

THE BUILDING BLOCKS OF A FOOD SAFETY PROGRAM

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Food safety is one of the chief concerns of all who work in the produce industry. The expectations and requirements of all who handle produce continue to proliferate and can be, at times, bewildering. Nearly all operators have a food safety program. Those that do not will almost certainly soon have to develop one. With all of the food safety requirements coming from regulatory bodies, buyers, consumers, advocacy groups and others, it may be appropriate to call a time out to reconsider what the building blocks of a robust food safety program should be. And to understand what those building blocks should be it is useful to return to first principals of food safety and build from there.

The first principal of food safety is "Evaluate your risks".

The second principal is "Prioritize your risks".

The third principal is "Address each significant risk to minimize or eliminate that risk".

The fourth principal is "Validate what you do to address each risk. Use available science".

The fifth principal is "Document what you do...if it isn't written down it didn't happen".

The first step is to define our terms so that we are all working from the same playbook.

GAP = Good Agricultural Practices: Originally outlined by the FDA in their 1997 publication "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables".

GMP = Good Manufacturing Practices from the Code of Federal Regulations 21 CFR110.

SOP = Standard Operating Procedure

SSOP = Sanitation Sanitary Operating Procedure

HACCP = Hazard Analysis Critical Control Point program.

Hazard = A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect - *Codex Alimentarius, 1997*

Risk = An estimate of the likely occurrence of a hazard.

Verify = Those activities, other than monitoring, that determine the validity of the HACCP plan and that verify the system is operating according to the plan.

Validate = The element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

How do I perform a risk assessment?

Performing a comprehensive risk assessment is fundamental to understanding what the risks are in your operation. While your risks may be the same or similar as those in other operations in your industry sector, some risks may be unique to your operation. In addition, performing a risk assessment is a powerful educational tool that allows your managers to better understand the risks inherent in the operation as well as the importance of effectively addressing those risks. For these reasons it is important that your team perform the risk assessment. Do not rely on outside consultants to do it for you, though they may be involved in working with and supporting your teams' efforts.

To perform a comprehensive risk assessment, start by assembling a team. Members of the team might come from operations, quality assurance, maintenance, senior management or whatever other staff

may be appropriate. Including a consultant or employee familiar with food safety science may also be helpful.

Next develop an accurate flow diagram of your operation. Include all unit operations and any inputs, such as chemicals, water, ice or packaging, that are part of the process. This can be done for farm operations as well as for harvesting, packing, cooling or processing operations. After confirming that the flow diagram is an accurate reflection of your actual processes, then number each step in the process. For example, “Receiving” might be #1, “QA Evaluation” might be #2, and so forth.

The team will then brain storm about each step in the process to list all of the physical, chemical and biological hazards that could occur at the process step. For example, hazards that could occur might include:

PROCESS STEP	BIOLOGICAL	PHYSICAL	CHEMICAL
#1 Receiving	<i>Salmonella</i> from raw product contaminated in the field. Insect parts. Mold on fruit.	Rocks. Wood slivers from pallets.	Unregistered pesticide residues.
#2 QA Evaluation	Human pathogens from hands of inspectors.		
#3 Dumping onto conveyor	Cross contamination from conveyor.	Plastic fragments from conveyor parts.	Residue from cleaning chemicals.

After hazards have been iterated for every process or handling step, the team will then go through and evaluate which hazards are reasonably likely to occur and to thus be of concern. This is the risk assessment part, risk being the probability that a hazard will occur. For example, on a farm the team may identify a hazard of flooding. But if that farm is not in a flood zone, and historically has not experienced flooding, the team may make a judgment that flooding risk is not significant for that farm or ranch and so does not need to be addressed.

The team can then go through each identified risk (significant hazard) and identify what to do about it. In other words, for every significant risk there must be a program or activity that will reduce or eliminate that risk. For example, if there is a significant risk that raw produce could arrive already contaminated with *Salmonella*, the team might require that all suppliers of those products demonstrate that they have audited GAP programs to minimize the risk. Or, if the team has identified a significant risk of cross contamination during washing, a water sanitation program could address that risk. Most risks will be addressed through what are called prerequisite programs. These include GAP, GMP, cleaning, sanitation, worker training and general hygiene programs. These will be described in more detail in the remainder of this paper.

How do I develop or evaluate a GAP program?

Good agricultural practices are a series of on-farm activities that address the main areas of concern where contamination may occur. Those areas have been outlined by US FDA in their 1997 publication “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”. The guide has been updated and there are many other documents describing GAPs that are available. These guidance documents tend to be general in nature and point out areas of concern rather than specific actions to take to address the concerns. For some commodities, such as leafy greens, melons, tomatoes, citrus,

herbs, green onions and others there are commodity specific guidance documents that provide greater detail. The USDA National Organic Program also provides detail regarding on-farm practices. However, performing a risk assessment as described above is an excellent way to describe and address the risks for your commodities in your particular organization. The guidance documents can then provide specifics such as water quality standards, compost standards and procedures, set-back distances from domestic animals and others. In addition, University Extension programs at Cornell, UC Davis, University of Florida and others provide excellent resources to help develop and monitor GAP programs.

