properly constructed mixing and loading site. When filling tanks, be sure to maintain an air gap between the water supply and the level of the mixture. Back flow devices should be installed in the water supply line and must be tested regularly to ensure that they function effectively. Stay with the tank while it is being filled and never leave the area unattended. Spills can occur from an overfilled tank or from an accident like a broken hose, resulting in contamination of the loading area and possible run-off into water sources or nearby fields. Workers should adhere to safe handling guidelines.
Application Method

Apply products only by the methods allowed on the pesticide label. These instructions are designed to ensure proper coverage and avoid overapplication, which could result in excess residues.

Maintain application equipment in good working order. This can prevent overapplication through leaky nozzles or connections and prevent major leaks or spills from burst lines.

Calibrate your equipment properly after any change in setup or whenever you change products. Maintaining and calibrating equipment helps to ensure good coverage while minimizing the likelihood of drift, achieve labeled rate for product delivery to maximize pest control, and avoid overapplication and prevent off-target deposition. Operate the sprayer at a constant speed to which it has been calibrated.

Follow all directions on the pesticide label. In the U.S. each pesticide is labeled in accordance with specific instructions and they are a matter of law. The label specifies site or crop; application method; type of equipment; application rate depending on the pest or soil type; the timing of application according to season; pest stage or crop stage; number of applications allowed per season; pre-harvest interval; and safety precautions for humans, wildlife, and the environment.

Take protective measures for sensitive areas. Follow restrictions for different soil types or geologic regions. For example, a pesticide might not be registered for application to sandy soils or geologic formations such as karsts with direct conduit to groundwater. Observe setbacks from surface water, wells or other sensitive areas. Use barrier strips with noncrop cover to help prevent run-off and when appropriate use an untreated strip as a buffer zone.

Be aware of any rules regarding the feeding of the crop to animals. Culled fruits and vegetables from the packinghouse often are disposed of by feeding to domestic animals. Animals produced for human consumption must not have residue levels above tolerance. Read the label and be aware of feeding restrictions.

Conclusion

The label is the law. Adherence to label directions will help ensure that tolerance levels are not exceeded and provide the grower and applicator a measure of protection against liability. Following proper handling practices will reduce the risk of contaminating the environment and injuring workers.

Summary

Growers must be aware of handling practices that provide the best efficacy for the product while avoiding injury to people, animals and the environment. Intentional misuse of a pesticide is illegal and is punishable by law.

If an excessive residue is discovered, growers must investigate the source of the residue and take steps to prevent a reoccurrence.

Protection of water sources is a major concern for Best Management Practices programs.

Pesticide carryover means that some pesticide remains in the soil after completion of the crop cycle. Ideally, growers would manage their production so that no carryover exists.

Pesticide resistance can occur when a pest has been repeatedly exposed to the same pesticide or a class of pesticides with the same mode of action.

Integrated Pest Management (IPM) programs can minimize pesticide use, carryover, resistance and residues.

The pre-harvest interval is the time that must pass between application of the pesticide and harvest of the crop to allow residues to degrade to the expected level.

Drift is the undesirable movement of pesticides in the air to nontarget locations. Growers should be aware of conditions that favor drift and design their pest management programs to avoid it.

Pesticides must be mixed in a manner that avoids contamination of the environment, injury to workers or overapplication to the crop.

Pesticide application equipment should be maintained in good condition.

The label is the law.
**Introduction**

Most countries that are major producers of fruits and vegetables have official standards to protect workers, such as the U.S. Worker Protection Standards (WPS) for the handling of pesticides. Such standards provide for specific protections to be provided by employers to pesticide handlers and field workers who may be exposed to residues. Adherence to these standards is required by law. Copies of the WPS training materials are available online from the websites of many land-grant universities.

This Module provides an overview of the potential risks to human health through exposure to pesticides as well as best practices to minimize exposure.

**Pathways of Human Exposure**

There are three routes of entry of pesticides into the human body: oral, or through the mouth; by inhalation, or through the lungs; and dermal, or through the skin. Oral exposure is most likely to occur if the worker eats or smokes during the handling of pesticides or does not wash hands properly after handling. Inhalation of fumes can occur during mixing or by entering improperly ventilated storage areas. Skin contact accounts for most exposure—up to 97% of all body exposure is by this route.

Different parts of the skin absorb pesticides with different efficiencies. Studies investigating how fast pesticides penetrated various body areas of volunteers have shown that the groin or genital area absorbs pesticides fastest; the scalp, forehead and ear canal absorb pesticides moderately fast, and the feet, hands and forearms absorb pesticides relatively slowly. However, it must be noted that the hands and forearms are often subject to the most exposure throughout the work day and that pesticides left on these areas will eventually penetrate through the skin.

The most common exposure scenarios for pesticide applicators are during mixing or loading of the concentrated material; by spills, leaks or improper cleaning and maintenance of equipment; during application; by recontamination through the use of leather items such as gloves, shoes, belts or bands inside hats that cannot be decontaminated, or by the reuse of contaminated protective equipment.

Pesticides may also be carried into the home and contaminate other people. Workers can carry the pesticide into their homes on their shoes, clothing or protective equipment that should have been removed before going home. Workers should wash thoroughly before greeting family members. Clothing worn while handling pesticides, including protective clothing and gear, should always be washed separately from household items.

Pesticide drift may enter homes through open windows or doors. Pesticides should never be stored within the home and empty containers should not be reused for a household purpose. Poisonings and deaths within homes have occurred through several of the practices mentioned here.

**Potential Adverse Effects of Pesticide Exposure**

Pesticide poisoning is categorized as either acute, chronic (delayed) or allergic.

Acute poisoning is defined as the occurrence of symptoms within 24-48 hours after exposure. Symptoms can occur almost immediately if the subject is exposed to a very high concentration or if the pesticide is extremely toxic.

In research studies with acute poisoning, scientists often use the terms LD$_{50}$ (Lethal Dose 50%) and LC$_{50}$ (Lethal Concentration 50%). Since genetic makeup influences how animals, including humans, respond to a toxic substance, the average dose to cause death is used as the best estimate. Thus, the LD$_{50}$ identifies the dose found to be lethal for 50% of the test animals. Similarly, the LC$_{50}$ identifies the concentration in the air or water that would be lethal for 50% of the test animals.

LD$_{50}$ and LC$_{50}$ are standard measures in toxicological studies and provide an estimate of the relative acute toxicity of different pesticides through different routes of exposure. LD$_{50}$ and LC$_{50}$ are presented in terms of mg pesticide per kg body weight. Therefore, a pesticide with low LD$_{50}$ and LC$_{50}$ is more toxic than a pesticide with high LD$_{50}$ and LC$_{50}$.
Chronic, or delayed, effects occur when a subject is repeatedly exposed to a pesticide over a long period of time. The likelihood of causing chronic effects is estimated by the maximum allowable dose in a subject’s lifetime. It is important to understand that the LD<sub>50</sub> and LC<sub>50</sub> measure acute effects and do not provide an estimate of the likelihood of having a chronic effect. A pesticide with a high LD<sub>50</sub> (low acute toxicity) may have the potential to cause chronic effects and, conversely, a pesticide with a low LD<sub>50</sub> (high acute toxicity) may not be associated with any chronic effects.

Allergic effects are more idiosyncratic and may be more difficult to characterize. Typically the first exposure sensitizes the subject to the foreign substance. Additional exposures cause the subject to begin to exhibit allergic symptoms, which can be expressed in a variety of ways, such as skin rashes or chronic respiratory conditions. Having an allergic reaction to a pesticide does not indicate any greater likelihood of having either an acute effect or a chronic effect from the pesticide. Individuals exhibiting allergic responses to a pesticide must either increase their level of personal protective equipment (PPE) and their handling precautions or stop using the particular pesticide as well as any other pesticides in the same class of chemicals that causes the reaction.

Practices that minimize exposure to pesticides will minimize the likelihood of having any adverse response, acute, chronic or allergic, to a pesticide.

**Personal Protective Equipment (PPE)**

Personal protective equipment (PPE), as the name implies, is used specifically for the protection of the worker. Appropriate use of PPE can dramatically reduce the risk of exposure.

All clothing items worn during pesticide handling are PPE and it is assumed that they are contaminated after handling. Always wear long pants, a long-sleeved shirt, socks, shoes and/or boots, and chemical resistant gloves while handling pesticides. Wear a hat if spraying above the head.

Wear any additional PPE required by the pesticide label, such as goggles or a respirator. Note that a dust mask is not a respirator and does not prevent the inhalation of pesticides. When mixing or loading concentrated pesticides, wear a chemical-resistant apron. Do not wear any leather items during handling, as leather cannot be effectively cleaned or decontaminated and re-exposure will continue to occur. If leather shoes or boots are worn, it is particularly important to wear chemical-resistant boots over them while mixing, loading or applying pesticides or while walking through treated areas.

Do not wear PPE for tasks other than handling pesticides. Wash PPE separately from the family laundry in hot water with detergent. Dry the garments by hanging outdoors or in a drying machine, as sunlight and heat both help to break down pesticide residues. After PPE is properly cleaned, store it separately from other clothing. If PPE cannot be cleaned right away, store it in a plastic bag and keep it separated from household laundry or other clothes.

**Heat Stress**

The risk of heat stress increases while wearing PPE. Workers can avoid heat stress by taking appropriate breaks and wearing a lightweight hat with a brim to avoid direct exposure to sunlight. Drink plenty of water but remember to wash hands before drinking.

The symptoms of heat stress are similar to the symptoms of overexposure to organophosphate or carbamate pesticides. Workers and supervisors should know the different symptoms for heat stress and pesticide poisoning so that anyone who exhibits symptoms can be treated promptly. Any time that a worker is in serious distress, medical attention should be provided without delay. Farm workers, supervisors and managers are not medical professionals and should seek assistance from trained professionals. The similarities and differences with pesticide exposure and heat stress are summarized in the following Table.

**Symptom Comparison**

<table>
<thead>
<tr>
<th>Pesticide Exposure</th>
<th>Heat Stress</th>
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<tbody>
<tr>
<td>Sweating</td>
<td>Sweating</td>
</tr>
<tr>
<td>Headache</td>
<td>Headache</td>
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<tr>
<td>Fatigue</td>
<td>Fatigue</td>
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<tr>
<td>Most membranes normal</td>
<td>Dry membranes</td>
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<tr>
<td>Slower pulse</td>
<td>Faster pulse</td>
</tr>
<tr>
<td>Nausea and diarrhea</td>
<td>Nausea only</td>
</tr>
<tr>
<td>Small or normal pupils</td>
<td>Dilated pupils</td>
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<tr>
<td>CNS depression – Coordination loss</td>
<td>CNS depression – Coordination loss</td>
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<td>– Confusion</td>
<td>– Confusion</td>
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<td>– Coma</td>
<td>– Fainting</td>
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</table>
Factors Affecting the Human Response to Exposure

A person’s response to pesticide exposure depends on a number of factors. The schedule and duration of exposure are significant. Long or frequent exposures may overwhelm the body’s biotransformation capabilities and cause acute poisoning. Short exposures followed by periods of nonexposure can allow the body time to metabolize the pesticide to a level that is below that causing a toxic response, which is termed the toxic effect threshold.

Human nutrition also is a factor. Proper diet is necessary to maintain adequate levels of biotransformation enzymes. Consumption of foods that are high in antioxidants is believed to provide some protection against the action of many toxic substances. In the body, antioxidants are scavengers of free radicals that cause injury to cells.

Size, age and gender of the person all impact the response to pesticide exposure. Larger individuals can safely absorb and metabolize larger doses than a smaller person. Infants and elderly people may have lower levels of biotransformation enzymes and be more susceptible to injury from exposure. Finally, male and female hormones both affect biotransformation pathways in manners that are not well defined. For some substances, women are more likely to exhibit an adverse effect, while in other cases men are more likely.

Smoking or chewing tobacco or other leaves has several negative consequences. It can serve as a means of direct ingestion of the pesticide if the hands are not washed before smoking or chewing. Further, it predisposes the individual to respiratory illness, which can have a synergistic negative effect when pesticides enter the body.

Consumption of alcohol also has negative effects. Excessive alcohol use decreases or can permanently impair liver function, which decreases the body’s capacity for metabolizing other chemicals. It is impossible to test all combinations of alcohol and pesticides for their effect on the body. Understanding that the combination can result in a more severe negative consequence allows individuals to make decisions about personal behavior that decrease their risks.

Drugs, whether they are over-the-counter, prescription or illegal “recreational” drugs, all may compete for the same biotransformation enzymes as pesticides. Drug use may result in increased toxicity of the pesticide, increased toxicity of the drug or inactivation of the drug by the pesticide. Interactions may be additive, synergistic or antagonistic. As is the case with alcohol, it is impossible to test the effects of all drug-pesticide combinations.

Personal hygiene practices of the individual are critical. Workers should wash their hands before eating, drinking or smoking to prevent the transfer of residues through the mouth. They also should wash before using the toilet to prevent the transfer to the highly absorptive genital areas of the body. Workers should shower at the end of the day and always put on clean clothing to begin the work day. Clothing and shoes that may be contaminated from the previous day’s work should never be reused without cleaning.

Good pesticide handling practices minimize exposure, help prevent accidents, and reduce the likelihood of adverse effects. Applicators should take care not to walk or drive through spray. They should take extra precautions, such as wearing a chemical-resistant apron, goggles, and respirator or a full face mask while mixing and loading because these activities pose the highest likelihood of exposure.

Treated areas should be posted with appropriate signage and no one should be allowed to enter treated areas before the reentry time specified on the label unless the worker has been specifically trained and properly equipped and the label allows such reentry. The label for some pesticides does allow early reentry but only if specified conditions are met for PPE and worker training.

Protection of Sensitive Species Other than Humans

Although this Module is dedicated to human exposure, it is important to mention other sensitive species in the environment. There has been widespread publicity about the possible reduction in bee populations due to pesticide use, and other species are also susceptible to certain pesticides. Pesticide application may cause direct kill, reduction of habitat or reduction in fertility of the species, all of which lead to an overall reduction in the population.

Growers should be aware of sensitive local conditions or populations. This includes nearby crops, endangered species, parasites and predators that contribute to biological control, and pollinators including bees. If pesticide application is necessary, protective measures should be taken such as applying at a time of day when sensitive species are not present or establishing untreated refuges.
Storage and Disposal of Pesticides

Improper handling, storage and disposal of pesticides, or use of empty containers have many negative consequences. Poor handling leading to cross contamination of pesticides can result in the generation of illegal residues when the product is applied. Contamination of the environment and endangerment of humans and other animals also is a serious concern.

Store all pesticide products with the label intact, attached to the container and legible. Herbicides should be stored away from all other pesticides or fertilizers. Leakage or spillage of herbicide into other products can result in illegal residues or it can kill crops directly.

Pesticides should be stored in a secure location that is away from foods and food containers. The storage facility should have proper signage, good lighting and ventilation, a roof to avoid exposure to rain or sun, a fence to keep out animals and a lock to keep out children and other unauthorized persons. Ideally, the pesticides would be stored in a building with a concrete floor so that spills could be contained. Storage should not be in an open area. Products should not be exposed to extreme temperatures. Freezing can damage some pesticides and destroy their usefulness.

Excess or leftover pesticide mixtures must be disposed of properly. The preferred method is to apply the material according to label directions on a registered crop or site at the recommended rate. Another option is disposal at a hazardous waste site, which can be very expensive. Any other disposal method can result in the negative consequences mentioned previously.

Empty containers should first be cleaned according to recommended procedures on the label. They may then be disposed of in a suitable landfill unless the label allows for other disposal methods. As emphasized previously, empty containers should never be reused for other purposes. This can be a major source of pesticide poisoning.

A typical practice for the decontamination of a container with a liquid formulation would be to rinse the container immediately after it is emptied into the spray tank. Fill the container to about ¼ of its capacity with the proper diluent, which usually is water or oil. Replace the closure (lid, cap, plug, etc.) and rotate the container a few times. Add the rinsate to the spray tank and repeat the procedure two more times. When the rinsing is completed puncture the top and the bottom of the container to prevent its reuse.

For containers holding dry formulations, empty the contents into the tank while shaking vigorously to remove as much residue as possible. Take care not to inhale the dust and try to ensure that dust does not escape to the surrounding area. After the container is emptied, open both ends to help remove any additional residue into the tank and to prevent reuse.

Conclusion

The health and safety of workers is far more important than the value of the pesticide or the crop. Managers and supervisors have legal and ethical obligations to follow the law and to take all reasonable steps to protect personnel.

Summary

Most countries that are significant producers of fruits and vegetables have Worker Protection Standards (WPS) that are designed to promote the health and safety of personnel.

The three pathways for pesticides to enter the body are oral, by inhalation and dermal. Up to 97% of all exposure is through the skin.

Personal protective equipment (PPE) includes all clothing and specialized equipment used to protect the worker from exposure.

Heat stress has similar symptoms to pesticide poisoning. Managers, supervisors and other workers should be aware of the symptoms and understand the practices that help prevent their occurrence.

The adverse effects of pesticide exposure are categorized by researchers and medical professionals as acute, chronic or allergic.

A person’s response to pesticide exposure is affected by the schedule and duration of exposure and the person’s nutritional condition; size; age; gender; consumption of tobacco, alcohol, or drugs; and personal hygiene.

Growers should be attentive not only to the protection of people but also to the protection of other sensitive species such as bees.

Pesticides should be stored in a suitable area that protects them from the environment and prevents access by children or other unauthorized persons.

