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Produce Industry Microbiological Testing Programs – Do I Need One? How Do I Create One? What Is The Purpose?

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Topics For Review

- **Some background information on produce food safety programs**
- **Do I Need a Microbiological Testing Program?**
  - FDA Actions
  - Client Requirements
- **How Do I Create a Microbiological Testing Program?**
  - Product and / or Environmental Programs
- **What Is The Purpose of a Testing Program?**
  - Risk Management and Food Safety
- **Example of Environmental Monitoring Programs**

Background and Other Information

- Historically, microbiological specifications or auditing requirements for fresh produce have not been imposed by the government. Instead, growers, packers, and processors often comply with microbiological specifications and other requirements established by purchasers in order to retain a preferred supplier status.
- FDA Action is underway that will likely change this
- The exception here is for sprouted seeds such as bean sprouts and alfalfa sprouts as requirements are already in place
- FDA actions are based on CDC outbreak data, high-risk produce associated with recent outbreaks include cantaloupes (melons), lettuce, green onions, tomatoes and sprouts.

Do I Need a Microbiological Testing Program

- **Some Historical Recalls and Outbreaks**
  - Packaged salads (Oct 2003; Feb 2004; May 2004)
  - Alfalfa sprouts (Nov 2003; June 2004)
  - Green onions (Nov 2003)
  - Sliced tomatoes (July 2004)
  - Spinach (September 2006)
  - Shredded Lettuce (December 2006)
  - Peppers (July 2008)
  - Cantaloupe (March 2008)
  - Sprouts (April 2009)
  - Several Others

Do I Need a Microbiological Testing Program – FDA Actions

- **Food Safety Enhancement Act**
  - Comprehensive food safety reform legislation is moving
  - H.R. 2749 is fast-tracked to pass the House of Representatives
- **What Does It Mean for Produce?**
  - **Authorizes FDA standards for fresh produce**
    - For *those types of* raw agricultural commodities for which the Secretary has determined that such standards *are reasonably necessary to* minimize the risk of serious adverse health consequences or death to humans or animals
  - **Risk-based inspection schedule**
  - FDA to divide facilities into three risk categories, based on type of foods handled, plant history
  - Category 1 inspections at least once a year
    - Likely to include most fresh-cut plants
  - Category 2 inspections at least every three years
  - Category 3 inspections at least every five years
    - Warehouses, low-risk facilities

Do I Need a Microbiological Testing Program – FDA Actions

- **What Does It Mean For Produce?**
  - **Provides for hazard analysis and preventive controls in food facilities**
    - Written food safety plans required for all facilities
    - Flexibility in individual choice of preventive controls and HACCP plans
    - *Requires description of facility's environmental and product testing programs*
      - Pilot project to evaluate potential benefit, feasibility of requiring finished product testing to be submitted directly to FDA (limited to Category 1 facilities)
      - *NOTE: Testing is only a piece of the program! Food safety and HACCP plans have to be in place as you cannot test your way to compliance.*
  - **Authorizes FDA standards for fresh produce**
    - May cover growing, harvesting, processing, packing, sorting, transporting, and holding
    - Provides for coordination with USDA, states in education and enforcement
    - Requires updating current GAP guidance document
      - Further evidence of *guidance* as tool that should be generally applicable to all produce
    - Allows recognition of impact on small farms and businesses, but does not exempt any entity from compliance

Do I Need a Microbiological Testing Program – Examples of Client Requirements

- **More and more of your customers are now requiring or will be requiring evidence of a testing program**
  - Most look for evidence of environmental programs
  - Some are requiring product testing programs
    - Geared more toward fresh cut and leafy green suppliers
    - Whole produce suppliers often ask to show validation that wash steps reduce microbiological contamination
    - Programs may not be limited to microbiological testing and require monitoring of chemical contaminants (pesticides)
- **Retailers**
  - Costco, Publix
- **QSR**
  - McDonald, BK, Yum!
- **Processors and Shippers**
  - Most large processors: Earthbound, River Ranch, Taylor Farms, Fresh Express

How Do I Create A Microbiological Testing Program?