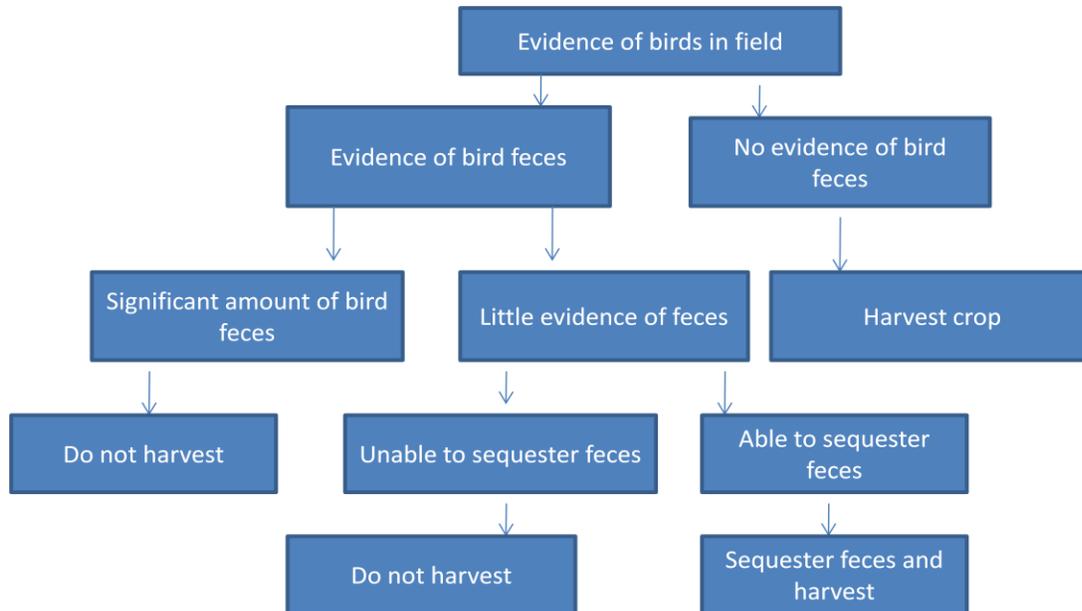
FDA Good Agricultural Practices Program Outline

Basic Principles of Good Agricultural Practices (GAP's)

1. Prevention of microbial contamination of fresh produce is favored over reliance on corrective actions once contamination has occurred.
2. To minimize microbial food safety hazards in fresh produce, growers or packers should use GAP's in those areas over which they have a degree of control while not increasing other risks to the food supply or the environment.
3. Anything that comes in contact with fresh produce has the potential of contaminating it. For most foodborne pathogens associated with produce, the major source of contamination is associated with human or animal feces.
4. Whenever water comes in contact with fresh produce, its source and quality dictate the potential for contamination.
5. Practices using manure or municipal biosolid wastes should be closely managed to minimize the potential for microbial contamination of fresh produce.
6. Worker hygiene and sanitation practices during production, harvesting, sorting, packing and transport play a critical role in minimizing the potential for microbial contamination of fresh produce.
7. Follow all applicable local, state and Federal laws and regulations, or corresponding or similar laws, regulations or standards for operators outside the U.S. for agricultural practices.
8. Accountability at all levels of the agricultural environment (farms, packing facility, distribution center, and transport operation) is important to a successful food safety program. There must be qualified personnel and effective monitoring to ensure that all elements of the program function correctly and to help track produce back through the distribution channels to the producer.

There is less control of the environment on a farm or ranch than would be found in an enclosed packing house or processing facility. For this reason some risks may be difficult to address directly. Remember that the FDA guidance says that the operator should use GAPs in those areas over which they have a degree of control. Nevertheless, it is not acceptable for a food safety program to ignore a significant risk simply because it is difficult or impossible to control. A common example of such a risk on farms and ranches is the presence of birds. Some birds have been shown to carry human pathogenic bacteria. Birds can and do enter fields and it is often impossible to completely prevent their ingress. A reasonable approach for a GAP program may be to minimize attractions for birds. Minimizing standing water in fields, keeping fields free of debris and growing for the fresh market in areas distant from bird gathering places such as land-fills could all be part of a GAP program if birds are considered to be a significant risk. Finally, a program of pre-harvest evaluation to determine the extent and seriousness of bird activity, such as looking for bird feces, can be used to construct a decision tree regarding whether to sequester an area of a field or not to harvest the crop or to divert it from the fresh market.

Decision trees can be a very useful tool in GAP programs as well as in other food safety programs. They allow the criteria for food safety decisions to be thought through in advance without regard to production and market concerns. An example of a simple decision tree for presence of bird activity in a field might be:



How do I develop or evaluate a GMP program?