Leftover pesticides should be disposed of in accordance with label directions.

Empty containers should be properly cleaned before disposal and should never be reused.
Developing an Effective Training Course

Module 1 Planning: Understanding Learners, Identifying Needs and Setting Objectives
Module 2 Preparing and Organizing the Course Content
Module 3 Conducting and Evaluating the Course
Introduction

In Section I the importance of GAP and GMP training was discussed. Ample justification was presented for the need to teach new skills or raise the level of existing food safety skills for all workers involved in the fruit and vegetable industries. In this Section the discussion will focus on developing an effective training program.

A training program is a complex activity that must be carefully planned in order to be successful. Thorough planning, or the lack of planning, will be obvious to the audience. This Module details planning steps to develop an effective training program that can address company training needs.

Basic Principles

It is important for planners to identify the objectives and anticipated outcomes of the course. Training is conducted to help the trainees enhance their capabilities for better job performance. It involves the transfer of new knowledge and skills while encouraging positive behaviors and attitudes to perform specific roles in the workplace. If successful, the outcome will be better informed employees who perform their jobs properly to reduce safety risks.

Developing a successful training program requires many elements. A qualified and competent trainer is essential. The trainers, or the technical experts who teach the course, must have extensive knowledge of the subject areas and must be capable of sharing this knowledge in a manner that establishes their credibility with the audience. Trainers may be University Faculty, particularly Extension professionals, governmental officials, industry personnel, consultants or others with special skills relevant to the area of food safety. Company personnel also may be trainers but may require additional education and training to be qualified.

Another important element is organizing the logistics of the training course. Trainers need the support of dedicated planner(s) or coordinator(s) to ensure that all of the details of course preparation have been considered prior to the opening day of the course. The training support staff plays an essential “behind-the-scenes” role in ensuring that effective delivery can be accomplished by setting up the training location, copying essential educational materials, and attending to details such as catering for breaks and lunch. Training logistics also requires scheduling the program at a time when trainees can attend. Agriculture is a highly seasonal industry. Selection of the appropriate time of year, day(s) of the week, or time of day will help ensure participation. Once the day and time are set, participants must be formally invited and encouraged to attend. This part of the training preparation may require more time than the delivery of the training course but is critical to success.

Lastly, a training program must be developed with the learner in mind. Understanding the needs of the learner allows a trainer to develop an educational program that has meaningful objectives that lead to the successful transfer of knowledge and skills. If a training program is not relevant to the learner, the value of the training is reduced and intended outcomes may not be achieved. Trainers should utilize the principles of adult learning when delivering a training program. Learning is strengthened when the message is delivered at the right level, when the message adds to or builds upon the trainees’ existing knowledge, and the learner is motivated and has the desire to learn. This will help bring about the desired change and achieve training objectives.

Learner Attributes

The educational background and competence level of the trainees (learners) must be considered during planning. An audience might include managers and workers from the farms, packinghouses or warehouses, i.e., any people who are responsible for growing and handling fruits and vegetables. Managers are likely to have different needs than laborers. Coordinators and trainers alike must consider the specific goals and objectives for their audience and tailor the presentations accordingly.

Motivation

Trainers have the responsibility of motivating the trainees to be receptive to the course message, learn the material, and put into practice the lessons that have been learned.
This can only be accomplished by emphasizing the importance and benefits of the course in a context that is understandable to the trainees. Following are some examples of benefits from participating in training that can serve to motivate learners.

Trainers should emphasize that the course may result in immediate and direct personal benefits for the trainee. By learning and implementing food safety skills, attendees may gain prestige and/or increase their income to provide better livelihood for themselves and their families.

Fresh fruits and vegetables have been associated with outbreaks of illness, some of which caused deaths. The occurrence of an outbreak in a far away location, often in an economically advantaged country, may not be a powerful motivational message. Trainees could be asked to consider the impact of such an event in their own country and on their own families. Training provides food safety skills that participants can implement to help ensure the safety of fresh produce and prevent illnesses. The fact that participants’ actions can directly and positively impact others, including their own families, can be a powerful motivation to implement new practices. This is a personal message that touches the hearts of most listeners.

Agriculture makes an important contribution to the economy of almost all countries. Food safety is important at every economic level, locally, nationally and internationally, because the delivery of unsafe food damages the reputation of the growers, handlers and the country itself. This message lets the workers know that their work is important not only to themselves but to the economy as well. As individuals, they still play a vital role in their industry and their actions can have economic consequences.

Finally, repeated emphasis of the fact that safety and quality controls are important at every stage in the food chain is essential to creating a culture of awareness. The chain is only as strong as the weakest link. Workers, managers, company executives and all others in the food business share equal responsibility for food safety. Everyone is important.

**Needs Assessment**

To ensure that information is delivered at the appropriate level the course planner(s) or coordinator(s) need to have as much advance information as possible about the existing level of knowledge that trainees have. During the course, trainers need to listen and be sensitive to the feedback from the target audience and adjust their delivery accordingly.

Perhaps one of the most important and often overlooked aspects of planning a training course is the needs assessment. This identifies the gap between “what is” and “what should be,” it indicates what the training should focus on, and it helps to define the training objectives and selection of training activities.

The needs assessment also helps avoid common mistakes in training, such as including topics that are already familiar or have little relevance to the trainees, or omitting a topic that is important. Delivery may be tailored to resolve problems that the trainees may have with material and to overcome constraints for the implementation of new practices.

The trainer may have a perception of the trainees’ needs but validation is essential. Validation can be facilitated by meeting with trainees in advance of the program, administering questionnaires, or reviewing key materials such as policy documents, annual reports, and evaluations of existing practices. The needs assessment ideally would be conducted in advance of the course. Even if it is performed in the initial stages of the course there will be time for trainers to make adjustments.

In essence, trainers must do their homework. All trainers, regardless of their perceived familiarity with the specific circumstances and working environment of the trainees, will benefit from a more in-depth and current needs assessment through field visits and discussions with supervisors and the trainees themselves. If nothing else, this effort will help overcome barriers to learning by demonstrating respect. Preparation is vital to the success of any training program.

**Identify Participants**

Identifying the target audience is important so that the needs of the learners can be determined. Target audiences may be identified in a number of ways.

In larger companies there may be a food safety officer who is responsible for training employees company-wide. Such an activity might also include a paid consultant to serve as a trainer. In this situation there may be separate courses for managers and workers because their needs are different. The managers would receive a train-the-trainer type of instruction with the objective that they would in turn deliver relevant information to workers. The training course
that the manager would deliver to workers likely would have a more narrow focus depending on the responsibilities of the trainees within the company.

Alternatively, external professional trainers might be approached by a group of persons with a specific need. This is a common occurrence for commodity organizations. Representatives from a well-organized commodity group, such as the tomato or leafy greens industry, might approach an Extension Specialist or a consultant to conduct training for a specific purpose. In this case, the organization likely would select key people from within the industry to attend the training.

As an example, a training program led by an Extension educator and organized by an industry group is attended by fresh produce growers, who are the target audience. Farmers carry out many of the tasks that affect the safety and quality of fresh produce, thus they are a primary audience for food safety training. Farmers generally have a great deal of knowledge and life experience about farming practices. The trainer can build upon this knowledge base by providing new information in such a way that the farmer can incorporate new practices into existing production systems. Trainers must recognize and respect farmers’ expertise in order to establish a productive learning environment and avoid the appearance of being arrogant or insulting. Farmers are independent business people who make all of the decisions for their operations. They may come to the training with strong fixed ideas on the subject matter. These ideas may interfere with the acceptance of new information or the need for new skills. Identifying the ideas that interfere or are in conflict with the new information allows the trainer to directly address these concerns during the training. A well-reasoned presentation that addresses the growers’ concerns will help ensure acceptance of new ideas and information. Farmers are, above all, practical thinkers. Trainers must provide real life examples in the context of current behaviors and practices so farmers understand how to implement new skills and practices.

Another example of a target audience is a packinghouse cleaning and sanitation (C&S) crew. This training could be conducted by a manager from within the company. It might include a discussion of mixing sanitation chemicals and specific worker safety protocols that must be adhered to while they work. It is likely that the sanitation crew is not involved in setting the standards for C&S or writing the SSOP, but they must follow company policies. It is the responsibility of planners and trainers to understand the

practices that learners need to know, the resources available to carry out the practices, and the concerns that may exist in order to conduct a successful training program.

Some audiences may have special needs that must be addressed in order to make training comfortable and accessible. Examples include audiences that have special dietary needs such as kosher foods, or audiences that have low literacy so they may require that educational materials be modified to be meaningful. Again, understanding the needs of the learners is a key to a successful training program.

Regardless of the manner in which the target audience is identified, it helps if everyone in the audience has similar needs. Attempting to conduct a training program where there are diverse needs and requirements can be very challenging. In this instance, it may be most efficient to break into smaller groups and deliver shorter, targeted training sessions.

Setting Objectives

Once a trainer had identified the target audience and the needs of the learners, specific training objectives should be identified. Training objectives state what will be accomplished as a result of the training. They are defined in light of the deficiencies in knowledge or practices that are identified in the process of needs assessment.

The objective for a training session might be as simple as raising awareness of food safety issues that are connected with the consumption of fresh produce. More complex objectives might state that trainees will display an understanding of certain concepts, demonstrate a given skill, or show a change in attitude. In an ideal food safety world the objective would be that the course would lead trainees to effect changes in behavior that would result in reduced food safety risks.

Course content, methods of instruction, training materials, lab exercises and evaluation strategies all are derived from identifying the training objectives. Without measurable objectives, learning cannot be successfully planned or evaluated.

Well-defined objectives serve to keep everyone, trainers and trainees alike, on the right track throughout the course. They provide the tangible link between needs assessment and the design and preparation of training materials. By determining if the objectives were met, the trainer can know if the course was successful in meeting the needs.
of the trainees. Thus the objectives provide the basis for evaluation once the course is completed.

In converting needs into objectives, three areas of performance may be identified: skills, knowledge, and attitude. Skills-related objectives state what the trainee will be able to do as a result of the training. Knowledge-related objectives state how the participants’ ability to identify or describe certain concepts will be improved following the training. Attitude objectives are more intuitive and can be difficult to define but often are judged by the degree of receptiveness to new concepts. Attitude evaluations can be done with a Likert scale, though trainer(s) should monitor changes in attitudes of trainees throughout the course to keep the training environment conducive to learning.

The trainer and the trainees should understand and agree on the objectives of the training course. It is a useful technique for the trainer to review the objectives at key moments during delivery to ensure that trainees are on track with achieving the objectives. When participants know what is expected of them they can organize their efforts more effectively and stay focused on training goals.

**Summary**

A training course is a complex activity that must be carefully planned. Careful planning, or the lack of planning, will impact the effectiveness of the training.

Support staff is an important part of any training because the staff organizes training logistics that impact the comfort and receptiveness of the learners.

Professional trainers must have the ability to motivate the audience to learn.

Emphasis on personal benefits to the trainee, health benefits for the consumer and economic benefits for the industry as well as the country are all useful messages to help motivate the audience.

An important part of planning is to identify the participants that are to be included in the course and to assess their needs. This will help the trainer plan an effective training.

The needs and competence level of the audience must be assessed as part of the planning.

Course objectives are prepared based on the needs of the trainees. These objectives provide a basis for evaluating the effectiveness of the course.
Introduction

The content of the training course should link directly with the subject areas identified in the needs assessment and the training objectives. The end result should be that the training content is presented at the correct level to meet the objectives and to ensure the best learning outcome for the trainees.

The Basic Outline

During the planning stage, it is useful to organize the course content in outline form to help prioritize the material and to determine the best sequence for the presentations. The training content and flow of information should be designed to present relevant information and maintain the interest of the audience.

In some instances the trainer may have a very clearly defined objective, even before the needs assessment. For example, when a new law or regulation is about to be implemented certain groups will need to be informed of the law and how their industry will be impacted. The trainees will need to know their specific responsibilities under the new rule(s). In this example the outline of the training session will be relatively simple and straightforward. Alternatively, if the needs are complex the trainer may need to spend a significant amount of time developing and refining the outline.

Each step in the outline and the corresponding presentation of the material may be organized into three main parts: introduction, body and conclusion(s). One or more messages may be presented in each session but the audience will be better engaged if the trainer stays within this format.

In the introduction, there should be opening statements that attract the attention of the trainees. The key points should be emphasized, such as the purpose of the session and the objectives, an outline of the information to be covered, how the material will be presented, how it will satisfy the purpose of the training, and the personal benefit to the trainees and the industry they serve. The trainer should acknowledge the skills that the trainees already possess and show how the session will reinforce and increase existing knowledge.

The body of the presentation should flow in a logical manner. The message should not be overloaded. Presentation of a few well-developed points will be more effective than attempting to cover too many points in a single session. If a large amount of material must be covered it may be necessary to modify the outline to break up the presentations into shorter segments for a more reasonable and logical approach. Remember, the adult attention span is approximately 20 minutes so long periods of lecturing may not be productive. The next section provides training method options that can be utilized to keep the audience engaged.

In the conclusion a summary of the main points should be made. New information should not be presented at this time. The trainer should close with a strong final statement. During the question and answer session the trainer should try to engage the audience in a discussion of the actions that trainees should expect to take as a result of the new things they have learned.

A trainer has the attention of the audience primarily at the beginning and the end of the session. Therefore the greatest impact will be achieved by making the key points in the introduction and summarizing them again in the conclusion. Public speakers are advised to “tell the audience what you are going to tell them, tell them, and then tell them what you told them.” Repetition, within reason, reinforces the message.

Training Methods

Once the course content has been identified, outlined and prioritized, planners should consider the best method for delivery. This is a critically important part of planning.

A training method is a strategy or tactic that a trainer uses to deliver the message so that the trainees achieve the learning outcome defined by the course objectives. One or more training methods may be employed in a single presentation. It is good to use a variety of methods throughout the course to maintain the interest of the
trainees. Ten of the most common training methods are discussed here.

**Lecture**
A lecture is primarily an oral presentation but it may be supplemented with visual aids or handouts. It is perhaps the most common method for training because it is easy to organize, a large amount of material can be presented within a relatively short time and it is suitable for either small or large groups of trainees. Lecturing involves delivery of information in one direction from the trainer to the trainees.

**Lecture/Discussion**
This is a variation of the lecture whereby the trainer encourages trainee participation through facilitation of discussion. In a formal setting the discussion may be restricted to specific times during the session. If the trainer is comfortable with an informal approach he or she may encourage questions and discussion throughout the presentation. The trainer may initiate discussion through the use of questions or by extending an invitation to the trainees to share their experiences with specific points covered during the session. It is the responsibility of the trainer to keep the discussion on track by choosing questions carefully and by steering discussion toward the topic at hand. This can be difficult if audience members are unhappy or wanting to discuss topics outside the scope of the presentation.

**Demonstration**
Demonstrations entail oral explanations combined with visual or tactile activities. Method demonstrations show processes, concepts and facts. These are effective in teaching a skill that can be observed. A result demonstration shows the outcome of some practice or innovation such as sanitizing treatments for water or a cleaning treatment for product. A demonstration may involve mixing methods and result demonstrations and may include hands-on activities for participants. The important point is that learning is reinforced by providing the trainees a visual or tactile activity.

**Group Discussion**
In this method the trainer leads the trainees through a group discussion of a given topic. The discussion may be preceded by a short explanatory lecture or it may be spontaneous if the trainer sees an opportunity during the session to reinforce learning. Trainees are afforded an opportunity to share personal experiences with the group, which in turn may critique the information in a positive and constructive way. As always, the trainer must maintain control of the discussion.

**Symposium**
This is a series of lectures presided over by a moderator. It allows several experts to present different points of view or to discuss different topics related to a common theme. Typically in a symposium the audience would have an opportunity to question or address the speakers at some point.

**Panel**
This is a dialogue among several experts sitting in the front of a room. A moderator would coordinate the discussion and may pose questions to the panel if discussion is lacking. This differs from a symposium in that panel members have an opportunity to discuss and interact with each other regarding their ideas and points of view. Audience participation may be permitted but must be controlled by the moderator.

**Forum**
Following one or more presentations, a forum allows the audience an opportunity to interact with the speakers and discuss the topics. This can elicit a wider range of views. If the subject matter is controversial, for example the introduction of a new food safety law, the discussion may become contentious and the moderator must be prepared to mediate.

**Discussion Groups**
This involves every member of the audience, which is divided into groups of typically 4 to 20 people. Groups may be assigned a leader or may be asked to elect a leader. Typically groups are assigned a specific topic and/or asked to develop a list of problems, issues, priorities, or questions. After the discussion, the group will report the outcome of their discussion to the main audience. Discussion groups have the advantage of encouraging and allowing every individual to participate, even if the main audience is large. Groups should be monitored during the activity to ensure that no one person is dominating the discussion and that the discussion groups are making progress in the intended areas.
Case Studies

Information is provided to trainees about a specific situation or problem. They are assigned, either as individuals or as groups, the task of analyzing the information and developing recommendations for the most appropriate action to solve the problem. This introduces a practical aspect into the training process and creates a problem solving situation, which allows them to apply knowledge they may have gained during the training. Case studies also provide an opportunity for trainees to draw from their own experiences, share the information with others and work as a team.