- **Product Specific**
  - There is not a one size fits all program
  - Depends on product, intended use, etc.
  - Environmental Monitoring Programs are typical of all processes
- **Fresh Product vs. Cut Product**
  - Fresh Product programs focus more on validation work and rinse monitoring
  - Cut programs focus more on quality product testing
- **Client Specifications and Requirements**
  - Clients typically provide detailed specifications and testing requirements
  - Programs should be designed to, at a minimum, meet these requirements
- **Consult with Laboratory or Industry Expert Regarding Program Design**
  - If there is uncertainty regarding program design, ask for help.
  - There are right and wrong ways to test, collect samples, evaluate data, etc. and programs should be designed to ensure you get useful information.

What Is The Purpose Of A Testing Program?

- **Risk Management and Food Safety**
  - Minimize the risk of product reaching the market place
  - Limit the likelihood of recalls associated with produce
  - Protect your Brand Name and business interest
  - Testing programs should be viewed as inexpensive insurance!
- **No Program Can Guarantee 100% That Contaminated Product Will Not Reach The Market Place**
- **Environmental Monitoring Programs Are A Key Component Of a Preventative Program**
  - Preventative programs
    - Designed to identify pathogen growth niches
    - Designed to verify the effectiveness of sanitation programs
    - Used to help limit microbial contamination

Environmental & Sanitation Monitoring Review

Q. Should I use Q-tip type swabs only? Why?

Answer: A sponge is a more appropriate sampling tool since it can test a larger area. More pressure can also be applied when using a sponge to sample. Test areas as large as 1 ft. x 1 ft. can be sampled. Q-tip swabs are good for hard-to-reach areas where a sponge cannot be used.

Q. For routine sanitation verification purposes, should both APC and coliforms tests be performed on the swabs? Why or why not?

Answer: APC can be used, unless you need to meet a customer requirement. Performing both tests may not be necessary. Routine sanitation must be product specific, however.

Environmental & Sanitation Monitoring Review

Q. Should you only use ATP testing for sanitation monitoring? What is ATP Testing?

Answer: ATP testing is a way to measure presence or absence of protein residue (dirt, dust, product, etc.) but not bacteria. ATP is a good training tool for sanitation employees. It will tell whether a surface is clean or dirty. Microbiological testing (looking for bacteria) is a more sensitive tool and allows for detection of specific groups of organisms.

Q. What is the distinction between Zone 1 and Zone 2 in food production lines?

Answer: Zone 1 is a product contact surface while Zone 2 is the equipment surfaces over, under or next to Zone 1.

Q. Which zone (1 or 2) should be the focus of pathogen (harmful bacteria) environmental monitoring? Why?

Answer: No pathogen tests should be performed on Zone 1 unless the product produced has been held, pending the results. In general, indicators can be performed on Zone 1. Keeping pathogens out of Zone 2 can prevent Zone 1 from becoming contaminated, so pathogen testing or indicator testing is critical for Zone 2.

Environmental & Sanitation Monitoring Review

Q. What actions should be taken should an environmental swab uncover a pathogen positive in a non-product contact surface?

Answer: Sanitize the area and retest. Utilize a vector or starburst pattern to do an additional number of sites around the positive site within a 5 to 10 foot radius. This will help to identify any additional niches where the organism may be lurking. Additionally, check previous history of positives to see if this incident fits into a trend or is in a spot where positives have occurred before. If site is still positive after re-sanitizing, then repeat the starburst.

Q. Can you test for multiple pathogen tests per environmental sponge?

Answer: It is not advisable as there is improved recovery of the target organisms using separate sponges. Sensitivity is increased with separate sponges

Environmental & Sanitation Monitoring Review

Q. "How many environmental swabs should I take and how frequently should I take them?"

Answer: The number should be determined after a baseline study or assessment of potential sites is performed. The correct number is what is needed to allow your company to reduce your risk of environmental contamination based on the baseline results.