Good Manufacturing Practices, or GMPs, are a series of rules regarding general cleanliness and hygiene for food handling facilities. GMPs are published in the US Federal Register (Code of Federal Regulations 21 CFR110) and have the force of law for processors preparing ready-to-eat foods. While GMPs are not legally required for packing sheds, harvest crews and coolers, they have become the *de facto* standard for such facilities and so most do follow those GMPs appropriate to their operation. In general terms, this statute mandates that food companies follow good manufacturing practices (GMP) to assure the processing, storing and transporting environments are clean and that no unacceptable substances enter the food product. Topics addressed as part of GMP include disease control; cleanliness; training; supervision; grounds; plant construction and design; general maintenance; cleaning and sanitizing substances; storage of toxic materials; pest control; sanitation of food-contact surfaces; storage and handling of cleaned portable equipment and utensils; water supply; plumbing; sewage disposal; toilet facilities; hand washing facilities; rubbish and offal disposal; equipment, utensil, systems, and instruments design, construction, maintenance and use; food operations; raw materials and ingredients; food manufacturing operations; and storage and transportation. A summary of GMPs for the 21st Century can be found on the FDA web site at:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/CurrentGoodManufacturingPracticesCGMPs/ucm110877.htm>

GMPs direct the operator to develop programs addressing:

1. General provisions
2. Buildings and facilities
3. Equipment
4. Production and process controls

5. Defect action levels

Within these categories the GMPs describe activities referring to:

1. Maintenance and sanitation processes
2. Personal hygiene standards
3. Transportation
4. Product information and consumer awareness
5. Training

Examples of GAPs referring to personnel would be that management take all reasonable measures and precautions to ensure that workers exhibiting symptoms of illness are excluded from operations that could lead to contamination of food, that all persons working in direct contact with food/food contact surfaces conform to hygienic practices while on duty, that outer garments shall be suitable to the operation, that workers maintain adequate cleanliness, that workers wash their hands properly and at appropriate times, and so forth.

Examples of GAPs that refer to buildings and facilities include that grounds shall be kept in a condition that will protect against contamination of food, that areas in the vicinity of the facility that may provide harborage for pests will be removed, that adequate drainage will be provided to prevent breeding places for pests, that buildings and structure will be suitable in size and design to facilitate maintenance and sanitary operations, that they be constructed in such a manner as to prevent drip or condensate from fixtures, ducts and pipes, that adequate steps be taken to exclude pests, etc.

GMPs are lengthy and quite specific. Become familiar with them and incorporate those that apply to your facilities and operations. Most are what many of us might call “common sense”, but they are comprehensive and so some may have been missed in your current food safety programs.

How do I develop SOPs for my operation?

Standard Operating Procedures (SOPs) are written instructions for performing standard tasks in a facility or on a farm. SOPs may cover any number of common activities from pre-operation checklists to instructions for supervisors to check workers hands for cuts and lesions. The SOPs serve as reminders to perform necessary tasks but also provide specific instructions as to what tasks to perform and how to perform them. A benefit of having written SOPs is that various workers can perform the tasks by following the SOP, even if they have not done so before. Another benefit is that the task is done in a consistent way and that it does not change over time.

An SOP should address a specific task or series of tasks and the purpose of the tasks, it should specify who is responsible for the task, how often the task must be completed, and what to do if the task was not or cannot be completed. An example of an SOP for entering a work area is:

SOP 1-01: Entering the Work Area

Purpose:

To ensure that all persons entering the work area have taken the necessary precautions to prevent food borne pathogens from contaminating the product.

Subjects:

All workers and visitors.

When:

Always when work is in progress and food products are present.

Procedure:

1. Only enter the work area if you are feeling healthy and well. Do not enter the work area if you are coughing, sneezing, having an upset stomach, having an open and exposed cut or sore on your hands, or otherwise feeling unwell.
2. Only enter the work area in shoes and clothing that are clean.
3. Remove all jewelry and other objects that might fall into food, equipment, or containers. Only a plain wedding band is permitted.
4. Fix hairnet or other headgear.
5. Wash hands thoroughly following Proper Hand Washing procedures.
6. If applicable, put on smock or apron.
7. Use hand sanitizer.
8. If applicable, put on clean gloves.
9. Anytime your hands become contaminated, leave the work area and follow steps 1-8 before re-entering the work area.
10. Anytime you feel unwell, leave the work area. Do not return to the work area until you are feeling healthy and well. Follow steps 1-8 before re-entering the work area.

Such an SOP can be used to remind workers and supervisors to perform the tasks appropriate to ensuring the terms of the SOP. It can also be used as a check list to document that the terms of the SOP have been completed. Constructing SOPs for common tasks helps ensure that they are completed in a correct, consistent and timely way.

How do I write and use an SSOP?