Field Visits

A visit to an organization or workplace such as a farm or packinghouse can be invaluable for demonstrating the practical value of the material that trainees are learning in the classroom. The owners and/or managers of the site must be informed of the purpose of the visit and policies about taking photographs or exposure to proprietary information must be discussed in advance. Trainees must be properly prepared. They should be informed of company policies and be willing to conform to same. The trainees are asked to make specific observations and be prepared to discuss those when they return to the classroom.

Several of the training methods defined above are utilized in the JIFSAN Train the Trainer course. By employing a combination of methods, trainers can present the scientific basis for practical exercises and trainees have opportunities to observe the application of the science in the work environment.

Factors to Consider when Selecting a Training Method

Planners must consider a number of factors when choosing the method(s) for conducting the training course.

The size of the audience is a very important consideration. Larger audiences may require a more formal structure, e.g., lectures, with less audience participation due to time constraints. This presents a challenge for maintaining the interest of the trainees. Insertion of a variety of methods such as group activities and brief discussion sessions will help to keep the trainees engaged in the course.

Available resources and the infrastructure of the training environment must be considered. If resources such as transportation and funding are limited it may not be feasible to use resource-intensive techniques such as site visits or elaborate demonstrations. The infrastructure may be limited to a single lecture room, in which case group activities will need to be carefully planned to ensure that they are effectively executed.

The amount of time available for conducting the course may limit the amount of information that can be presented and the methods employed. Planners must give adequate time to prioritizing the subjects that will be discussed. Lecture-oriented methods allow the most information to be delivered in the least amount of time. Group activities, case studies, etc., require considerably more time. Course objectives must be balanced with the available time to choose appropriate training methods.

The experience and proficiency of the trainer should be known to the planners. Public speaking skills and the ability to interact with the audience are critical to effective delivery. The trainer must be aware of the expectations of the audience and be comfortable with the teaching methods that have been chosen.

Finally, planners must consider the need for training aids to support each method and the time and resources required to produce the materials. Training aids must be made available to trainers well in advance of the course to allow for adequate time to prepare the delivery. Planning and preparation enables the trainer to project confidence and control throughout the session.

In preparing for a course or a single presentation, remember the 5 “P”s: Proper Planning Prevents Poor Performance. It will be obvious to trainees if planning is well done and it will be painfully obvious if planning is not well done.

To provide an example of a situation that uses multiple training methods, consider training regarding the use of field sanitation units. The trainer might begin in the classroom with a lecture and photographs describing the appropriate design of a unit, the supplies that the company must provide and an overview of appropriate employee practices. The lecture could be followed by a group discussion about the practical issues and social attitudes that discourage the use of the units and how these obstacles could be overcome by managers in the field. During the site visit, trainees could assess the situation involving the units in the field and determine how best to implement appropriate practices if they are not already in place. Trainees should look for positive as well as negative behavior. In a follow-up meeting at the site, or after returning to the classroom, trainees may discuss the overall
When developing training aids, the trainer must consider the message from the perspective of the learner. If the trainee is seeing the information for the first time, what can be done to make the presentation flow smoothly and enhance the learning experience? Training aids assist in several ways. They give visual reinforcement and help to clarify points that may not have been clearly spoken by the presenter. Anything that can be quantified or is factual can be presented visually. This brings a more relaxed atmosphere to the classroom and facilitates learning.

Visual aids should be tested on others before using them in the classroom. It is important to check the availability and functionality of equipment required for visual aids as part of planning and on the day of the course, before participants arrive. The development of data projectors and PowerPoint technology has dramatically improved the way information is presented, but these technologies can fail and should be tested.

A variety of print materials can be used to enhance learning. These may include handouts, summary notes, workbooks or manuals. The advantages of printed materials include the option of providing additional information beyond the oral delivery. They can reduce note taking and provide reference material for the trainee to take home for use after the course is over. A disadvantage is that they may distract from the trainer. Care should be taken not to overwhelm the trainees with too much printed information that might cause them to lose focus on the trainer.

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<tr>
<th>Training Method</th>
<th>Percentage of Learners Retaining Knowledge</th>
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<tr>
<td>Oral</td>
<td>10%</td>
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<tr>
<td>Visual Alone</td>
<td>35%</td>
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<td>Visual &amp; Oral</td>
<td>65%</td>
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When trainees participate with hands-on exercises, the symbolism of words is converted to images within the learners’ minds. Visual aids and hands-on activities help transform an abstract concept into a practical reality that enhances the process of storing the information in the long-term memory, e.g., improves retention and recall. This is illustrated in the graphic below. Material that is presented orally is retained by only 10% of the listeners. Visual information is retained by 35% of the learners, but a combination of oral plus visual presentation increases retention to 65%.

Training aids refer to all forms of educational materials prepared for use in a training program. As shown above, carefully chosen, well-prepared materials can make an important contribution to effective training, especially if the information is presented in a logical, clear manner with emphasis on the most important points. This makes it easier for the learner to understand and retain the message.

Preparation of Training Materials

Research has shown that learning is enhanced when trainees are required to use at least three of the five senses. The trainer(s) should attempt to employ training methods that appeal to the senses of sight, hearing, smell, taste and touch.

In general, instruction by spoken or written word is more effective when it is supported by methods that stimulate the other senses. When trainees participate in hands-on exercises, the symbolism of words is converted to images within the learners’ minds. Visual aids and hands-on activities help transform an abstract concept into a practical reality that enhances the process of storing the information in the long-term memory, e.g., improves retention and recall. This is illustrated in the graphic below. Material that is presented orally is retained by only 10% of the listeners. Visual information is retained by 35% of the learners, but a combination of oral plus visual presentation increases retention to 65%.

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Organizing the Delivery of the Training

All of the planning for course content, delivery methods, and supporting materials eventually places the burden of delivery on the individual trainer(s). Each trainer should attempt to visualize the flow of the course before it begins, taking time to consider potential questions from the audience or problems that might arise during the delivery. The more prepared the trainer is, the more relaxed he or she will be during the presentation of information.

The trainer should consider how each topic will be introduced and whether it should begin with a powerful declarative statement or with a question to the audience. The trainer also should choose the most appropriate method of delivery to strengthen the message. If questions to the audience are to be used to provoke discussion, the trainer should decide in advance what to ask and should try to anticipate what the responses from the audience might be. The trainer also must decide the appropriate times to take breaks and be sensitive to the mood and body language of the audience in case adjustments to break periods are needed.

A schedule or program for the course should be developed and made available to the audience. The trainer should have a copy at the podium since the program has the time allowed for presentations, the scheduled break times, and other organizational information. Every attempt should be made to stay on schedule since the trainees may be trying to balance work responsibilities with their participation in the course.

A cell phone policy during training time should be emphasized. At a minimum, phones should be placed on silent or vibration mode. It is extremely distracting for everyone when a trainee takes a call during a session.

The program is essentially the final draft of the outline that was used to develop the course. The program guides the trainer in leading the course, organizes the flow of information, and ensures a balance between theoretical information and practical sessions. Further, the program helps prevent repetition of information between different trainers, states the allowed time for the sessions and for breaks, and helps ensure the interest and motivation of the trainees by keeping them informed of the plan for the day.

Attention spans vary from person to person, with the subject matter involved, with the comfort of the training facility, with the skills of the trainer, and with any number of other variables in the training environment. Under ideal circumstances about 20 minutes is the maximum time recommended for an oral presentation and 45 minutes for a practical session or a case study. In reality, much longer times are needed for the delivery of complicated material. It is the trainer’s responsibility to allow time for adequate interaction with the audience when using questions, leading discussions, conducting exercises or using visual aids.

The use of demonstrations, illustrations or question periods during a lecture will help to break the monotony that can occur during a long oral session. It is important, however, that the change to a different method of delivery supports the main body of the message. Time must also be allowed periodically for trainees to stretch their legs and use the toilet facilities.

An experienced trainer will be attentive to the audience at all times and make adjustments in the program if he or she perceives the need to do so. An audience that is not comfortable will not learn as much as a group that feels comfortable with the instructor and with the training environment.

Summary

The content of the training course links directly to the areas identified in the needs assessment and identification of training objectives.

Preparing and organizing the content of a training course should begin with an outline that will be revised several times until the final program is decided upon.

Each session in the outline should have an introduction, the body of the message and a conclusion.

In the introduction, the trainer may begin by stating objectives and telling the audience what will be covered. The body of the presentation includes content details and in the conclusion the main concepts will be reviewed.

Ten common methods of information delivery were identified in this Module. Planners and trainers should work together to choose the method(s) that will be most effective for each session.

When choosing a delivery method, trainers must consider the size of the audience, available resources and infrastructure, the time available to cover the material and the need for training aids.
Remember the 5 “P”s: Proper Planning Prevents Poor Performance.

Trainees will retain and recall information better when the delivery method stimulates several of the five senses. The combination of oral and visual presentations is over six times more effective than oral delivery alone.

When preparing their delivery, trainers should try to visualize themselves in the place of the trainee and choose methods that will be most effective.

The trainer will be more effective by having a copy of the program at the podium and following the plan as closely as possible. An expert trainer will sense the mood of the audience and make adjustments in delivery when necessary.
Introduction

Once the planning and organization is completed it is time for trainers and trainees to come together and conduct the course. Success in meeting the course objectives now depends on effective delivery. This Module addresses key considerations for ensuring that the course meets the needs of the audience. Significant focus will be placed on how to evaluate a course to determine trainee learning and course effectiveness. Evaluation allows for continuous improvement of the course and provides critical feedback for trainers.

Using a Training Team

If a training course requires several hours, several days, or if a variety of topics will be covered, the planners should consider organizing a team to complete the delivery. It can be difficult for a single speaker to hold the attention of the audience for an extended period of time. The team approach gives trainees a break from hearing only one presenter and it offers the significant advantage of drawing upon the expertise of different experts in the room.

Planners should select team members that have complementary styles, skills and knowledge. All trainers must be technically competent in their subject area and have experience in training. Credibility must be established with the trainees in order to gain their respect and facilitate learning. In addition to being technically competent, the trainers must be familiar with the real circumstances in which the trainees work and the problems they face.

Trainers must be willing to participate in the total training activity. It makes a bad impression upon trainees if a trainer leaves the course immediately after delivering his or her presentation(s). Trainers may be called upon to add comment to a co-trainer’s topic, contribute as needed to practical exercises, or prepare for an additional training session if one is needed. They also should be available to interact with trainees during breaks, meals and at other free times between the training sessions.

In team teaching it is advantageous to have a leader or facilitator to coordinate the course. The leader may be responsible for the selection of the team members and should create a teamwork atmosphere by taking steps to ensure that all trainers know each other. During planning, the team leader may need to arrange for meetings or conference calls with planners and team members to assess the progress of planning and determine when changes or improvements are needed.

The facilitator provides leadership in developing the course schedule or program and briefing team members on their roles during course delivery. It is important that co-trainers understand and agree upon the course objectives. They should take time to become familiar with each other’s strengths and use each other as a resource. The leader will provide team members information about the participants and local circumstances so that everyone can prepare their deliveries appropriately. Any ethnic or cultural concerns should be addressed during these planning sessions.

Logistical Support

In addition to the extensive planning and preparation discussed previously, there are logistical arrangements that must be considered before, during and after the course. The planner, facilitator, and co-trainers if a team is involved all should be engaged in assuring that these arrangements are in place and satisfactory to accommodate each session of the course.

Before the Training

Assure that travel and hotel accommodations have been made for the instructor(s), trainees and interpreters if they are required. A suitable contract or agreement with the interpreters should be in place. If transportation is needed for a field trip this also should be planned in advance.

Select a suitable venue. Ideally the lecture room should be well lit and well-ventilated with adequate space away from sources of noise or other distractions. Seating arrangements, tables, etc., should be comfortable.

Trainees should be identified through appropriate channels and notified of the dates, times and location of the course.
Training material, including handouts, visual aids, manuals, etc., should be prepared.

Assure the availability of appropriate training equipment. This may include various types of projectors (LCD, slide and/or overhead) and spare bulbs, a screen, computer(s), microphone(s), chalkboard and chalk, flip charts, writing materials, etc. It is distracting for the audience if any equipment or supplies have to be found after the course has started.

Organize the training room. Seating arrangements, name cards, and position and functionality of the equipment should be checked. Trainers should decide where they will stand or sit during their presentations. They should be positioned for maximum visibility for the audience and in a convenient location for the interpreters to see them and any visual aids they will use.

Coffee breaks and meal breaks should be planned. The location of restrooms should be noted and announced to the audience at the beginning of the course.

**During the Training**

In a team-teaching setting, the facilitator or team leader will take charge when the course begins. This may follow an opening session led by a local organizer or official. The team leader will introduce and thank the trainers, introduce visitors and have trainees introduce themselves.

As the program proceeds, the leader will be vigilant in monitoring the functionality of equipment and availability of supplies. He or she will be sure that course materials are distributed and remind other trainers of the times for their presentations. All members of the training team should assist the leader with these duties to ensure that the course moves as smoothly as possible.

**Following the Training**

After all presentations have been delivered and the course evaluation (discussed later) is completed, a formal closing ceremony may be held. Often certificates of course completion are awarded to trainees. It is extremely important that trainer(s) and trainees alike all are in attendance and that each trainee is congratulated individually for his or her participation. Trainees should leave the course with a sense of accomplishment and the knowledge that they are prepared to make use of the valuable information that they have learned.

Leaving the room tidy and return equipment and teaching aids to their proper locations. Compile any comments, feedback or evaluations from course participants. Prepare thank you letters as needed for guest speakers, volunteers, etc. Prepare the final report on the course. Be sure that all trainers receive a copy of the compiled evaluations so that they may continually improve content and their presentation approach.

**Checklists**

Even the most experienced trainer or team leader can forget something important. Checklists are a useful tool for reminding trainers of the details that need to be attended to from planning until the course responsibilities all are completed.

A sample checklist for the day before a training course might include a visit to the training room to learn how to control lights and air conditioning, check the arrangement of furniture, confirm catering arrangements for breaks and lunches, and check the functionality of all equipment and the availability of supplies.

For a field exercise, a visit to the farm or packinghouse, the day before should include a check of scheduling to confirm that time is budgeted reasonably, ensure that work will be in progress during the visit, and verify the practices that trainees need to observe. Explain the objectives for the visit to the owner or manager and review any rules the company has regarding photos or behavior of the group during the visit.

Although a mention of checklists here may seem overly simplistic and merely common sense, all of us have attended meetings at some time when details were overlooked. Attention to detail is an important part of planning and execution of any program.

**Course Evaluation**

Although course evaluation is presented as the final topic on developing effective training, it is important to plan the evaluation strategy well before the training takes place. Evaluation is not merely an exercise at the end of the course, but rather is an ongoing process throughout the course that allows the trainer(s) to assess how well the course is progressing and that the objectives are being met.

Training evaluation has been defined as a systematic process for collecting information for and about a training activity, which can then be used for guiding decision making.
making and for assessing the relevance and effectiveness of various training components. It gives a measure of the extent to which the training has been successful in accomplishing the course objectives. Evaluation methods result in feedback from the trainees and allows for continual improvement of the program.

Evaluation strategies have been categorized into four distinct groups: pre-training, process, terminal and follow-up. The choice of evaluation strategy depends upon the purpose of the evaluation.

**Pre-training Evaluation**

This occurs during course development and allows for pre-testing the adequacy, scope and coverage of the training program while it is still in preparation. It serves to identify shortcomings of the training and allows corrective steps at an early stage. Pilot tests of presentations are part of the pre-training evaluation.

**Process Evaluation**

This is conducted while the course is in progress. An ongoing assessment allows for adaptations to be made during the course as needs are identified. This evaluation may involve a formal procedure where feedback is requested from trainees at the end of each day, each session or on some other relevant schedule. It may also include observations from the trainer(s) regarding trainees’ responses.

**Terminal Evaluation**

A terminal evaluation is conducted upon completion of the course. This is the most commonly employed evaluation strategy. It allows trainees to give feedback on the usefulness of the training, the quality of instruction, if objectives were met, and on aspects that could be improved for future courses. This gives the trainer(s) an immediate idea of the course effectiveness. A test administered at the beginning of the course and again at the end of the course gives trainers additional insight on knowledge gained by trainees.

**Follow-up Evaluation**

Ideally, a follow-up evaluation is conducted at some point after the training. Unfortunately follow-up evaluations often are forgotten after the course is over. Since a training program is conducted to bring about changes in behavior or attitudes related to working methods of the trainees, the course effectiveness is best assessed after a period of time has lapsed. Two months is suggested as a reasonable time since the course material hopefully would still be remembered by the trainees and sufficient time will have passed to determine if permanent behavioral change has occurred. This allows for the implementation of the work to be assessed.

It may be difficult to quantify long-term results but there are some specific questions that can give valuable insight. For example, in a follow-up evaluation of a Train the Trainer course it is reasonable to ask the course participants how many programs they conducted and how many people received training based on the course material. They may also be asked how many workers exhibited changes in behavior as a result of being trained. For a food safety course, it would be ideal if a reduction in foodborne illness could be quantified as a result of training, but these data are difficult to collect because quantifying prevention is impossible.

Four criteria have been suggested to evaluate training programs: reaction, learning, behavior and results. Each criterion is used to measure different aspects of the training program.

**Reaction**

Measures how trainees liked the program in terms of content, duration, trainers, facilities, and management.

**Learning**

Measures the trainees’ skills and the knowledge they gained from the course.

**Behavior**

Concerned with the extent to which trainees were able to apply the new knowledge to real work situations.

**Results**

Concerned with the tangible impact of the training program on individuals, their job environment or the organization as a whole.