Q. Should I only test drains for pathogen environmental monitoring purposes?

Answer: Drain testing has fairly low value as it cannot pinpoint pathogen niches or allow for meaningful corrective action.

Q. How do I use the data I get from sanitation and environmental monitoring?

Answer: Map the positives, or elevated counts, on the plant floor plan. Trend the positives.

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How To Take Environmental Samples

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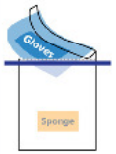
Microbiology Laboratory Services

EZ Swab Environmental Sampling Kit

Instructions and Suggested Guidelines for Hassle-Free Sampling

STEP 1: Remove an EZ Swab bag from the foil pouch. Reseal the foil pouch to ensure the shelf-life of the EZ Swab units. On the bag, fill in the appropriate sample and test information with a permanent marker. (It's easier / safer to do before swabbing.)

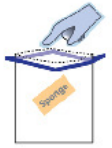


STEP 2: Without touching the bag opening, tear open bag with adheared glove pouch attached.

STEP 3: Before putting on the gloves: Without touching the sponge or reaching into the bag, push the sponge up so that it is above the bag top. DO NOT reach into or touch the top of the bag. It is important that the sponge is above the bag top to eliminate potential contamination of the sample.

STEP 4: Touching only the cuff of the sterile glove, carefully remove it from the pouch and put it on the sampling hand. Make sure that you only touch the cuff of the glove. This part of the glove will not come in contact with the sponge or bag.

STEP 5: Squeeze the bag while removing the sponge with your gloved hand to make a wide opening later when the sponge is placed back into the bag. Swab the desired area.



STEP 6: After sampling, put the sponge back in the sample bag. DO NOT touch the sponge to the outside, the top or reach inside the sample bag. Once the sponge is in the sample bag, remove your glove.

STEP 7: To avoid possible risk of contamination, remove your glove. To close, roll the top of the bag inward and fold over the wire tabs to secure. Place the labeled EZ Swab bag in a shipping container.

STEP 8: Close and seal the container. Send samples to your Silliker lab.

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Suggested Sampling Guidelines and Shipping Instructions on Reverse side.

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How To Take Environmental Samples

Suggested Sampling Guidelines:

Deciding where and when to sample in an environmental surveillance program is as important as using good sampling technique. Sites should be chosen that will give you the maximum amount of information per sample. For that reason, it is important to seek out sites in the plant which have the greatest potential for harboring microbial growth and / or pathogens.

Any site that holds the elements necessary for microbial growth (water, nutrients, and incubation time) is a potential microbial growth niche. In short, any area of the plant or plant equipment that contains uncontrolled water (roof leaks, wet product residue, standing water, or condensate) is a potential growth niche and a good place for sample collection.

Shipping Instructions:

EZ Swabs should be delivered to the Silliker laboratory within 24 hours of taking the sample.

When it is necessary to store samples prior to shipment, they should be stored at refrigeration temperature (0° to 4.4°C). Swabs are considered "refrigerated products" and should not be frozen.

Swabs should be transported in a clean insulated shipping container with sufficient refrigerant (i.e. ice packs or dry ice) to maintain the samples at 0° to 4.4°C until arrival at the laboratory. Swabs should not come into direct contact with the refrigerant since this can cause destruction of certain microorganisms. Do not use loose ice as this may cause product contamination.

Log On To www.silliker.com to learn more about our **"Swabbing Techniques for Sampling the Environment & Equipment"** training program, designed to effectively train new employees, standardize best practices among experienced technicians, and help prevent common mistakes in wet processing environment.

Summary & Questions

- **Microbiological Testing Requirements For Produce Manufactures Are Going To Become More Regulated**
- **Proactive Action Will Help You Prepare And Also Enable You To Minimize Risk Associated With Your Product and Thus Your Brand Name**
- **Environmental Programs Are The First Preventative Step To Implement To Help Limit Risk**

- **Questions?**

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Thank You