A Sanitation Sanitary Operating Procedure (SSOP) is an SOP specifically for a cleaning, sanitation or food safety task. Their use is a central building block of a rigorous food safety program. Facility sanitation tasks are typically described in the form of SSOPs or "Sanitation Standard Operating Procedures." Each SSOP describes a specific cleaning and sanitation task in the form of a detailed recipe for performing that task. The "recipe" should be detailed enough, and clear enough, so that a sanitation shift worker can follow the procedure and achieve a sanitary surface.

An SSOP should include the task, why the task is important, how often it must be completed, all tools and inputs needed to complete the task, and detailed instructions for completing the task. An example of an SSOP is:

SANITATION OF CONVEYOR BELTS

Goal: Prevent buildup of organic matter and microorganisms on conveyors so that they do not become a source of contamination of product.

Importance: Dirty conveyor belts can become a source of contamination of products that contact them.

Frequency: Monthly

Tools and Equipment: Potable water, hose, stiff plastic long handled brush, soap, pressurized soap applicator, peroxide sanitizer, backpack sprayer, check sheet.

Procedures:

- a: Remove belts from conveyors.
- b: Thoroughly rinse equipment, from top to bottom, with a pressure washer until all loose carrot sludge, bits and pieces have been removed.
- c: Mix soap as follows: _____
- d: Apply soap with the pressurized soap sprayer.
- e: Scrub vigorously to remove small pieces of carrot and to remove invisible films.
- f: Rinse thoroughly a second time to remove all of the soap. The soap must be rinsed in order for the sanitizing solution (peroxide) to be effective.
- g: Reinstall the belts.
- h: Mix Peroxide solution as follows: _____
- i. All of the belts must be sprayed with the peroxide solution. The sanitizing solution is applied with a backpack sprayer.
- j: The Sanitation Crew Chief then inspects all sanitized surfaces.
- k: The Sanitation Crew Chief writes the time and date and signs the sanitation log for each individual belt. If any belt does not pass inspection, the crew chief notes that in the log and the crew must re-wash and re-sanitize that belt until it passes inspection.
- l. Replace belts.

After an SSOP guided task has been completed, the cleaned and sanitized surface can be swabbed and the swab sent to an appropriate lab for testing. The result of the swab should be that there are few, or none, viable bacteria on that surface. If that is the result, then the effectiveness of the SSOP has been validated. If, instead, there are significant numbers of viable bacteria on the surface, then the SSOP is ineffective and needs to be improved. In this way all of the SSOPs can be improved and validated. Having done that, it then becomes the task of the sanitation team to follow the SSOPs with confidence that, having done so, the result will be sanitary surfaces. Such an approach of developing validated SSOPs for all cleaning and sanitation tasks results in a rigorous sanitation program that has been proven to work. The operator will thus have a high degree of confidence that the surfaces that have been cleaned and sanitized are, indeed, sanitary and reliably free of contaminants. Another of the benefits of this approach is that it becomes unnecessary to constantly swab surfaces to verify that they are sanitary. The validated SSOP ensures that they are so. The sanitation crew must only faithfully follow the validated procedures written in the SSOP. Periodic re-validation of the SSOP is necessary if products, processes or procedures change. In addition, periodic revalidation is important because microorganisms evolve and change their survival characteristics or may become resistant to the sanitizers in use. But the frequency of swabs can normally be much reduced, thereby saving significant money.

How do I develop a HACCP program?

Hazard Analysis Critical Control Point programs were developed for the American space program so that astronauts would not have to endure food borne illness while in space. HACCP is designed to identify opportunities for contamination of food with physical, chemical or biological contaminants, and to prevent that contamination from occurring. Rather than testing finished products in an effort to detect contaminants, HACCP seeks to systematically prevent them. HACCP is already required by law in the meat, poultry, seafood and food canning industries as well as for fresh juices. HACCP is the *de facto* food safety standard for food processors and fresh-cut processors and, though not required by law, is widely adopted throughout the produce industry.

The heart of a HACCP program is a systematic hazard analysis and risk assessment, as described above. But HACCP goes further. Based on the risk assessment, HACCP seeks to identify critical food safety processes that, if controlled within predefined critical limits, will significantly reduce or eliminate risks of contamination. However, HACCP can only function as the final stage of an integrated food safety program that includes Good Agricultural Practices (GAP's), Good Manufacturing Practices (GMP's) and Sanitation Standard Operating Procedures (SSOP's). In fact, HACCP can only be effective if these other programs are in place and functioning properly.

There are seven principles that underlie a HACCP program:

1. Conduct hazard analysis and identify preventive measures
2. Identify critical control points (CCPs) in the process
3. Establish critical limits
4. Monitor each CCP
5. Establish corrective actions
6. Establish verification procedures
7. Establish record-keeping and documentation procedures

Conducting a hazard analysis has been described above. Identifying critical control points (CCPs) is the next step. But a CCP has certain characteristics that limit its use to certain well defined situations. First, a CCP is a place in a process that, when not controlled, a significant hazard could result. Second, a CCP must be a point where a hazard could be controlled through controlling the process. Thirdly, it must be possible to quantify the process so it is possible to know if it is within critical limits. And, finally, it must be possible to monitor and/or measure the process at that point to know if the process is within the critical limits.