Evaluation can be informal or formal. Informally, trainer(s) observe feedback from trainees through the tone of language, questions, interest and enthusiasm for the topic. The trainer(s) may request more formal feedback by asking questions to assess the trainees’ understanding and appreciation of the subject matter. Common formal evaluation methods include written evaluations, a questionnaire completed by the trainee or a structured interview with the trainee.

Evaluations should be analyzed. This will allow the trainer(s) to amend and improve materials for subsequent training. It may also identify deficiencies in training that
need to be addressed. It is essential that the best use is made of all feedback received and that it is not simply an exercise on paper.

In addition to feedback from the trainees, self-evaluation by the trainer also is essential. Every time training is conducted, a trainer should consider how he or she functioned as a trainer and make adjustments for future programs. If a team teaching approach is used, team members should be asked for input regarding training organization and effectiveness. A meeting of the teaching team after the course, with open and honest dialogue, is a good way to conduct this evaluation.

Trainers sometime view the evaluation process as a necessary nuisance with little value. This is unfortunate since evaluation can be an effective tool for measuring how well objectives were achieved, improving the efficiency of training to allow better use of limited resources, highlighting the value of the course, increasing the organization’s commitment to the process and fostering interest in training at all levels within the organization.

**Summary**

If the training course entails a considerable length of time the planners should consider organizing a team to complete the delivery.

Training team members must be committed to the course, must understand the objectives, and should draw upon the varied expertise that different individuals bring to the classroom.

In a team environment, one person should assume the role of team leader or facilitator.

Logistical support is needed from the planners and all team members before, during and after the training program. Attention to details is needed at all phases.

Checklists are a useful tool for keeping track of the many details involved in a training course.

Evaluation is a critical process that is conducted at all stages of the training program, from pre-training through the training process to the end of the program and as a follow-up exercise.

Evaluation from the trainees and self-evaluation by the trainer(s) will allow for constant improvement of the course.
Section VII

Food Laws and Regulations

Module 1 The U.S. Food Safety System for Fresh Produce
Module 2 Investigating Outbreaks of Foodborne Disease
Module 3 International Laws and Regulations
Introduction

In the U.S. there are a number of federal, state and local agencies that regulate and have oversight for the safety of various food groups. Meat, poultry, seafood, milk, eggs, processed fruit and vegetables, etc., are all subject to specific rules and regulations. This Module focuses primarily on the entities that are involved with the fresh produce industry. It is not intended to provide a comprehensive review of all laws and regulations regarding food safety, but to provide an informative overview.

Basic Requirements for Food

All foods consumed in the U.S., whether produced domestically or internationally, must conform to a simple set of principles. Food must be pure, wholesome and safe to eat, produced under sanitary conditions and properly labeled. The globalization of our food supply during the past few decades has dramatically complicated the work of the regulatory environment by creating the challenge of ensuring that imported foods meet the same standard of quality and safety that is demanded of domestic products.

Although the above requirements appear to be straightforward, they all are subject to interpretation. In order to achieve uniformity in food quality and safety, the regulatory system in the U.S. has evolved into a complex set of laws enforced by numerous agencies. The complexity of the system is evident in the following list of agencies that are involved.

Federal Agencies Involved in Food Safety

The U.S. Department of Health and Human Services (HHS) has within its organizational structure two units that have food safety responsibilities. These are only two of the units housed in HHS, an agency with many other responsibilities not discussed here.

The Food and Drug Administration (FDA) regulates all foods other than meat, poultry and processed eggs. FDA plays many vital roles in support of the fresh produce industry and these are discussed in more detail throughout this Module.

The Centers for Disease Control and Prevention (CDC) work closely with state and local public health epidemiologists and laboratories to identify illnesses and clusters of illness that may be foodborne. They study environmental and chronic health problems, administer national programs for prevention and control of vector-borne diseases, and fulfill other important roles in service to the domestic and international communities.

The U.S. Department of Agriculture (USDA) has broad oversight for issues in practically all segments of the agricultural industry. Several units within USDA have roles in food safety assurance.

The Food Safety and Inspection Service (FSIS) is responsible for regulation of meat, poultry and processed eggs. Because of the potential for commingling and cross-contamination between different food groups, the FSIS is increasingly involved in discussions and issues surrounding fresh produce food safety.

The Animal and Plant Health Inspection Service (APHIS) addresses animal diseases that could affect food safety and maintains a comprehensive system of import inspection and controls. Through monitoring activities at airports, seaports and border stations it guards against the entry of foreign agricultural pests and diseases that affect both plants and animals.

The Foreign Agricultural Service (FAS) is primarily responsible for the USDA’s overseas programs, including market development, international trade agreements and negotiations, and the collection of statistics and market information. The FAS is well positioned to assist other agencies with evaluating food safety capabilities and identifying training opportunities in foreign countries.

The Agricultural Marketing Service (AMS) carries out programs aimed at facilitating the marketing of
This involves many Acts, or Laws. A few of those Acts that are relevant to the fresh produce industry are:

- Federal Food, Drug and Cosmetic Act
- Fair Packaging and Labeling Act
- Bioterrorism Act
- Nutritional Labeling and Education Act
- Food Allergen Labeling and Consumer Protection Act
- Dietary Supplement Health and Education Act
- Public Health Service Act

Although the U.S. Congress passes legislation to establish the above Laws and Acts, the FDA is responsible for developing and implementing regulations. These FDA Regulations are codified in Part 21 Code of Federal Regulations (21 CFR), which is available online at www.fda.gov and include the following:

- Good Manufacturing Practices: 21 CFR 110
- Dietary Supplements: 21 CFR 111
- Canned Foods: 21 CFR 113
- Juice HACCP: 21 CFR 120
- Seafood HACCP: 21 CFR 123
- Nutrition Labeling: 21 CFR 109
- Veterinary Drugs: 21 CFR 500-589

To aid the food industry in interpreting these regulations, the FDA develops guidelines and recommendations. One of these documents, the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, is largely the basis for many of the principles discussed throughout this manual. Commodity-specific guidelines also have been developed, with industry collaboration, for leafy greens, tomatoes, melons and sprouted seeds. The development of resources to assist food industries is an ongoing task of the FDA.

State and Local Agencies

Each state has its own set of agencies that address food safety issues within the state. They may also regulate interstate movement of some agricultural products. Counties, municipalities or other localities often have agencies that assume a food safety role that typically is restricted to oversight of food service facilities, restaurants, local markets, etc. These state and local agencies and their various powers are beyond the scope of this manual, although state and local rules may influence exporters of food to the U.S.

The Food and Drug Administration (FDA)

The FDA is charged with protecting consumers from food that is impure, unsafe, produced in unsanitary conditions or fraudulently labeled. The responsibilities that FDA has are enormous. A few of FDA’s activities include inspecting production facilities and food warehouses; collecting and analyzing samples for all types of hazards; establishing GAP, GMP and HACCP in appropriate locations; sampling and inspecting imported foods; working with foreign governments; taking appropriate enforcement actions; and educating consumers.

Imported Fruits and Vegetables

FDA is the principal food safety regulatory and enforcement agency for most foods imported into the U.S. despite the myriad of agencies listed previously. The key rule to remember is that all imported foods, including fresh produce, must comply with all applicable U.S. laws and FDA regulations. Considerations for imported foods are discussed throughout the remainder of this Module.
The Bioterrorism Act

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, commonly referred to as the Bioterrorism Act, created a number of new requirements for food handlers. The FDA is charged with enforcement of these requirements, which are reviewed here.

Registration of Food Facilities

Owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack or hold food (subject to FDA's jurisdiction) for human or animal consumption in the United States must register the facility with FDA. The requirement applies to each covered facility, not to firms or companies as a whole. For example, a large fresh fruit and vegetable company with 10 packing and storage facilities must register each of those facilities separately with FDA.

The list of food products covered by this law is lengthy and can be viewed at the FDA website. Since fresh produce is the focus of this Manual, only the impact on fresh produce will be discussed.

The intent of the facility registration rule is to assist FDA with quickly determining the location and cause of a potential threat to our food supply and to be able to notify other facilities of the threat so that they may respond in a timely manner to protect consumers’ health and safety.

There is a special exemption from the registration rule for certain foreign facilities that handle food if a subsequent foreign facility further handles the food. Anyone who believes that their company is affected by this exemption should refer directly to the rule on the FDA site since this Manual is not intended to be a comprehensive resource for information about food law.

The following information is required for food facility registration: name; full address and phone number of the facility; the parent company if there is one, and the owner, operator or agent in charge; all trade names the facility uses; name of U.S. agent and contact information (foreign facilities only); emergency contact phone number (domestic facilities only) and food product categories. Registration can be completed online.

Prior Notice of Imported Food Shipments

The FDA requires advance notice of foods that are to be imported into the U.S. The purpose of this law is to allow FDA time to evaluate information before the product arrives and, if necessary, shift resources to target inspections. This allows the FDA to help intercept contaminated goods and to help ensure movement of safe food into the market.

The following information must be provided in the prior notice: description of the food article, manufacturer and shipper of the article, the grower (if known), country of origin, country from which the article is shipped and anticipated port of entry. Note that most of this information is common invoice data usually provided by importers to U.S. Customs when goods arrive in the U.S.

Unless an exception has been approved, the rule applies to all food for humans and animals that is imported or offered for import into the U.S. for use, storage or distribution. This includes food for gifts and trade, quality assurance/quality control samples, food for future export, transshipment through the U.S. to another country or for use in a U.S. Foreign Trade Zone (FTZ), and food sent by mail or by express couriers.

The required time for prior notice depends upon the method of shipment as follows: by land via road requires no less than 2 hours before arrival, by air or by land via rail requires no less than 4 hours and arrival by water no less than 8 hours. For food carried by or accompanying an individual, the time is based upon the method of transportation. Prior notice cannot be submitted more than 5 days before arrival except for items sent by international mail, for which notice is submitted prior to mailing. Other restrictions may apply due to detention orders, reconditioning options, import alerts or refusals for non-compliance with other rules.

Establishment and Maintenance of Records

The Bioterrorism Act established laws for the maintenance of records to allow food to be traced back to its previous source or traced forward to its recipient. This is discussed in detail in Module 2 of this Section on the Investigation of Outbreaks of Foodborne Illness.

Administrative Detention

The FDA has the authority to detain an article of food if there is credible evidence or information indicating that the food presents a threat of serious adverse health consequences or death to humans or animals. The circumstances leading up to a detention order and the
owner’s or consignee’s options in responding to such an order are discussed later in this Module.

**FDA’s Enforcement Organizational Structure**

The FDA operates with a set of five Centers as follows:

- Center for Drug Evaluation and Research (CDER)
- Center for Biologics Evaluation and Research (CBER)
- Center for Devices and Radiological Health (CDRH)
- Center for Veterinary Medicine (CVM)
- Center for Food Safety and Applied Nutrition (CFSAN)

Responsibility for food safety resides in CFSAN and CVM. These agencies have worked with the University of Maryland to establish the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), which now provides much of the FDA-required training in food safety.

Although education is one of the goals of FDA, regulation and enforcement are its primary missions. To this end, the FDA has developed a number of compliance programs for foods with the goal of improving the quality, safety and security of our food supply. Many of those programs are listed below. The reader will note that a few of these have only a marginal connection to the safety of fresh fruits and vegetables. However, the fact that fresh produce is blended or commingled with many other food groups during preparation for consumption, such as in salads, demands that these compliance groups be in communication with each other to identify potential food safety hazards and work together to eliminate those hazards.

**FDA Compliance Programs for Foods**

- Import and Domestic Low Acid and Acidified Canned Foods Programs
- Import and Domestic Cheese and Cheese Products Program
- National Drug Residue Milk Monitoring Program
- Domestic Food Safety Program, General
- Imported Food Safety Program, General
- Domestic Fish and Fish Products Inspection Program
- Imported Seafood Products Program
- Juice HACCP Inspection Program
- Pesticides and Industrial Chemicals in Domestic Foods Program
- Pesticides and Industrial Chemicals in Imported Foods Program
- Chemotherapeutics in Seafood Compliance Program
- Toxic Elements in Food and Foodware, Import and Domestic Program
- Mycotoxins in Domestic Foods Program
- Mycotoxins in Imported Foods Program
- Food and Color Additives in Imported Foods Program
- Retail Food Protection Program
- Milk Safety Program
- Molluscan Shellfish Evaluation Program
- Interstate Travel Program
- Medical Foods, Import and Domestic Program
- Domestic and Import Food Labeling Programs
- Infant Formulas, Domestic and Import Programs
- Dietary Supplements, Domestic and Import Programs
- Animal Drug Manufacturing Inspection Program
- Feed Contaminants Program
- Feed Manufacturing Compliance Program
- Illegal Drug Residues in Meat and Poultry Program (CVM cooperates with FSIS)
- National Drug Residue Milk Monitoring Program
- BSE/Ruminant Feed Ban Inspections Program

**FDA Organizational Structure for Import Enforcement**

There are three offices responsible for enforcement of the above compliance programs for imported foods.

The Office of Regulatory Affairs (ORA) is the lead office for all FDA field activities and provides leadership on imports, inspections and enforcement policy. It supports the 5 FDA Product Centers mentioned previously by inspecting products and manufacturers, conducting sample analyses, reviewing products offered for entry into the U.S., and developing policy on compliance and enforcement. ORA staff are located in sites throughout the U.S.

The Office of Regional Operations (ORO) coordinates and manages field operations. It is intricately involved in development and execution of policy between FDA and...
In addition to these administrative instruments, all traditional enforcement mechanisms also are available to the FDA where warranted:

- Product seizures (FFDCA Sec. 304)
- Permanent Injunctions (FFDCA Sec. 302)
- Criminal Prosecution (FFDCA Sec. 301 and 303)
- Debarment (FFDCA Sec. 306)

Section 801(a) of FFDCA gives authority to FDA to “Refuse Admission” of any article that “appears” to be in violation of one of these laws:

If it appears from the examination of such samples or otherwise that... It has been manufactured, processed, or packed under unsanitary conditions... It is forbidden or restricted in sale in country in which it was produced or exported... It is adulterated or misbranded... then such article shall be refused admission...”

The significance of the appearance standard under FDA law is important in that the Government is not required to prove that an actual violation of law or the regulations has occurred. Rather, the FDA must be able to show that there exists an “appearance” of a violation to refuse admission of goods. If that “appearance” exists, the FDA can refuse entry to goods that appear to be adulterated or misbranded or appear to have been manufactured not in accordance with Good Manufacturing Practices (GMP). Further, FDA is allowed to make admissibility decisions using historical data, physical examinations (vs. sample collections), or based upon information from other sources or other evidence. In essence FDA has the authority and the obligation to use any and all resources available to judge the admissibility of food into the U.S.

**FDA Coverage at U.S. Ports of Entry**

The FDA is physically present at geographical locations covering only about 100 of Customs’ approximately 300 ports of entry. However, the FDA CVM cooperates with FSIS Customs and Border Protection to cover remaining ports of entry. Regardless of their physical presence, the FDA receives notice of entries through Customs at all ports of entry.

**FDA’s Enforcement Approaches and Practices for Imported Foods**

The FDA’s authority over importation of FDA-regulated products is derived principally from Section 801 of the Federal Food, Drug and Cosmetic Act (FFDCA). Its import procedures are mainly “administrative” in nature and operate through a set of administrative mechanisms that include the following:

- Review of entries as declared by Importers/Customs House Brokers
- Review of documents and product through field examinations, label examinations, and physical sample analyses
- Detentions, Refusals of Admission, and Re-labeling or Reconditioning of goods that are found to be in violation of regulation(s)
- Verification of final disposition of refused goods

**The FDA Import Process**

When a food is being prepared for importation into the U.S., a specific process is followed to assure that it meets FDA standards and is compliant with other rules for admission. First an entry notice is made to Customs. If the food is regulated by FDA, Customs forwards the entry notice to FDA. All food imports must comply with the requirements for prior notice and facility registration information under the Bioterrorism Act as discussed earlier.

If these preliminary requirements are met, the FDA will then review the shipment for admissibility. If all further
requirements are in compliance the FDA may rule that the shipment “may proceed” for admission and distribution.

FDA may decide to detain the goods without examination based on a failure to submit required information if there are import alerts relevant to the shipment (discussed later), or if more information needs to be obtained through additional documentation or through examination of the food and possibly with sample collection.

**Notice of Sampling**

FDA enforces this policy by employing 21 CFR 1.90—NOTICE OF SAMPLING.

When a shipment arrives, the owner or consignee is provided with a notice, initially through a Customs House Broker, when the FDA intends to examine the shipment.

This regulation requires the importer to hold the imported goods intact until the examination is completed. If an importer fails to hold goods that the FDA has indicated it intends to examine, the FDA will request Customs to demand redelivery of the goods in order for the examination to occur. The importer is then obligated to return the merchandise according to the terms of its Customs entry bond. Customs is able to enforce 21 CFR 1.90. If Customs demands that the importer redeliver the goods and the importer fails to do so, the conditions of the Customs entry bond gives Customs a civil cause of action to claim “Liquidated Damages.”

**The FDA import process is summarized as follows:**

If a release (“may proceed”) is issued, the product may be distributed. However, FDA still has jurisdiction and the release decision does not preclude FDA action if a problem is found later.

A detention order may be issued by FDA if there is an “appearance” of a violation. The “appearance” decision can be based on examinations, sampling, historical data or a lack of required processes and/or approvals. Regardless of the nature of the detention the importer has the right to give evidence to refute the appearance of a violation. Based on the evidence, the detention will either stand (refusal) or be overturned (release).