There is no minimum or maximum number of CCP's in any given operation. What is important is that all potential hazards be addressed through prerequisite programs or through HACCP. Those hazards that can be controlled or minimized through quantitative control of a process may be designated CCP's and included in a HACCP program. Fresh-cut processors may have as few as two CCP's in a perfectly adequate HACCP plan. Examples of CCPs may be metal detection and water sanitizer activity. Both prevent significant hazards, both can be measured, both can be maintained within predetermined levels that will prevent the hazard, and their operation can be documented. These are the hallmarks of CCPs.

When considering applying these principles to a farm operation, one can see immediately the difficulty in controlling naturally occurring hazards on farms. For example, bird droppings in an orchard may potentially represent a hazard from the spread of *E. coli* O157:H7 or *Salmonella* spp. But it may not be a CCP because there is no way, by controlling a process, to prevent that hazard. Furthermore, there is no way to quantify and measure bird droppings to know if they are within critical limits. This would also be true of *Listeria monocytogenes* cells in soil. Though they may represent a potential hazard, it would not be appropriate to establish soil as a CCP because it is not practical to measure the spores in soil or to control them through any known process. In fact, most agricultural hazards cannot, and should not, be prevented through HACCP. Instead, the use of GAP's has been identified by the FDA and the produce industry as a more appropriate way to address these hazards.

The next step in HACCP is to identify critical limits for each CCP. Critical limits are measurable factors that define the limits of control of a process. A minimum time and temperature in a pasteurization process are examples of critical limits. The important aspect of critical limits is that they have been validated. That is to say, there is evidence that a process within the established critical limits does, in

fact, reduce or eliminate the hazard. A system to monitor and measure the process to assure that it is constantly within the established critical limits is the next key part. Defining what is to be measured, how often it will be measured and who will be responsible for measuring are all necessary. Corrective actions must then be established. These are predetermined actions that will take place in the event that the process is found to be operating outside the defined critical limits. An example of a corrective action would be running all products through a recalibrated metal detector if it is found to be outside the critical limits of its calibration. A HACCP plan must then be verified. Verification involves checking the implementation and effectiveness of the HACCP plan. Is the plan being followed? Is it achieving the desired results? Finally, a record keeping system must be established. All aspects of HACCP must be documented and those responsible for the operation and documentation functions must be properly trained to fulfill those responsibilities.

HACCP may not be appropriate for all produce operations. But the principals of HACCP; hazard analysis, prevention, measurement of performance, corrective actions, and documentation are useful concepts for anyone handling fresh foods.

How do I validate my food safety processes?

Validation of food safety activities is a key part of ensuring that your food safety program is doing what you believe it is doing. In the absence of validation, we operate in an environment of assumption and hope, neither of which can be expected to be consistently effective. Validation is based on collecting and evaluating scientific and technical information to determine if food safety processes, when properly implemented will effectively control the hazards. Validation may be as simple as administering exams to workers as follow up to food safety training. Validation may involve measuring bacteria in wash water to show that the sanitizer activity is sufficient. Validation of cleaning and sanitation processes was discussed above in the context of performing micro swabs of sanitized surfaces to demonstrate the efficacy of an SSOP. Validation is based on measurement of performance and so forms the scientific bedrock on which food safety activities are based. As such, it is a key element of a rigorous food safety program.

Why do I need in a traceability program?

Despite the best laid plans, things can go wrong. This is as true in food safety as in any other walk of life. When a contamination event does happen, or may have happened, it is crucial to limit the extent consequences of the risk as rapidly as possible. The consequences are almost always economic but may also extend to public health. Speed and completeness of response are thus very important. You can't limit the effects of a contamination event if you don't know where the contamination came from or where it went. In recent years response teams from FDA and other regulatory agencies have been very frustrated by opaque distribution chains within the produce industry that prevent them from rapidly determining the source and extent of contamination and associated threat to public health. There has been a great deal of pressure on the produce industry to adopt clearer and more uniform trace back and trace forward procedures to facilitate emergency response.

Much progress has been made to this end, including an industry wide effort called the Produce Traceability Initiative. This initiative is a collaboration of several industry organizations and members of the industry to introduce a uniform case-level traceability program that will follow products from field to retail or food service. You can learn more about this initiative at their web site (www.producetraceability.org). Whatever form of trace back program you adopt, you must be able to track all of your products one step back and one step forward. This is to say, where did you get the product and where did you send it. This applies not only to fruits and vegetables but also to packaging

materials and any other products that you ship, such as croutons, plastic forks and the like. In addition, you want to be able to trace and recover those products rapidly and efficiently. The evolving industry standard is that you should be able to account for 99% of a shipped product within two hours. Many operations have automated this process and can complete it within minutes. What you do not want to do is to find yourself in the midst of a recall trying to figure out where your products came from or where they went. It is far better to have evaluated your trace and recall systems in advance and performed mock recalls to demonstrate that they work seamlessly.