The importer also can also petition to recondition the goods to bring them into compliance. The reconditioning, which must be approved by FDA, may include re-labeling a misbranded product, cleansing an adulterated product or making a product that is not FDA regulated. All of these decisions are costly to the importer, so they should be made carefully.

All FDA field personnel are trained in examination and sampling techniques so there is some confidence that when they uncover the “appearance” of violations, a violation actually does exist. Field personnel will physically examine for evidence of filth, decomposition, packaging defects or misbranding. If there is justification, samples collected by field personnel are analyzed by FDA laboratories.

When a shipment is deemed to be “not in compliance,” the FDA can issue either of two rulings regarding the shipment: Detention or Refusal.

Detention is a preliminary action whereby the FDA provides notice to the importer of an appearance of a violation and grants an opportunity for the importer to be heard. The importer and the FDA discuss the apparent violation and the importer is granted a chance to overcome the appearance before a definite refusal, discussed later, is issued.

The importer has several options following a detention notice. The importer may appeal the detention to the FDA, submit a private laboratory report of analyses, provide a certification of the product (where applicable), remove the product from FDA’s jurisdiction, submit an application to recondition or re-label the product (under FDA supervision), or request an immediate Refusal of Admission.

If an article that was detained under section 801(a)(3) can, by re-labeling or other action, be brought into compliance with the Act, or rendered other than a food, drug, device or cosmetic, final determination as to admission of such article may be deferred. FDA supervises this process through a reconditioning/re-labeling agreement (FDA Form 766). Reconditioning is either successful, resulting in release of the shipment into U.S. commerce, or reconditioning is unsuccessful, resulting in refusal of admission. The FDA may grant approval to attempt a second reconditioning.

**U.S. Refused Admission**

Refusal of admission is a FINAL action by FDA preventing a particular shipment from being imported. Once admission is refused the importer has two options: export the product under Customs supervision within 90 days of the date of

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refusal, or destroy the product under FDA supervision within 90 days of the date of refusal.

Charges to the Owner/Consignee (Sec 801(c)) state: All expenses (travel, per diem or subsistence, and salaries) in connection with the destruction or re-labeling/reconditioning provided for in sections 801(a) and (b) shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against future importations.

**FDA Import Alerts**

Import Alerts are issued by FDA to communicate information to the field offices. Field agents can use the information to detain goods without examining them, e.g., Detention Without Physical Examination (DWPE). When the FDA detains a product without examination, it is providing notice to the importer that there appears to be some violation of law or regulations based upon something other than examination.

Field agents can also use this Import Alert to determine what products to examine or sample. A firm or product may be added to the DWPE order based on evidence from field offices or based on evidence from foreign inspections.

Foreign firms (shippers and manufacturers), products, countries of origin and importers of record may, in varying combinations, appear on an Import Alert. The Alert itself does not constitute evidence that there appears to be a violation, rather, the substance of the Alert describes evidence that the Agency has obtained. Under an Import Alert/DWPE, the importer is granted an opportunity to be heard and to offer testimony (oral, written or documentary) to overcome the “appearance” and obtain release of the entry.

There are a number of reasons for invoking Import Alerts: a shipper or manufacturer may have prior history of products in violation of FDA rules; foreign inspection may indicate processing, packing, or manufacturing problems at a particular foreign facility, or product may be from geographic locations that have experienced environmental events affecting the safety of products. Any of these situations can be the basis for the issuance of an Import Alert.

When a shipment that has arrived to the U.S. is held under DWPE the importer does have some options to have the shipment released. For example, when a firm has had prior violations, additional shipments from that firm can “appear” to violate the Federal Food Drug and Cosmetic Act (FFDEA). This prior history can result in a DWPE even though there are no apparent violations on the current shipment. The importer can offer testimony or evidence that “this current shipment” is not in violation, thereby overcoming the appearance of a violation and effecting release. Usually the evidence/testimony takes the form of private laboratory analyses or some compelling documentation about the company’s practices.

**Removal of Import Alert/DWPE**

Firms may petition the FDA to be removed from DWPE. FDA reviews the petition submitted by the firm and generally requires evidence of non-violative shipments that are analyzed by a laboratory at importer expense.

FDA needs reasonable assurance that the cause of the violation has been corrected. Where a violative inspection caused the issuance of the Alert, a follow-up inspection may be required to overcome the appearance. Where a history of violative shipments resulted in inclusion in an Import Alert, the Agency may require a certain number of consecutive non-violative shipments, e.g., typically a minimum of five consecutive shipments, in order to remove a firm from DWPE.

When all of these requirements are satisfied a recommendation for removal from Import Alerts/DWPE can originate from an FDA District or from an interested party, e.g., grower, exporter, importer or foreign government. If the appearance of the violation has been removed by adequate demonstration to FDA that the cause of the deficiency no longer exists, FDA can remove the firm from DWPE.

**Pesticide Residues on Fresh Fruits and Vegetables**

Tolerances for pesticide residues on many raw agricultural commodities, including fruits and vegetables, have been established under Section 408 of the FFDEA. The EPA establishes, revokes, or changes tolerances as the facts warrant such action. It is the responsibility of the grower, shipper or their representative to know the rules governing pesticide residues on their own products. They may contact EPA for this information. This topic was addressed in some detail in Section IV.
APHIS Import Authorization System

Certain fruits and vegetables from certain countries must undergo phytosanitary inspection and in some cases, quarantine treatment before they are allowed entry into the U.S. Entry requirements can be obtained from the APHIS website: www.aphis.usda.gov. These requirements focus on the protection of U.S. crops from insects and diseases that impact crop production.

Summary

Numerous federal, state and local agencies are involved in food safety in the U.S., but the FDA is the principal regulatory and enforcement agency for the safety of fresh fruits and vegetables.

In order to provide the best assurance that all foods (domestic and imported) are safe for consumption, the FDA has a complex enforcement and organizational structure involving numerous Centers and Offices that adhere to specific compliance programs.

The CDC investigates foodborne illnesses, working in collaboration with the FDA when appropriate.

The Bioterrorism Act of 2002 formally placed four general requirements on the produce industry: domestic and foreign food facilities must register with FDA, foreign entities must provide prior notice of imported foods, records must be maintained that allow food to be traced back to its previous source and traced forward to its subsequent recipient, and the FDA has the authority to detain an article of food under specific circumstances.

Imported foods are subject to the same laws, rules, acts, regulations, etc., as food produced within the U.S.

The FDA conducts surveillance and enforcement programs for imported foods that are intended to ensure that imports comply with applicable laws and regulations.

The FDA may detain import consignments that “appear” to violate U.S. law.

Detention Without Physical Examination (DWPE) may be invoked against foreign growers, handlers or manufacturers that violate U.S. laws and regulations.

Foreign entities can work directly with the FDA to overcome problems associated with their products.
Introduction

When an outbreak of foodborne illness or injury occurs, prompt identification of the food and the type of contamination is important both to ensure adequate treatment of sick persons and to protect the public from the risk of reoccurrence or spread of the incident. Biological, chemical or physical hazards all can potentially lead to an outbreak of illness or injuries. In recent years, the most publicized outbreaks have been those resulting from biological causes.

Surveillance of Illness in the U.S.

Possible outbreaks of disease or injury may be identified in a number of ways. Consumers who suspect that a food they ate caused them to be sick may report the incident to the local health department. If they seek medical treatment, the physician may report the illness, which is required for certain diseases. Medical personnel who notice unusual numbers of cases also may report to public health officials.

In the U.S., the reports described above are likely to be forwarded to a central data collection location. Officials who review these surveillance data have the advantage of receiving information from many sources throughout the country. Two surveillance networks, FoodNet and PulseNet, monitor foodborne disease on a national level.

FoodNet is the Foodborne Diseases Active Surveillance Network. It a collaborative project of the Centers for Disease Control (CDC), the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA) and 10 states throughout the U.S. The project involves active surveillance of foodborne diseases caused by at least nine pathogens or parasites. It is designed to assist public health officials with better understanding foodborne illnesses and their causes.

PulseNet is a national network of public health laboratories that perform DNA “fingerprinting” on bacteria that may be foodborne. The network permits rapid comparison of these fingerprint patterns though an electronic database at CDC. The system is designed to share fingerprints and other relevant information when an outbreak of disease occurs and determine if the bacteria are related.

FoodNet and PulseNet both have been invaluable resources for the early detection of disease. This assists physicians with diagnosis and treatment of new cases as they appear and it helps epidemiologists to mobilize quickly to identify food(s) that may be linked to the outbreak.

Components of an Outbreak Investigation

Once an outbreak is recognized an investigation is begun immediately to determine the cause. The primary purpose is to prevent additional illnesses from occurring. However, it is still important to conduct an investigation even if no additional illnesses are appearing. Information may be used to evaluate prevention strategies to avoid similar outbreaks in the future, describe new diseases, learn more about existing diseases and address public concerns about the outbreak.

Foodborne disease investigations generally have three major components: epidemiological, laboratory and environmental.

Epidemiology is a branch of medical science that deals with the incidence, distribution and control of a disease within a population. Thus, an epidemiological investigation is intended to identify the range of onset of symptoms, provide case definitions, and determine the association between exposure to a specific food and the occurrence of illness. The linkage of illness to specific food(s) can suggest sources of contamination and eventually lead to strategies for mitigating risk. Sometimes a definitive linkage between a specific food and illness can not be determined and statistical analyses of outbreak data are employed to determine the most probable cause of the outbreak. Epidemiology is not always an exact science.

The laboratory component of the investigation involves analysis of clinical samples, food samples (if implicated portions or lots are still available) and environmental samples. Analysis of clinical specimens is conducted to identify the biological, chemical or physical hazard that
caused the illness or injury and can help to determine if cases are linked. Further, results of clinical analyses are compared to results for food and environmental samples to aid in determining the cause of the illness and source of the hazard.

Environmental investigations usually focus first on the point of food preparation. If the investigators conclude that the contamination most likely did not occur at the point of preparation, a traceback investigation (discussed later) is initiated that focuses on the production and handling environments to which the food has been exposed. Areas investigated may include farms, packinghouses, processing facilities, storerooms, mode of transportation, etc. The potential for temperature abuse, cross-contamination and any other potential risk factor is considered as part of the investigative process.

To summarize, the anatomy of a disease investigation involves: disease surveillance, epidemiological investigation, laboratory analyses, environmental investigation, traceback and traceforward (discussed later) and investigation of the manufacturer/processor and the farms. Collectively these investigations allow authorities to determine where, when and how in the production and handling chain the product became contaminated.

In a perfect world all of the preceding steps would be completed and accurate information would be available prior to the notification of consumers and removal of the product from the market. However, in the interest of protecting consumers, investigators sometimes must take steps to remove product from the market prior to completion of the investigation based on statistical evaluation of available data.

**The Importance of Rapid Response**

Foodborne disease outbreaks can spread rapidly through large populations. This is due in part to the fact that our food supply today is global, involving trade between states, nations and continents. Distribution networks within a market area, e.g., a country, region, state, etc., may be so well developed that the contaminated food rapidly reaches the hands of consumers. Further, biological and chemical hazards both may cause illness in low doses and can degrade rapidly, making them more difficult to identify with the passage of time. All of these factors emphasize the need for timely action by health authorities.

Rapid response to a foodborne illness outbreak must rely heavily on epidemiological data, which must be shared by county, state, national and international agencies in order to obtain control of food distribution and limit exposure to the hazard. Guidelines for improving the coordination and communication on multi-state foodborne illness outbreaks have been developed in the U.S.

International efforts to allow rapid detection of foodborne disease outbreaks require a constant exchange of information and surveillance data. This involves coordination and open communication between various agencies within countries plus a point of contact for sharing the information at the international level. All of this must be supported by an infrastructure of personnel and facilities that allow for accurate sampling and adequate laboratory investigations. Further, the produce industry must maintain accurate information about the source and movement of product to facilitate traceback and traceforward. Many countries do not yet have the resources or networking capability to facilitate the tracking of food in the distribution system, or to monitor foodborne illness outbreaks.

In summary, foodborne illness outbreak investigations are most effective and conducted most rapidly when there is early identification of the outbreak, rapid and coordinated response by all investigative bodies, identification and confirmation of the product(s) and source(s), confirmation of the accuracy of all results obtained in the preceding steps, and the availability of scientific evidence linking the agent to the illness.

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**Timeline for Reporting of Cases**

- **Patient Eats Contaminated Food**: 1–3 Days
- **Time to contact with health care system**: 1–5 days
- **Stool Sample Collected**: Time to diagnosis = 1–3 days
- **Shipping time**: 0–7 days
- **Salmonella Identified**: Serotyping and “DNA fingerprinting” = 2–10 days
- **Case Confirmed as Part of Outbreak**: 1–3 days
steps, and a plan to utilize the information to prevent future outbreaks.

Although the above steps and requirements for rapid response are clear, in the real world there are a number of factors that slow the process. The preceding graphic shows approximate delays that can occur with the identification of an outbreak caused by *Salmonella*. As much as three weeks may elapse from the time the patient consumes the food, contracts the illness, reports to a physician, provides a stool sample for identification of the bacterium, and analysis by health authorities who must fingerprint the microorganism and determine if other similar cases have been reported.

In the case of illness caused by a virus, such as Hepatitis A, the process outlined above is much longer. The development of disease may not occur for several weeks and the methods for identification of viruses are somewhat more complicated that those employed for bacteria. Many consumers may be exposed to the virus before the outbreak is identified and the cause confirmed.

**Traceback and Traceforward of Fruits and Vegetables**

As stated in the previous Module, The Bioterrorism Act requires fresh produce companies to maintain records that allow food to be traced one step back to its source and one step forward to its recipient(s).

A *traceback* investigation starts with the consumer or point-of-purchase and traces the steps in the handling and distribution of the product back to the specific production area on the farm. This is a key process in response to a foodborne illness outbreak.

A *traceforward* investigation begins with the manufacturer/distributor or the farm, and traces forward to the consumer. This process is used primarily for product recall, but it also can be useful in outbreak investigations.

Traceback investigations are conducted to determine the source of contaminated products, to determine the distribution network for the implicated products, and to help identify potential points in the production and handling system where contamination could have occurred.

An effective traceback provides investigators with clues that may lead to identification of a specific region, field, packinghouse, processing facility, etc., as the contamination source. This allows authorities to narrow the scope of the outbreak rather than implicating an entire commodity group. There are examples of past outbreaks in which specific traceback for the implicated commodity, e.g., tomatoes, melons and others, could not be completed and the industry as a whole suffered because of the consumers’ perception that all products were contaminated. Once the traceback has been successfully completed a traceforward can be conducted so that potentially contaminated products can be recalled. An example of a traceback flow diagram is shown here:

**Traceback Flow Diagram Example**

Although every traceback investigation is unique, there is a general process that investigators employ. Initially, investigators visit the Point of Service (POS) where the product was purchased or prepared for consumption. This might be a food service establishment or the consumers’ homes. All records related to the food would be examined. This would include documentation for receiving, inventory, stock rotation, handling and shipping.

From these records, suppliers/distributors would be identified and visits to these establishments would be conducted. Records of shipping and distribution would be examined and charted for the time period covering the shelf life of the product.

These records should identify storage facilities, packinghouses or processors who had possession of the product. Visits to the handlers of the product and examination of their records should identify the farm(s) where the product was produced.

Farm investigations are discussed later. If the product was imported the scope of the investigation would have to be expanded dramatically to include the international producer and distributor.

It is obvious from the above summary that a traceback investigation can be a complex and time-consuming process.
process. Some unique challenges exist in the fresh produce industry that makes traceback investigations more difficult.

Fruits and vegetables have a relatively short shelf-life and may have been completely consumed or otherwise removed from the market before an outbreak is identified.

Produce items may have been commingled at retail, during distribution or at the POS, which make the identification of a specific product very difficult.

If an implicated location such as a farm or packinghouse can be identified, the contamination may no longer be present by the time investigators arrive.

The above variables and lack of a direct determination of cause have resulted in a high degree of uncertainty in some investigations, leading to false associations. The economic burden of a false association is especially troublesome for those industry segments that may later be proven not to have been involved in the actual outbreak.

The following two illustrations provide examples of traceback investigations that were either conclusive or inconclusive. In the first example, several clusters of illness were associated with various distributors. Records from those distributors eventually revealed a direct association of the product with Farm A. In the second example, which involves produce from domestic and foreign sources both, many different distributors received product from many different farms. A clear and direct association between the POS and product source could not be established.

In past investigations, the FDA has faced one highly significant challenge in addition to those mentioned previously. During the investigation an outbreak may be ongoing. This places tremendous pressure on FDA to make an early decision in the interest of protecting consumers.

An early decision, which later may be proven to be wrong, results in criticism of the FDA by the industry that may have faced severe economic hardships due to recalls or lost sales.

Further, there may be large numbers of sporadic cases for which there is no clear association with a specific food. Consumers generally have poor recollection of what they have eaten over a period of several days or they might have eaten the same produce item every day during the period in question. Multiple product types or varieties might be identified. For example, the consumer might recall eating tomatoes but may not be able to say if they were round, roma, cherry, or grape tomatoes or if they appeared to be a field-grown type versus a greenhouse-grown type. The tomatoes might have been mixed with other products, as in salsa or guacamole, which would preclude the identification of the specific type. The popularity of salad bars, fruit medleys, and other fresh foods made from a number of produce items are especially challenging for traceback investigators.

**Considerations for Record-Keeping**

Most of the above challenges for traceback could be overcome with the implementation of thorough record-keeping practices. This is much easier said than done. Large companies that are fully vertically integrated are best positioned to track their products from the farm through the

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**Example of a Conclusive Traceback**

![Diagram of a Conclusive Traceback](image1)

**Example of Inconclusive Traceback**

![Diagram of an Inconclusive Traceback](image2)

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FDA Public Meeting on Product Tracing October 16, 2008
distribution system. There are examples of companies that have control over growing, packing, shipping, re-packing and distribution. In this instance all critical records are held within a single company and can be made more readily available.

In the produce industry it is much more common for the product to pass through the hands of several different companies. Under this system, as stated earlier, FDA requires that each of these companies must have business records that allow tracking of the product only one step backward to the supplier and one step forward to the receiver. This makes traceback extremely cumbersome. It is difficult for a farmer to assign a label with a code to the product and expect that the same label will pass through the handling and marketing system with appropriate addition of new information from every handler to the consumer. Smaller companies are clearly at a disadvantage and must work with their business partners to develop appropriate protocols.

It is important for a company to examine current procedures and develop labeling methods to facilitate traceback. Ideally a label would contain the following information: the commodity type; farm and field location; lot number if one is assigned; date and time of harvest; harvest crew; date of packing; product code if one is assigned; date(s) of storage, ripening or other postharvest treatments; date of shipping; receiver identification; date received; date repacked; date reshipped or distributed; and identification of the final receiver. Under ideal circumstances, FDA would be able to quickly develop a flow chart containing all of this information. Companies identified on the flow chart could be contacted using Facility Registration information.

When tracking product from foreign sources, the FDA can make use of Facility Registration and Prior Notice data to help identify product(s) and source(s). Reliance on the company records and cooperation from the foreign government is still necessary for onsite investigation(s).

Personnel records within individual companies also should be available to traceback investigators. It should be possible to use these records to determine who handled the product at each step. This information is critical to determine if product handlers may have been ill at the time they were working.

Technologies have been developed and are constantly being improved to facilitate rapid traceback. In fact, this has emerged as a new distinct business niche in the food industry as a whole. These include highly specialized labeling systems, such as bar codes, radio frequency devices, stamps, stickers, etc., that allow for rapid identification of the product source and its history in the distribution chain. It is beyond the scope of this Module to review all of the technology that is available today and it is expected that new innovations will be developed on a regular basis.

**Farm or Source Investigations**

It is important to note that if a traceback investigation successfully tracks to the farm level, it does not necessarily indicate that the farm(s) are the source(s) of the product contamination. Further investigation is required to identify the specific source. The news media often present reports with the inference that the farm is culpable simply because it has been identified, which is not a fair assumption. Contamination might occur at virtually any step identified in the flow chart that is developed in conjunction with a traceback and investigators are expected to have the skills to recognize likely contamination sources.

Farms are investigated in the same thorough manner that is applied to handlers and processors to locate possible sources of contamination. Efforts are focused on factors such as irrigation water quality management, worker health and hygiene, proximity of domestic and wild animals, the effectiveness of animal exclusion methods, field drainage, potential for run-off from surrounding areas during flooding, waste management, manure usage, sanitation and handling of tools and equipment, weather conditions such as prevailing wind direction or other environmental conditions, and any other concern that could potentially result in contamination on the farm. All factors discussed in Section II of this Manual are considered.

The FDA has developed a Farm Investigation Questionnaire that provides an outline of the factors that are studied to identify potential points of contamination. Efforts are focused on factors such as irrigation water quality management, worker health and hygiene, proximity of domestic and wild animals, the effectiveness of animal exclusion methods, field drainage, potential for run-off from surrounding areas during flooding, waste management, manure usage, sanitation and handling of tools and equipment, weather conditions such as prevailing wind direction or other environmental conditions, and any other concern that could potentially result in contamination on the farm. All factors discussed in Section II of this Manual are considered.

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Producers are urged to obtain a copy of this document and to perform a self-evaluation as a part of their GAP program.

The Reportable Food Registry (RFR) is an electronic portal to which the food industry must submit reports when there is a reasonable probability that an article of food will cause serious health consequences if it is consumed.

Summary
During an outbreak investigation, prompt identification of the food and the cause of illness or injury are important to limit exposure to the hazard.

Surveillance of possible outbreaks is conducted by physicians, local health authorities and national organizations such as FoodNet and PulseNet.

Foodborne disease investigations generally have three components: epidemiology, laboratory and environmental.

Rapid response by authorities to an outbreak is required in order to limit consumer exposure by informing the public that a hazard exists and by removing contaminated food from the supply chain.

Rapid response also is needed because our food supply in the U.S. is sourced from many different countries, distribution methods are rapid and efficient, and some hazards are rapidly degraded. The timeline for reporting cases of ill persons and the determination of the cause of illness or injury can be long.

Traceback starts with the consumer or point of service and traces the steps in handling and distribution back to the specific farm or product source.

Traceforward starts with the farm, manufacturer or distributor and traces forward to the consumer to facilitate product recall.

Companies in the produce industry are required to maintain records that allow investigators to trace product one step backward to the supplier and one step forward to the receiver.

Thorough and accurate record-keeping by companies that detail all critical information about product production and handling are required in order for effective traceback investigations to be achieved. Foreign entities must adhere to the same practices as domestic entities.

New technologies are emerging to assist growers and handlers with developing effective traceback systems.

The FDA has developed a Farm Investigation Questionnaire that provides an outline of the factors that are studied to identify potential points of contamination.
Introduction

In this Module the term sanitary standard refers to those affecting human and animal health. The term phytosanitary standard refers to matters of plant health. International standards are necessary to ensure that food is safe for consumers, to prevent the spread of diseases among animals and plants, and to ensure fair practices in trade. World food trade has benefited from discussions and agreements that provide a more precise framework for business and define the rights and obligations of all partners.

Codex Alimentarius

The term Codex Alimentarius is taken from Latin and translates literally as “food code” or “food law”. It is a series of food standards, codes, and regulations adopted by the Codex Alimentarius Commission (CAC) that countries can use as models in their domestic food regulations. Their use in international trade is a step toward consistency in food laws among countries. Codex is the prevailing international law governing food.

Ideally, the application of Codex standards would assure that any food produced and handled according to its codes of hygienic practices are safe, nutritious and protect human health. In reality, food can never be assured to be completely safe food, but since its inception Codex has dramatically improved the quality and safety of food internationally.

The CAC was created in 1963 by two United Nations (UN) organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Since then, the CAC has been responsible for implementing the Joint FAO/WHO Food Standards Program.

The CAC is an intergovernmental body with a current membership of 183 governing entities. Membership is open to all FAO and WHO member nations and associate members. Additionally, observers from the scientific community, food industry, and food trade and consumer associations may attend sessions of the Commission and of its subsidiary bodies. While observers may participate in the Proceedings of meetings, only Member governments can participate in any decision making process.

The CAC is overseen by a Secretariat and an Executive Committee that is assisted by Regional Coordinating Committees. The work of CAC is divided among three general groups: General Subject Committees address issues that cut across all food classes or groups; Commodity Committees work with specific foods within a class or group, and; Intergovernmental Task Forces work to develop standards, guidelines, and recommendations for foods derived from biotechnology, for animal feeding, and for fruit juices. CAC is a dynamic organization and the number of Committees changes as the needs arise.

There are five documents from CAC, which can be viewed at the Codex Alimentarius website, that have direct relevance to the safety of fresh fruits and vegetables, listed below. The reader will note that specific technical recommendations are largely omitted from the discussion. Rather, they are general in nature and define the minimum requirements for food production, handling, and related areas.

- Principles for Food Import and Export Inspection and Certification CAC/GL 20 -1995
- Principles and Guidelines for the Conduct of Microbiological Risk Assessment CAC/GL 30 – 1999
- Principles and Guidelines for the Conduct of Microbiological Risk Management CAC/GL 63 – 2007
- Principles for the Establishment and Application of Microbiological Criteria for Foods CAC/GL 21 – 1997

In the first document (Code of Hygienic Practice) a discussion of contaminants, including additives and pesticides, is included. Although the CAC has evaluated industrial and environmental contaminants and has published maximum residue levels for many agricultural chemicals, growers and handlers will find more utility in studying the label for any specific chemical and conforming
All Codex standards are developed according to the same procedure. The CAC determines if a standard is needed and assigns the task to an appropriate subsidiary body. A draft standard is prepared and circulated to member countries for comment. The subsidiary body reviews the comments, makes revisions to the draft as needed, and forwards the draft to CAC. If the CAC finds the draft to be acceptable, it is again forwarded to member countries for further review. The CAC and the subsidiary body review the final comments and if the standard is found to be appropriate, it may be adopted as an official Codex Standard.

The Uruguay Round Agreements

The Uruguay Round of Multilateral Trade Negotiations, which concluded in 1994, established the World Trade Organization (WTO) to replace the General Agreement on Trades and Tariffs (GATT). The Negotiations dealt first with the liberalization of trade in agricultural products, an area that had not been included in previous negotiations, and secondly, with reducing non-tariff barriers to international trade in agricultural products.

Two binding agreements were reached: The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and The Agreement on Technical Barriers to Trade (TBT). A summary of those agreements follows. It is important to note that the adoption of SPS and TDB Agreements resulted in new emphasis and importance on the work of Codex in establishing international food quality and safety regulations.

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)

This agreement confirms the right of WTO member countries to apply measures necessary to protect the life and health of humans, animals, and plants. Rules established by countries must not allow arbitrary or unjustifiable discrimination in trade between countries where the same conditions prevail. It also attempts to establish that the rules developed by Member countries are not disguised restrictions on international trade.

With regard to food safety measures, the SPS requires that WTO members base their requirements on international standards, guidelines, and recommendations adopted by FAO/WHO/CAC. A member country may adopt stricter measures if there is scientific justification or if the Codex standard is inconsistent with the level of food safety practices generally used in the country.

The SPS covers all food hygiene and food safety measures including control of pesticides and other agricultural chemicals. SPS recognizes the International Plant Protection Convention (IPPC) as the organization responsible for establishing international standards and encourages countries to base their phytosanitary measures on IPPC standards as a step towards harmonization.

Finally, SPS states that food policies in general must conform to the Codex Standards, thus acknowledging the importance of Codex. SPS also calls for a harmonization of rules among countries based on international standards.

The Agreement on Technical Barriers to Trade (TBT)

The TBT has the objective of preventing the use of national or regional technical requirements, or standards in general, as unjustified barriers to trade. It does not cover food standards related to sanitary or phytosanitary issues as these are addressed elsewhere. It does include measures designed to protect consumers from deception and economic fraud, for example in its policies related to quality and labeling.

The TBT basically provides that all technical standards and regulations must have a legitimate purpose and that the impact or cost of implementing a standard must be proportional to its purpose. If there are two or more ways of achieving the same purpose, the least trade restrictive should be followed. It places emphasis on international standards and obliges WTO members to use them unless they are judged to be ineffective or inappropriate for the national situation.

Call for Harmonization

Harmonization entails the establishment of national measures that are consistent with international standards, guidelines, and recommendations. The premise is that if all countries are playing by the same rules it will facilitate international trade.

Two examples of harmonization efforts in the fresh produce industry are the Global Food Safety Initiative (GFSI) and, in the U.S., the Produce Traceability Initiative (PTI).
The Agreement on Technical Barriers to Trade has the objective of preventing the use of national or regional requirements, or standards in general, as unjustified barriers to trade.

Harmonization entails the establishment of national measures that are consistent with international standards, guidelines, and recommendations. The premise is that if all countries are playing by the same rules it will facilitate international trade.

Those involved in harmonization efforts recognize that countries have the right to adopt standards they feel appropriate to protect human, animal, and plant health, and the environment. They also have the right to take steps to ensure that these standards are met. However, preventing these standards from becoming barriers to trade between countries is important for the promotion of trade.

The TBT does not specifically name the international standard setting body, however the SPS specifically recognizes the CAC as having this role. National regulations that are consistent with Codex meet the requirements of SPS and TBT both. When joining the WTO, countries agree to conform to SPS and TBT for the assurance of the safety and quality of food, and to use Codex standards as their point of reference for business policies and for the resolution of trade disputes.

**Summary**

The term *sanitary* refers to matters of human and animal health and *phytosanitary* refers to plant health.

*Codex Alimentarius*, which means food code or food law, is a series of standards, codes and regulations adopted by the Codex Alimentarius Commission (CAC).

The CAC is an intergovernmental body composed of 183 governing entities. Membership is open to all FAO and WTO member nations and associate members.

The CAC documents that address the quality and safety of fresh fruits and vegetables may be viewed at the Codex Alimentarius website. These documents are general in nature and define minimum requirements for the production and handling of fresh produce and other foods.

The Uruguay Round of Multilateral Trade Negotiations in 1964 established the World Trade Organization and concluded its work with the adoption two binding agreements for member countries to follow in the international food trade.

The Agreement of the Application of Sanitary and Phytosanitary Measures (SPS) confirms the right of WTO members to apply measures necessary to protect the life and health of humans, animals, and plants.

With regard to food safety, the SPS requires that WTO members base their measures on international standards defined by the CAC.
Section VIII

Practical Exercises

Introduction

Experiments/Demonstrations

Water as a Contamination Agent
Product Integrity and Produce Contamination
Handwashing
Chlorine Concentration and Water Quality Management
Fruit Spoilage
Experiments Using Artificial “Germs”
Fresh Produce Quality

Problem Solving

Traceback Investigation
Planning for an Effective Training Course on GAPs: 3 Scenarios

Field Site Visit Guide
Introduction

It is helpful in food safety training programs to have practical activities to reinforce the passive lecture. Frequently, the need to provide lab space and limited instructional time and supervision prevents inclusion of activities. In addition, trainers may be reluctant to sacrifice time needed for presenting new concepts to allow time for activities.

However, if food safety training is to have a lasting impact, involvement of the trainees is essential. All participants, as groups or individually, should take part in practical activities such as experiments, discussion groups and problem solving exercises. Time also should be allowed for feedback from these activities. In addition to critical listening, this leads to critical thinking.

Trainers are encouraged to use as many practical exercises as possible to complement the lecture material. Trainers may decide to use any of the following activities or to use ones from other sources. Use of activities not only will increase comprehension of the material by those being trained as trainers, but will also provide them with ideas for involving the participants in training they conduct.

The Experiments and Demonstrations presented in this section have been designed to be simple, inexpensive, and to use minimum equipment. Although some require a source of water and one involves preparation of materials in a laboratory, none require an actual laboratory in the classroom so they can be conducted in almost any training setting.

Discussion questions provide an opportunity for input by course participants. These may be addressed by the group as a whole or may be discussed within small groups with a summary session for the whole group.

A Problem Solving exercise contains brief story problems that allow trainees to apply lesson concepts as they work through the problem. Trainers may choose other exercises for this purpose.

A Field Site Visit Guide provides a brief outline of key points to observe during site visits. Similar tools are referenced in the Additional Resources section.

Case Studies, not included here, have been developed with direct input from producers in the region to ensure that topics and presentation are appropriate. It is always helpful if a case study relates closely to a practical situation that might be faced by the trainees, i.e. the use of a specific crop or production situation that is familiar to the audience. They are intended to build understanding and awareness of practices that may be presented to individual growers, packers, and shippers for consideration and incorporation into their own operations.
Water as a Contamination Agent

Purpose:
To investigate how water can serve as a source of contamination for fresh produce

Materials for each group:
- Fresh produce sample of two or three whole pieces per group. Produce may be a product produced by participants or may be representative of various types of products such as a leafy product, a product with an edible skin and a product with skin that is removed before eating.
- Knife
- Bowl
- One liter water
- Ice if available
- Blue food coloring or dye
- Slotted spoon, tongs, or other tool to remove fruit from water

Procedure:
1. Divide class into groups of 3 – 4 people.
2. Assign each group a produce product and give each 2-3 whole pieces of produce. The same product may be assigned to more than one group.

Results
Use the following scale to record amount of dye penetration:
4 = lots of dye  3 = moderate dye  2 = some dye  1 = slight dye  0 = no dye

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Discussion Results
1. How much dye was on the surface of the product?
2. How much in the interior?
3. What kinds of barriers prevented the dye from penetrating throughout the product?
4. Suppose the dye represents microorganisms in the water. What conclusions can be drawn about water as a means for these organisms to contaminate produce?
Product Integrity and Produce Contamination

Purpose:
To investigate how product integrity can affect water infiltration into the product.

Materials for each group:
- Fresh produce samples of 1-2 pieces of intact product and 1-2 pieces of damaged product (bruised, insect damaged, cut, etc.) per group. The damage might be from insects or mechanical injuries already present on the product. Damage may inflicted, such as cutting or scraping the product surface, by the group prior to starting the experiment. Produce may be a product produced by participants or may be representative of various types of products such as a leafy product, a product with an edible skin and a product with skin that is removed before eating.
  - Knife
  - Bowl
  - One liter water
  - Ice if available
  - Blue food coloring or dye
  - Slotted spoon, tongs, or other way to remove fruit from water

Procedure
1. Divide class into groups of 3 – 4 people.
2. Assign each group a produce product and give each 1-2 pieces of intact product and 1-2 pieces of damaged product. The same product may be assigned to more than one group.
3. Place water and ice in bowl. Add 10 drops of food coloring (or dye) to the water. Stir to mix.
4. Submerge the intact samples in the water for 10 minutes.
5. Remove fruit from the water and allow it to drain for 10 minutes.
6. Observe the amount of dye on the outer surface of product. Record observations in chart below.
7. Using a sharp knife, remove a slice about 1 inch from the stem end of the product. Observe and record the amount of dye penetration.
8. Clean the knife to remove any dye. Cut the product in half. Observe and record the amount of dye penetration on the cut surface.
9. Repeat steps 4-8 for the damaged samples. Clean the knife and cut into the damaged areas. Observe and record dye penetration.