To prepare for a recall start by assembling a crisis management team. Identify a Recall Coordinator and a recall team. The recall coordinator should be knowledgeable about every aspect of the company's operation. Team members should include production, quality assurance, marketing/sales and public relations. A recall organizational chart should be constructed whereby the primary and alternate individuals and both their work and home phone numbers are listed so they can be contacted immediately when a situation arises. The recall coordinator and team would be in charge of determining the extent of the product withdrawal and releasing statements to the customers involved, press and governmental agencies. Establish a means of product tracking and customer identification. The law already requires this and there are many commercial and industry resources to help structure the program. Then, test the program to make sure that it functions smoothly, even under the worst circumstances. Recalls don't happen when they are convenient to you. They may well happen on a Friday night, a Sunday morning or on Christmas Eve. Are you prepared to respond at all times and under any circumstances? If not, you need to revisit your trace/recall program and make sure that it is robust. Remember, a smooth and efficient trace and recall process may someday save your company from ruin.

How can I use micro testing to enhance my programs?

There is increasing pressure to test fresh fruits, vegetables and nuts for microorganisms. Much of this pressure comes from customers, especially large buying organizations. While testing for microorganisms can have a place in a food safety program, there are significant limitations to testing and you would do well to understand the power and the limitations of your proposed tests before embarking on a testing program. While testing can yield useful information, it can also confuse, mislead and serve as a false basis for expensive decisions.

The first thing to understand about testing for microorganisms on fresh produce or in produce environments is that you might find them. If you start looking for microorganisms you had better have a plan of action in place in case you find what you hope is not there.

There are several legitimate purposes for micro testing of fresh produce. The first is because a customer requests or requires tests. A second is to detect the possible presence of pathogens. Another is to validate process elements through detection of indicator organisms. Yet another purpose is to model or understand the microbiological ecology of a system. Finally, microbial testing can be used to track the fate of indicator organisms to better understand the microbial dynamics of that system. Before embarking on a micro testing program it is essential to clearly define the purposes of that testing as the structure of the test will be informed by the goals of the test.

The choice of test organism will largely depend on the goals of the test. In the produce industry most testing of water relies on detection of an indicator organism, generic *E. coli*, as a surrogate for fecal contamination. Since *E. coli* is thought to often be associated with animal or human feces, it is

likely to be present in water that contains fecal contamination. While *E. coli* is not necessarily fecal in origin, and the presence of generic *E. coli* does not necessarily mean that there are human pathogens present, it indicates a likelihood of their presence since most food and water borne pathogens are fecal in origin. Testing for individual pathogens may be more difficult and more expensive than testing for generic *E. coli*, and testing for an individual pathogen might miss the presence of other pathogens. Hence, *E. coli* tends to be the test organism of choice. In some cases tests for total coliforms or for fecal coliforms will take the place of tests for generic *E. coli*. Coliforms are a group of bacteria characterized by their cylindrical shape. Fecal coliforms are coliform bacteria that grow at temperatures found in warm blooded animals. While coliforms and fecal coliforms may be fecal in origin, many are not. Many coliforms and some fecal coliforms are common inhabitants of agricultural soils and are not associated with feces at any part of their life cycle. Therefore, while presence of these bacteria may indicate fecal contamination, it may not, and results of these tests are ambiguous and so are not recommended.

To validate the efficacy of a wash water sanitizing chemical one might test for total plate count (TPC), also sometimes called aerobic plate count. This test enumerates the populations of aerobic bacteria that may be present in the water. Since an effective water sanitizer should kill most such bacteria on contact, the TPC should be at, or near, zero. If it is not, then the sanitizer is not exhibiting the desired efficacy. Similarly, tests to validate the efficacy of environmental sanitizers usually test for TPC.

Some restaurant chains or other food service providers are asking produce suppliers to test for specific pathogens in the hope that contaminated lots of produce can be excluded from the supply chain. In most cases they request tests for *Salmonella* (of which there are thousands of different forms, or serotypes) and for *E. coli* O157:H7, a very virulent pathogenic form of *E. coli* that has been found on lettuce, spinach, basil and other leafy vegetables. *Salmonella* has been a problem on tomatoes, melons, mangoes, sprouts and many other products. Since these two pathogens have accounted for a large proportion of food borne illness outbreaks associated with produce they are the objects of most pathogen testing.