Discussion Results
1. How much dye was on the surface of the product?
2. How much in the interior?
3. What kinds of barriers prevented the dye from penetrating throughout the product?
4. What effect did damages to the surface of the product have on the amount of color penetration?
5. Suppose the dye represents microorganisms in the water. What conclusions can be drawn about product damage as a means for these organisms to contaminate produce?
# Results

Use the following scale to record amount of dye penetration:

- 4 = lots of dye
- 3 = moderate dye
- 2 = some dye
- 1 = slight dye
- 0 = no dye

<table>
<thead>
<tr>
<th>Product</th>
<th>Outer Surface</th>
<th>Stem End</th>
<th>Cut Surface</th>
<th>Damaged Area</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
Handwashing

Purpose: To observe the effect of washing time and the use of soap on the removal of microorganisms from hands.

Materials:

- Facilities for washing hands
- Markers
- For each pair of students:
  - Two petri plates containing nutrient agar
  - Soap

Procedure:

1. On the bottom of the petri dishes, draw lines to divide each plate into four quadrants.
   a. Label the quadrants on each plate 1 through 4.
   b. Label one plate “Water,” the other “Soap.”
2. One student in each pair should work with the “Water” plate.
   a. Quadrant 1 should be touched lightly with one or more fingers.
   b. Hands are then rinsed with water (without soap), excess water is shaken off, and, while hands are still wet, Quadrant 2 is touched.
   c. Step b. is repeated twice more, touching Quadrant 3 and then 4.
3. The second student in the pair should use the plate labeled “Soap.” Step 2 above is followed except soap is used in each of the washing steps.
4. Plates should be covered and incubated, inverted, at 35°C or room temperature for 24 to 48 hours.

Discussing Results

1. How effective was rinsing with plain water for removing microorganisms from hands?
2. Was the effectiveness improved with more rinsing?
3. What was the effect of adding soap to the washing process?
4. In our experiment, each step added to the amount of time the hands were washed. Were more microorganisms removed by using a longer wash and more soap?

Results

Record the results in the table below using the scale:

<table>
<thead>
<tr>
<th>Plate</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soap</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4 = maximum growth    3 = moderate growth    2 = some growth    1 = a little growth    0 = no growth
**Chlorine Concentration and Water Quality Management**

**Part A: Calculating Volume of Chlorine Needed to Obtain a Specific Concentration**

**Purpose:**
This discussion provides experience in calculating the volume of chlorine (sodium hypochlorite) needed to provide the desired concentration of free chlorine (ppm) in a solution.

**Procedure:**
The following formula is used to determine how much sodium hypochlorite (NaOCl) to add to potable water:

\[
\text{Volume of NaOCl needed} = \frac{\text{desired ppm of free chlorine} \times \text{total tank volume}}{\text{(% NaOCl in concentrate) \times (10,000)}}
\]

For this small scale demonstration, we have the following criteria:

- The concentrated NaOCl is 5.25% chlorine (approximately the concentration of household bleach). Since 5.25% is the same as 5.25 parts per hundred, we would multiple this number by 10,000 to get parts per million (ppm).
- The desired free chlorine concentration in our processing water is 100 ppm.
- We want to make a total volume of 500 ml for our processing tank.

To calculate the amount of NaOCl that would be needed, plug the above values into the formula and calculate as follows:

\[
\text{Volume of NaOCl needed} = \frac{(100 \text{ ppm of free chlorine}) \times (500 \text{ ml})}{(5.25) \times (10,000)} = 0.95 \text{ ml}
\]

Taking it a step further:

Remember: This is a small demonstration. A more reasonable volume of water in a commercial setting might be 500 to 5,000 gallons in the processing tank. The values from this small scale calculation can be applied to any volume to prepare a solution with 100 ppm free chlorine from a 5.25% NaOCl concentrate by calculating a dilution factor. This factor is derived by dividing the total volume of solution, in this case 500 ml, by the amount of chlorine concentrate to be added, which is 0.95 ml:

\[
\text{Dilution factor} = \frac{500 \text{ ml}}{0.95 \text{ ml}} = 526, \text{ which is a unit-less term.}
\]

Precision is not essential for this calculation. Note that the calculated dilution factor is 526, but for a practical application we can round the dilution factor to 500.

Suppose there is a tank size of 8,000 liters. To determine how much chlorine concentrate would be needed to yield 100 ppm free chlorine, divide 8,000 by the dilution factor of 500.

\[
\frac{8,000 \text{ liters}}{500} = 16 \text{ liters}
\]

Therefore, 16 liters of chlorine concentrate would be added to the 8,000 liter tank to give approximately 100 ppm free chlorine.

**Part B: Influence of pH and organic matter on free chlorine levels.**

**Purpose:**
To observe the effects of pH and organic matter on the free chlorine levels in a solution. This exercise may be conducted in the classroom but for convenience a demonstration using PowerPoint is provided.

**Materials:**
- 500 ml deionized water
- chlorine test strips
juice quickly lowers the pH to about 4.5, but most importantly it completely depletes the amount of free chlorine to near zero.

**Discussion Questions:**

1. What effect does adding chlorine have on the pH of water?
2. What effect does lowering pH and adding organic matter have on the chlorine concentration?
3. What are the implications of these effects to a fruit or vegetable operation using chlorine as a sanitizing agent?

**Conclusion:**

Any substantial adjustment of the chlorine concentration in water will require an adjustment of pH as well. Water quality management involves many parameters, not just chlorine.

**Results**

Use the following table to record the results of the tests in the steps above.

(Instructor’s note: Column of values from previous experiments may be used as a guide for expected values or for discussion if teaching conditions do not allow actually performing the experiment)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Values obtained from previous experiments</th>
<th>Measured</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH of deionized water (Step 1)</td>
<td></td>
<td>6.6</td>
</tr>
<tr>
<td>Chlorine concentration after adding 0.95 ml chlorine concentrate (Step 3)</td>
<td></td>
<td>100 ppm</td>
</tr>
<tr>
<td>pH of the chlorinated solution (Step 4)</td>
<td></td>
<td>9.8</td>
</tr>
<tr>
<td>pH after adding organic matter (Step 6)</td>
<td></td>
<td>4.5</td>
</tr>
<tr>
<td>Chlorine concentration after adding organic matter (Step 6)</td>
<td></td>
<td>about 0</td>
</tr>
</tbody>
</table>
Fruit Spoilage

Purpose:
To demonstrate the effects of produce handling and storage conditions on product spoilage.

Materials:
For each group:
- Produce – select kinds most likely to be encountered by class participants
- Knife
- Plastic bag

Procedure:
For a 1-day class, set up this experiment early in the day and look at the results at the end of the day. For a multiple day class, evaluate the products 24 to 48 hours after the experiment is set up.

1. Divide class into groups of 3-4 people.
2. Provide each group with several pieces of the same product. Have participants assess the quality of the produce, noting the presence of any defects.
3. One piece of the product should be placed in the coolest possible place in the teaching area. If a refrigerator is available, this could be used. Place a second piece in a warmest available location. A third piece should be placed in a plastic bag, the bag closed and placed in the warmest location.
4. A fourth piece of product should be cut into three pieces. Place one of the pieces in each of the locations described in step 3 above.

Discussing the Results
1. What spoilage/deterioration factors played a role in the changes observed in these products?
2. What are the implications of observations from this experiment on how produce should be handled during storage and transportation?

Results
At the end of the experiment evaluate the product condition using the following scale:
4 = high quality product, good condition  3 = good quality, slight spoilage  2 = fair quality, moderate spoilage  1 = poor quality, extreme spoilage

<table>
<thead>
<tr>
<th>Product</th>
<th>Storage Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-Storage</td>
</tr>
<tr>
<td>Intact</td>
<td></td>
</tr>
<tr>
<td>Cut</td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td></td>
</tr>
<tr>
<td>Cut</td>
<td></td>
</tr>
</tbody>
</table>

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Experiments Using Artificial “Germs”

GloGerm® and Glitterbug® are commercially available products that contain plastic “germs” which fluoresce when exposed to UV light. The products come in both lotion and powder forms. They are useful to represent microorganisms in demonstrations. The following are ideas for experiments using these products. Instructors’ needs and situations may suggest additional ways these products can aid in demonstrating sanitation practices.

Note: Because some people have expressed concern about working with “germs” in these experiments, be careful to reassure participants that these are simulations and that the “germs” are not real nor are they in any way harmful.

Handwashing

Depending on class size, time and facilities, this experiment may be done with a few volunteers demonstrating to the class or it may be an activity for the entire class.

a) Participants apply a small amount of the lotion form of the product to their hands, rubbing it on like hand lotion. When they look at their hands under a UV light, they should be covered with glowing “germs.”

b) Participants then wash their hands as they would normally. After washing, look at their hands under the UV light again. If handwashing was thorough, there should not be any “germs” remaining. Any areas not washed well will glow.

c) A variation of this demonstration would be to observe the “germs” on unwashed hands. Instruct one person to rinse their hands with water. Instruct another person to wash their hands with soap for at least 20 seconds. Observe any remaining “germs” after washing.

Discussion:

• Was the handwashing procedure complete so that all of the “germs” washed off?

• If not, where were problem areas (between fingers, around cuticles, etc)?

Describe for participants the correct handwashing procedure.

Repeat the activity above with participants using this procedure.

Discuss:

• Was this procedure more effective in removing germs? Why?

How Germs are Spread - I

a) Prior to the arrival of class participants, the instructor rubs the Germ product on their instructor hands. As the class participants arrive, the instructor greets several with a handshake.

b) After a period of time, a UV light is passed over participants.

c) “Germs” spread from the instructor’s greeting should glow on participants’ hands and on articles they have touched. Likely places for glowing to appear include participants’ hands, pencils and paper, chairs, clothing, hair, etc.

Discuss:

• Ease with which germs were spread from the instructor’s hands to the participant’s and then to anything they touched.

• Implications of the easy spread of germs in produce production and handling situations.

How Germs are Spread - II

a) Prior to the arrival of class participants, a light dusting of “germ powder” is placed in various areas of the teaching room - on tables, counters, etc.
b) During the class session, students should move about the room normally. As this occurs, the powder will be spread to their hands, clothing, and other parts of the room.

c) At the end of a suitable period, a UV light is used to look at where the “germs” are in the room.

**Discuss:**
- Ease with which germs were spread
- Implications of the easy spread of germs in produce production situations
- Importance of proper cleaning and sanitation in preventing the spread of microorganisms

**Germs and Produce**

a) Place several pieces of produce in 3 bags. Add a small amount of the “germ powder” to one of the bags and shake to distribute the powder on the product.

b) Ask class participants to look at the treated product under a UV light and to note the presence of “germs.” Ask them to compare this product with product from a bag that was not treated with the powder.

d) Check the fruit under the UV light.

Discuss:
- Were “germs” on the untreated product? How did they get there?
- Have participants look at their hands under the UV light? Are “germs” present on their hands? Where did they come from?
- What are the implications of these observations in terms of product handling procedures?

c) Place the product from all three bags into a fourth bag.

Discuss
- What has happened to the fruit that was not treated with the “germs”?
- Were “germs” on the untreated product? How did they get there?

Suggest to participants that this is similar to what happens when fruit from several locations are combined in a packinghouse.

- What are the implications of these observations in terms of produce handling procedures?

GloGerm is available from:
Glo Germ Company
P.O. Box 537
Moab, Utah, 84532 USA
Phone: 435-259-5831

Glitterbug is available from:
Brevis Corporation
3310 South 2700 East
Salt Lake City, Utah 84109 USA
Phone: 801-466-6677
Web address: www.glitterbug.com

Sources of UV lights include either of the companies above, scientific supply companies, and novelty suppliers.
Fresh Produce Quality

Purpose:
To observe attributes affecting produce quality.

Materials:
Produce – samples of the same product from several different sources, such as farms, packinghouses, and grocery stores.

Procedure:
- Divide the class into groups of 3-5. Assign a produce product to each group (be sure the same product is assigned to at least 2 groups).
- Ask the groups to develop a set of Standards for their assigned product.
- Have available samples of the products assigned to the participants. Provide groups with samples of their product from several sources - such as from farms, packinghouses, and grocery stores. Ask the groups to rate these based on their established standards.
- Have groups with the same products compare their list of standards and the ratings assigned to products from the different sources. Provide time for the groups to discuss their lists and to explain why they chose the criteria they used. Multiple groups with the same product should be allowed time to discuss the items that on their standards lists and to reach agreement on items to include.

Discussion:
1. What factors were considered in setting up the standards?
2. When standards were actually applied to produce, was there a need to alter or revise original criteria? Explain.
3. Was it easy for different groups to reach a consensus on a single set of standards? Why or why not?

Discussion Questions
1) Using your country as an example, how could application of programs to enhance the safety of produce enhance:
   a) The export potential for local agricultural products?
   b) The domestic market for fresh produce?
   c) Give examples of each.

2) An outbreak of foodborne illness may have serious effects on the health of those who ate the contaminated food. However, its long-term effects may go much further. Within your country, how would a foodborne illness outbreak affect
   a) The economy?
   b) The labor force?

3) With the goal of harmonizing your country’s food laws and regulations with those of trade partners (or Codex) how would you go about:
   a) Accessing information on national laws?
   b) Obtaining comparable data on trading partners or from international sources?
   c) Writing a step-by-step procedure for your industry on “How to export fresh produce to the U.S.”?

4) What fresh produce standards would you like to adopt for your local industry and why?

5) What components should be considered in developing for industry use:
   a) Inspection protocols for surveying the GAP compliance status of fresh produce farms.

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b) An industry protocol for monitoring and responding to fresh produce-induced food illness outbreaks.

6) Discuss the target groups you anticipate training.
   a) What characteristics are unique to this target group?
   b) What techniques will you employ to best get the message across to this group?

7) Discuss how the above principles apply to the produce industry in your country
   a) Describe the food safety system in your country. Identify the various government Agencies, Departments or Ministries involved in ensuring the safety of fresh fruits and vegetables and the responsibilities of each.
   b) Discuss how the produce industry should approach interacting with each of these?
   c) Discuss ways that you can obtain information from these groups that is relevant to your fresh produce industry. For areas that you are uncertain about, prepare a list of questions that you can take home with you for further research about obtaining this information.
Traceback Investigation

Multistate Outbreak of *E. coli* O157:H7 Infection

In the State of Michigan during June 1997, 52 cases of *E. coli* O157:H7 infections were reported compared to only 18 cases reported in June 1996. Based on laboratory testing, it was suspected that the cases of *E. coli* infection resulted from a common source.

The cases were spread over 10 counties in Michigan indicating the source was relatively widespread. Onset of symptoms among known cases extended over approximately one month suggesting that the source of contamination was either a product with an appreciable shelf-life or that there was on-going production of a contaminated product.

Interviews were conducted with a limited number of patients to explore all potential sources of infection. Interviews revealed that most patients had consumed lettuce and alfalfa sprouts in the week before they became ill. No single restaurant or special event was identified that all patients had attended. A traceback was triggered when further epidemiological studies indicated a statistically significant link between alfalfa sprouts and the outbreak.

Of the 16 patients who ate sprouts for whom the source of the sprouts could be traced, 15 led to a single sprouting facility in Michigan. Investigations of the source of the alfalfa sprouts led to a single sprouting facility.

Sprouts grown in the facility at the time of the outbreak came from two lots of seeds: one from Idaho and one from Australia. At this point in the investigation, a concurrent outbreak of *E. coli* O157:H7 infection was reported in the State of Virginia. Epidemiological studies also linked this outbreak to alfalfa sprouts. In Virginia the source of sprouts could be traced for 13 patients and all led to a single lot of seed harvested from Idaho. This was the same lot as the one used at the implicated facility in Michigan.

Traceback of the seed to the distributor identified it as part of a 17,000-pound lot of which 6,000 pounds still remained. The implicated seed lot was a blend of 5 lots from fields of four farmers and was harvested between 1984 and 1996. The seed processor and the farmers were located in Idaho. Because two sprouting facilities (in two states) were associated with the implicated alfalfa sprouts and a single lot of seeds (from Idaho) were common to both it was likely that the contamination of the seeds occurred before sprouting.

Immediate control measures were put into place, including removing the 6,000 pounds of seed from the marketplace. Meetings were held with public health officials explaining to seed growers the need to protect alfalfa seed in sprouting from contamination during growing, harvesting and packing. Public television and radio announcements were made to advise the public about the risks of contaminated sprouting seeds. The sprout industry explored ways to treat sprouts to make them safe for human consumption.

Further Investigation:

Inspection of the alfalfa fields revealed three possible sources of contamination: cattle manure, irrigation water and deer feces. Although manure is not normally applied to alfalfa fields in Idaho, cattle feed lots were common in the area and alfalfa fields of one farmer were adjacent to a feed lot. Manure may have leaked or been illegally dumped into the alfalfa fields or run-off water from neighboring fields.

Water contaminated by manure may have been used to irrigate the fields. In addition, three of four farmers occasionally saw deer in their fields and one field was located near a wildlife refuge. The seed from each farmer was harvested and mechanically cleaned at the same seed processing plant. The seeds were then placed in 50-pound bags. No further processing occurred.

Most of the seed was produced to plant alfalfa fields (e.g., to produce hay for livestock feed): the relatively small amount of seed used for sprouting was not handled any differently than the raw agricultural commodity seed. In the situation described, the source of contaminated seed was identified.
1. Using visuals from the traceback module in the manual, prepare a flow chart of this traceback.

2. What information did the investigators need at each step of the investigation to proceed to the next step? What difficulties might have prevented them from getting the information needed?

3. After identifying the source of the seeds, what additional steps would be needed to help prevent outbreaks from occurring in the future?

4. In inspecting the alfalfa fields and harvesting process, what possible points of contamination should be considered?

1 Information on this case study was taken from the Centers for Disease Control and Prevention (CDC) Case Study: A Multistate Outbreak of E. coli O157:H7 Infection: Instructors Version. The case study was based on two-real life outbreak investigations undertaken in Michigan and Virginia in 1997. Some of the information on the actual traceback had been altered to better serve as a learning exercise. The complete case study is available on the CDC’s website: http://www.cdc.gov/phtn/casestudies

2 For more information on safe handling of sprouts, see FDA Publications in Additional Resources section.
Planning for an Effective Training Course on GAPs:

3 Scenarios

The following exercise is designed to allow trainees to apply the ideas presented in Section VI on Developing an Effective Training Program. Sample situations are provided below. The information for each situation and the questions to be discussed should be printed on handouts or on a visual so the trainees can easily view them.

The exercise may be conducted as part of each of the training modules in this section or at the completion of the entire section. For the exercise, assign the trainees to small working groups. Each group can be presented with a separate training situation or the same situation may be discussed by all of the groups.

Situation 1: Cooperative – Farm Worker Supervisors

The agriculture department wants assistance in developing and delivering a training course aimed at the supervisors of farm workers at a local snow pea cooperative.

Situation 2: Tomato Packinghouse Personnel

The owner/operator of a large tomato packing facility has requested a training course for plant workers. Consider groups of employees in the facility that perform common tasks. For example, one group may consist of people who are grading the tomatoes, another group could be the cleaning and sanitation crew, another could be the facility maintenance crew that repairs equipment, etc.

Situation 3: Fresh Produce Warehouse

A training team of technical advisors has been asked to deliver a training course for warehouse workers and supervisors.

Groups should consider the following questions about the organization and delivery of a training course for their assigned situation:

1. How will the needs of the participants be identified and confirmed?
2. What are the training objectives?
3. What method of organization of the training content will be the most logical (outline form only)?
4. What training methods will be used and on what basis were they selected?
5. What type of training material will be used and why?
6. What is an interesting way to organize the training course?
7. How will the course be evaluated?

After the working groups have completed their summary, each small group should present its plan to the entire audience for discussion and feedback. Trainers should encourage discussion and refer trainees to appropriate sections/pages in the manual for guidance in answering the questions.

1. Methods to determine and validate participants needs should be listed.
2. Training objectives should be measurable and should address changes in knowledge, behavior/practices and/or attitude.
3. Organization of the training content should have a logical flow.
4. The training methods selected should be specified and justified.
5. The type of training aids to be used should be justified.
6. The organization of the course should fit the time allotted and include meals and breaks.
7. An evaluation should include measures of reaction, learning, behavior and results.
Field Site Visit Guide

The purpose of field site visits may vary depending on the needs of the participants and the focus of the training course. Once determined, the purpose of the field site visit should be made clear to the trainees prior to the visit and should serve to reinforce the Principle material presented in the course. Having trainees take an active role in making observations and in class discussion after site visits is useful to make the visits more meaningful.

Trainers are encouraged to visit the site prior to the visit by trainees. During this preliminary visit, the trainers can note practices and be prepared to point these out during the training visit. This preliminary visit would also offer a good opportunity for the trainers to obtain the information to answer trainees’ questions during the visit.

Name of Farmer/Operation: ____________________________________________

Location: ______________________________________________________________________

Date of Visit: ___________________________________________________________________

Crops Grown: ___________________________________________________________________

Agricultural Water

- What activities in this operation use water? What is the source of the water used?

- Has the quality of the water been determined? How? Results?

- Were treatments needed to improve the water quality? What treatments? When were they applied?
• Were efforts made to identify possible sources of water contamination? What control measures were used to prevent water contamination?

Manure Management

• Is animal manure used for fertilizer?

• Is the manure composted? How?

• How is manure applied?

• Are records kept of manure use, dates applied?

Animal/Pest Management

• What controls are in place to limit farm animals and domestic animals near production fields?

• What controls are in place to limit wild animals (birds, rodents) from fields?

Treatments/Fertilizers/Pesticides

• Are chemical fertilizers used?

• What records are kept of their use?
• What is the source of water used to mix with chemical fertilizers?

• What methods are used to control pests (use of pesticides, biological treatments, etc.)?

• What is the water source for mixing and applying pesticides?

• What records are kept on fertilizer and pesticide use?

**Harvest Tools and Equipment**

• What harvest methods are used? (i.e. bare hands, gloved hands, automated machines)?

• How are harvest tools cleaned and sanitized?

• What types of harvest containers are used? (i.e., re-usable, made from what materials)

• How are containers cleaned and stored when not in use?

• How is large crop equipment cleaned? (i.e. blades, chutes, conveyors)

• Is equipment used for hauling fresh produce also used for other tasks such as hauling garbage, manure? If so how is it cleaned?
Packing Facility

- How is packing facility cleaned?

- What is the water source for cleaning the packing facility?

- Does the packing facility recycle water? If so explain procedure.

- Is the produce cooled? How is it cooled? (i.e. water spray, hydro-cooler, hydro-vac, forced air). What is the source of the water?

- Is water with a disinfectant used in the packing facility? How are residues of the disinfectant monitored and recorded?

- If hydro-coolers are used, are they cleaned and how often? How often is the water changed?

- If ice is used, what is the source of the ice?

- What is the disposal method for wastewater?

- What controls are taken to limit reptiles/insects, birds inside the packing area?

- What measures are taken to avoid cross-contamination within the packing facility?
Transportation: Vehicles and Equipment

- What types of vehicles are used to transport produce from the field to the packinghouse? Are the vehicles also used for transporting animals, manure, or chemicals?

- What measures are taken to ensure trucks are clean and sanitary? Are they inspected?

- Is the produce temperature monitored while it is being transported?

Worker Health and Hygiene

- Are there health and hygiene and sanitation training programs for workers? If so, are they in their own language?

- Is there supervisory oversight for worker health/hygiene/sanitation? What measures are taken to ensure that ill workers are not handling produce?

- What type of toilets and handwashing facilities are provided for workers? Where are they located? Are they being used?

- What is the disposal method for wastewater/sewage?

- What measures are taken to ensure handwashing and toilet facilities are well supplied with soap, water and drying devises and that workers use the facilities?
Improving the Safety and Quality of Fresh Fruits and Vegetables: A Training Manual for Trainers

Section IX

Additional Resources

Introduction

List of Websites and Reference Information

Joint Institute for Food Safety and Applied Nutrition
U.S. Government Sources
University Sources
Industry Support Organizations
International Sources
Introduction

Since the publication of the First Edition of this Manual in 2002, the amount of available literature on the subject of fresh produce safety has increased dramatically. The continuing development of the internet as an information resource has facilitated the search for literature on practically any topic. Most documents containing practical information relevant to the production and handling of fresh fruit and vegetables can now be accessed at no cost to the internet user.

The following list is intended to guide the reader toward useful information related to topics covered in the preceding Sections. The list is not comprehensive and new material becomes available on a regular basis. However every attempt has been made to include sources of relevant guidance documents, audit metrics, commodity-specific information and other materials.

List of Websites and Reference Information

JIFSAN

Joint Institute for Food Safety and Applied Nutrition (JIFSAN)

www.jifsan.umd.edu

This manual and other training program information are available at the JIFSAN site. Recent news and announcements regarding food safety are posted.

U.S. Government Sources

U.S. Food and Drug Administration (FDA)

www.fda.gov

At the FDA home page readers have the option of searching for specific information within the website. Suggested keywords include: fresh produce, fruit and vegetables, guidance documents, training center, or a specific commodity name. A few important documents from FDA are listed here:

- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (also available in Spanish, French, Portuguese and Arabic)
- Guide to Minimize Microbial Food Safety Hazards of Tomatoes
- Guide to Minimize Microbial Food Safety Hazards of Melons
- Guide to Minimize Microbial Food Safety Hazards of Leafy Greens
- Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables
- Reducing Microbial Food Safety Hazards for Sprouted Seeds
- Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production
- Guide to Produce Farm Investigations
- Guide for Third-Party Audits and Certification
- Produce Safety from Production to Consumption: 2004 Action Plan
- FDA Rules Implementing the Bioterrorism Act of 2002
  - Registration of Food Facilities
  - Prior Notice of Imported Food
  - Recordkeeping (Traceback and Traceforward)
  - Administrative Detention
- Foodborne Pathogenic Microorganisms and Natural Toxins Handbook
- Hazard Analysis and Critical Control Points (HACCP)
U.S. Centers for Disease Control and Prevention (CDC)

www.cdc.gov

The CDC website is an excellent resource for those interested in surveillance, epidemiology, or progress reports regarding ongoing outbreaks. Users can use the keywords fruits and vegetables to go immediately to any significant events related to the fresh produce industry.

The Morbidity and Mortality Weekly Report (MMWR) addresses current human health issues, diseases and injuries, topics of international interest and notices of events of interest to the health community. Past issues are archived.

The Food Safety Homepage links users to the following useful sites:

An Index for Foodborne Illnesses provides details about human pathogens and symptoms of illness.

The Laboratory and Surveillance section covers CDC investigative processes, partners and systems such as FoodNet and PulseNet.

U.S. Environmental Protection Agency (EPA)

www.epa.gov

Selected food safety resources available at the EPA site are listed:

Pesticide Tolerances
Pesticides and Food: What the Pesticide Residue Limits are on Food
National Agricultural Assistance Center: Food Safety
Food Quality Protection Act
Agricultural Publications: Food Safety
Analysis of Composting as an Environmental Remediation Technology
Biosolids Generation, Use, and Disposal in the United States

U.S. Department of Agriculture (USDA)

www.usda.gov

As mentioned in Section 7, USDA is composed of numerous divisions that fulfill different roles in the various agricultural disciplines. One topic that is common to all divisions of USDA is food safety. From the USDA homepage, users who initiate a search with the keywords food safety will be directed to many locations. Selected sites are listed:

The Agricultural Marketing Service (AMS) provides a document entitled Good Agricultural Practices and Good Handling Practices Audit Verification Program. This is an audit metrics document that all growers and handlers of fresh produce should access and utilize for conducting self-audits of their farms and facilities. AMS also is the home for fresh produce quality descriptors.

The Economic Research Service (ERS) posts economic assessments of food safety events domestically and internationally, often providing statements regarding the impact of outbreaks on commerce in fresh produce.

The Food Safety and Inspection Service (FSIS) does not have direct oversight of the fresh produce industries, however the scientific information provided about food safety practices often applies to fresh fruit and vegetables as well as other food groups.

The Education and Outreach pages contain many fact sheets and other food safety resources that are useful training materials.

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University Sources

In the U.S. land-grant University system, each state has an agricultural program. Almost all of these programs have an Extension component for education in food safety. The following list includes several University programs that have gained prominence in the area of fresh produce food safety. Users of this manual are encouraged to search the sites of other Universities that may address specific commodity interests.

Cornell University

www.gaps.cornell.edu

This is the home of the National GAPs Program for Fruit and Vegetable Safety. It includes GAPsNET, a Good Agricultural Practices Network for Education and Training. Posters, videos and other training materials are available. Selected items are listed:

Food Safety Begins on the Farm: A Grower’s Guide
University of Florida
www.ufl.edu
The University of Florida’s Institute for Food and Agricultural Sciences (IFAS) is the home for Extension information. A search of UF/IFAS Extension food safety will direct the browser to the following useful sites:

- Produce Safety Center
- Electronic Data Information Source
- National Food Safety Database
- Solutions for Your Life

Iowa State University
www.extension.iastate.edu
The topics of well construction, remedial actions for contaminated wells and numerous other groundwater concerns are addressed at this University site. The following article is recommended as a starting point for researching this important topic.

- Coping with Contaminated Wells

University of California - Davis
www.ucdavis.edu
In addition to its robust GAP research and education programs led by the Faculty, UC-Davis is the home of the Western Institute for Food Safety and Security. Selected publications are listed:

Under the heading of ‘Key Points of Control and Management of Microbial Food Safety’ the following four publications are available:

- Information for Growers, Packers, and Handlers of Fresh-Consumed Horticultural Products
- Edible Landscape Plants and Home Garden Produce
- Information for Producers, Handlers and Processors of Melons
- Information for Producers, Handlers and Processors of Fresh Market Tomatoes

Cantaloupe Brochure

Guidelines for Controlling Listeria monocytogenes in Small- to Medium-Scale Packing and Fresh-Cut Operations

Oxidation-Reduction Potential (ORP) for Postharvest Disinfection Monitoring, Control, and Documentation

Ozone Applications for Disinfection of Edible Horticultural Crops

Postharvest Chlorination: Basic Properties and Key Points for Effective Disinfection

Postharvest Handling for Organic Crops

Growers’ Compliance Costs for the Leafy Greens Marketing Agreement and Other Food Safety Programs

The Cornell Waste Management Institute (http://cwmi.css.cornell.edu/) focuses on organic residuals and includes good resources for composting.
Texas A&M University
www.tamu.edu

The Texas A&M University Office of Safety and Security maintains a webpage for Environmental Health and Safety. The following publication is recommended:

_TAMU Food Safety Manual_ includes a section on the Development of Sanitation Standard Operating Procedures (SSOP) with examples of SSOP that are useful training tools.

Clemson University
www.clemson.edu

Search for the Clemson University food safety site for the following manual:

*Food Microbiology: An Introduction for Food Safety Educators*

**Industry Support Organizations**

Many organizations have developed food safety information specific to commodities or industry segments. In some cases access to information is for “members only”. Following are a few of the organizations that make information available to the public.

United Fresh Produce Association (UFPA)
www.unitedfresh.org

After accessing the UFPA homepage users should navigate to the Food Safety Resource Center for the following publications:

_Microbiological Testing of Fresh Produce White Paper_

_Audits Benchmarking Matrix_. This site provides links to a number of public- and private-sector auditing tools to facilitate side-by-side comparison of food safety auditing standards.

_Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain_

2009 *Global Conference on Produce Food Safety Standards Presentations*. Some participants in this conference made their presentations available for public viewing.

Association of Food and Drug Officials (AFDO)
www.afdo.org

AFDO was established in 1896 with the mission of ‘Resolving and Promoting Public Health and Consumer Protection Issues’. From the AFDO homepage, users gain access to numerous documents related to food safety, including position statements on current food safety government and industry policies. For specific information on fresh produce users should access:

_AFDO Model Code for Produce Safety_

Western Growers Association
www.wga.com

_Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens_

_Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Value-Added Unit Operations of Green Onions_

National Leafy Greens Marketing Agreement
www.nlhma.org

This Agreement, supported by various industry groups and administered by USDA, is the basis for current food safety guidelines for leafy greens.

California Strawberry Commission
www.calstrawberry.com

Growers and handlers of strawberries should browse this site. Although much of the information is for ‘members only’, there are documents available that address microbial and pesticide food safety.

Florida Tomato Exchange
www.floridatomatogrowers.org

_Tomato Best Practices Manual_

_T-GAP Tomato Good Agricultural Practices_
California Tomato Farmers
www.californiatomatofarmers.com

The Fresh Standard for Food Safety

National Watermelon Association
www.nationalwatermelonassociation.com

Commodity Specific Food Safety Guidelines for the Fresh Watermelon Supply Chain

HowToCompost.org
www.howtocompost.org

This site addresses all aspects of composting and has many valuable links to other sites with similar information. Commercial growers are recommended to navigate from the home page to the page entitled Large Scale for details.

FightBAC
www.fightbac.org

FightBAC is the website for The Partnership for Food Safety Education and is a consumer food safety resource. Many educational documents are available for download at no cost.

ServSafe
www.servsafe.com

ServSafe food safety training is offered through a number of avenues, including some University Extension programs in the U.S.

International Sources

CODEX alimentarius
www.codexalimentarius.net

From the homepage, navigate to Official Standards and initiate a search for any fresh produce commodity of interest to view quality and safety standards. Information about pesticides and microbial food safety is found at various locations. The following articles are of special relevance:

Pesticide Residues MRLs Database

Code of Hygienic Practice for Fresh Fruits and Vegetables
Recommended International Code of Practice for the Packaging and Transport of Fresh Fruit and Vegetables

Global Food Safety Initiative (GFSI)
www.mygfsi.com

From the homepage, navigate to Information Resources to find information about GFSI certification requirements.

GLOBALGAP
www.globalgap.org

From the homepage, navigate to Standards and go to Fruit and Vegetables to find relevant documents.

National Service for Sanitation, Safety and Quality of Agricultural Foods
Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria
www.senasica.gob.mx

This governmental body in Mexico is responsible for national programs in food safety, pesticide registration and other regulatory affairs for food and agriculture.

International Organization for Standardization (ISO)
www.iso.org

Home for international management standards