Finally, there is a special case of an environmental pathogen that can become established in handling and processing facilities and so many facilities perform specific tests. *Listeria monocytogenes* is a natural inhabitant of soils and can survive for long periods in soil and on plant material. It will survive and grow within a broad range of pH and temperatures and, once established in a processing plant, it is difficult to eradicate. The bacterium survives preferentially in areas that are constantly cool and wet such as drains, pipes, refrigeration units and areas where condensate collects. Because *Listeria* may be repeatedly introduced into processing facilities on raw produce, rigorous sanitation of those areas where it is likely to survive is necessary to prevent its establishment. There is particular concern about the virulence (ability to cause disease) of *L. monocytogenes* in susceptible populations. It can cause illness and even death in infants, pregnant women and immune-compromised individuals, though generally not in healthy people, when consumed in low numbers. It may not cause major sensory changes in the produce that would indicate its presence to the consumer. Thus, most operators of processing facilities test areas that may harbor *Listeria* to validate that their sanitation processes are effectively excluding it.

So what is the problem with testing for microorganisms? No problem at all if your testing program is meant to validate a process such as wash water sanitation or cleaning/sanitizing processes. The problem comes when looking for specific microorganisms, such as human pathogens, on produce or in the environment. Microorganisms on produce, or in the environment, are typically not uniformly

distributed. They may be found in some parts of a field but not in others, or on some individual fruit or vegetable and not on others. This makes sampling and testing a difficult and often complicated enterprise. The probability of finding what you are looking for, if it is present at all, depends largely on the ability to test enough samples to find it. In the case of human pathogens on raw products in the field, or on finished products in a packing shed or processing facility, they are usually not present at all. If they are present, they may be unevenly distributed and present in low numbers. This makes them difficult to find, even using the most sensitive of tests. If *Salmonella* occurs on one melon out of every hundred, it would take a lot of test samples to have a reasonable chance of detecting it. This is the central problem of pathogen testing. While there are very fast, very sensitive test methods that can detect pathogens, the number of samples required may be so great that it is impractical to do the tests.

Here is the problem. If a pathogen is present on produce or in the produce environment (a rare event in itself), it may very well be present only sporadically and at a low frequency. Years of testing by many companies and agencies show this to be generally so. The International Commission on the Microbiological Criteria for Foods points out that if one were to take 60 samples from a lot that was known to be contaminated at the 0.5% level, one would have a 74% probability of accepting this contaminated lot.

Probability of accepting a defective lot with indicated proportion of defective sample units

% Contaminated	Number of Samples			
	15	30	60	100
0.1	0.99	0.97	0.94	0.90
0.5	0.93	0.86	0.74	0.61
1	0.86	0.74	0.55	0.37
2	0.74	0.55	0.30	0.13
5	0.46	0.21	0.05	0.01

Adapted From: Microorganisms in Foods 7 - Microbiological Testing in Food Safety Management, 2002 International Commission on Microbiological Specifications for Foods (ICMSF) Kluwer Academic / Plenum Publishers NY, NY.

Example

Defect Level: 0.5%

Samples Units Tested: 60

Analysis: 74% probability that all 60 samples will be found negative and the lot will be accepted. That is to say, even after testing sixty samples from the lot, there is only a 26% probability that the pathogen will actually be found. A sample size of 100 would still miss the pathogen 61% of the time.

This simple statistical argument highlights the pitfalls of pathogen testing. You will probably not find it, even when it is there (which is rare enough), and when not finding it you may interpret the result to mean that the product is safe when it is not. Testing for pathogens is an expensive and generally ineffective way to assure the safety of fresh fruits and vegetables.

Before embarking on any testing program it is very important to understand the implications of the results and to have developed a plan of action in case an undesirable result is returned. In the case of pathogen testing, all products should be held so that they can be destroyed if a pathogen is detected. Water tests should be conducted prior to the use of that water so that alternative

sources, or alternative management schemes, can be employed if the water does not meet the microbiological specification. Sanitation chemicals and processes should be validated in advance of their use in case they are shown to be ineffective under some environmental conditions. Whatever the test, the operator should always have a plan of action in advance of the test.

What can I do about all the audits I have to endure?

Audits are a way of life in the produce industry and they are not going away any time soon. While there are continuing efforts to harmonize audits and thus reduce their number, for the present many operators will have to submit to multiple, possibly redundant audits. It is expensive and time consuming to prepare individually for each audit, but different audits, and different auditors, have different requirements. There is no easy solution to this problem. The best you can do at this time is to have a comprehensive, robust food safety program and complete, well organized documentation to back it up. This paper has argued that the heart of a robust food safety program is a systematic hazard analysis. A program based on such an analysis, with specific validated activities that address the significant risks will stand up to any audit. You may not get a perfect score on them all, but you should have little trouble demonstrating the rational basis for what you are doing. With such a program as a base, you need only specifically prepare for the idiosyncrasies of the individual audit, a relatively simple process.

How can I train my staff to operate all these food safety programs?

The best food safety program will be of little value if it is not operated properly. Monitoring activities, measurements and documentation must all be done properly. Health and hygiene of workers is essential for the safety of the food products. These can only be achieved through effective and frequent training. Most workers want to do the right thing, but they need guidance in order to do so. Teaching general principals is important. All workers need to understand the importance of personal hygiene, proper hand washing and not coming to work sick. If you want workers to perform specific activities, they need to be taught to perform them properly. Different people learn differently. Line workers and field workers are often poorly educated and may be functionally illiterate. Visual learning aids may be more effective than presenting text. Frequent short training sessions may be more effective than infrequent long sessions. And training should be validated just like any other food safety activity. If you train workers to measure chlorine concentration in water, for example, test them on the process to validate that they have learned how to do it properly. If you train a crew to perform a sanitation activity, validate that they can do it properly. In this way training is no different than any other part of your food safety program.

What comes next...the future of food safety in the produce industry?

The food safety landscape in the USA and globally is rapidly evolving, both technically and from a regulatory standpoint. While, to paraphrase Yogi Berra, it is always dangerous to make predictions, especially about the future, a new food safety law in the USA will clearly have an impact. The Food Safety Modernization Act of 2010 provides FDA, the federal agency responsible for fruit and vegetable safety, with additional powers and additional responsibilities. The FDA is currently working to translate the law into regulation, but some things will certainly be imposed on the produce industry.

- FDA will have to power to order a recall, not just suggest one. This change may not be as great as some groups have made it out to be, since it would be a rare event indeed if a produce supplier refused and FDA request to recall a food.
- Food facilities will be required to register biannually with FDA. This provision does not include farms, restaurants, retail food establishments or nonprofit food establishments in which food is prepared and served directly to consumers,

- Registered food facilities are required to conduct hazard analyses and to develop and implement written preventive controls plans. The plan must include: hazard analysis, preventive controls, monitoring, verification, corrective actions, and recordkeeping. You would do well to start this process sooner rather than later.
- FDA is required to write regulations exempting very small facilities and certain kinds of farm activities. Nevertheless, this paper strongly recommends that even exempt farms and facilities prepare a hazard analysis and substantially follow the regulatory requirements. It is just good sense to have the strongest food safety program as is practicable.
- Food importers are required to implement foreign supplier verification programs and to take steps to verify that the food they import is safe.
- Laboratory tests to be used for regulatory purposes must be performed by either a Federal laboratory or an accredited non-Federal laboratory, and lab test results must be sent directly to FDA.
- Food facilities will be inspected with greater frequency and not less often than once every 5 years.
- FDA is authorized to require that an article of food offered for import is accompanied by a safety certification from an accredited third-party auditor as an additional condition of granting admission.

What does this mean for the produce industry? It means that FDA is going to expect most operations to have a hazard analysis and a food safety plan based on that analysis. FDA is going to expect you to have a workable and efficient trace and recall program. The new law also places greater emphasis on proper handling of allergens and on food defense plans. The new law and the ensuing regulations will place greater responsibility on the operator to construct a rigorous food safety program and to be able to demonstrate its' operation to FDA. Now is the time to review your food safety plans to make sure that the necessary building blocks are there, that they have been thought through in a systematic way and that they are operating as planned.

References and Guidance Documents:

Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN), October 26, 1998.

(<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm>).

Code of federal Regulations 21CFR 110: FDA Good Manufacturing Practices:

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=cefdff5373327b34dfa6f87642959825&rgn=div5&view=text&node=21:2.0.1.1.10&idno=21>

Codex Alimentarius, 1997, FAO/WHO Food Standards:

http://www.codexalimentarius.net/web/index_en.jsp

The California Leafy Greens Marketing Agreement (LGMA): <http://www.caleafygreens.ca.gov>

Commodity Specific Food Safety Guidelines for the Melon Supply Chain - 1st Edition;

<http://www.fda.gov/Food/FoodSafety/Product->

[SpecificInformation/FruitsVegetablesJuices/GuidanceComplianceRegulatoryInformation/ucm168609.htm](http://www.unitedfresh.org/assets/files/Tomato%20Guidelines%20July08%20FINAL.pdf)

Commodity Specific Food Safety Guidelines For The Fresh Tomato Supply Chain:

<http://www.unitedfresh.org/assets/files/Tomato%20Guidelines%20July08%20FINAL.pdf>

Mushroom Good Agricultural Practices Program:

http://www.unitedfresh.org/assets/food_safety/Mushroom_gap_2009.pdf

Florida Citrus Packers/Indian River Citrus League 2011 Food Safety Good Agricultural Practices:

http://ircitrusleague.org/documents/CommoditySpecificFSGAPs_V2_Complete_May9_2011.pdf

herbs, green onions and others there are commodity specific guidance documents

University of California Good Agricultural Practices Program: <http://ucgaps.ucdavis.edu/>

Cornell University Good Agricultural practices Network for Education and Training:

<http://ucgaps.ucdavis.edu/>

University of Florida, IFAS, Sanitation, Food Safety and Security:

<http://irrec.ifas.ufl.edu/postharvest/index/sanitation.shtml>

The Produce Traceability Initiative: www.producetraceability.org)

Microorganisms in Foods 7 - Microbiological Testing in Food Safety Management, 2002 International Commission on Microbiological Specifications for Foods (ICMSF) Kluwer Academic / Plenum Publishers NY, NY.