Key Questions and Considerations when Developing Pathogen Sampling & Testing Programs for Fresh Produce

Background & Introduction

In 2010 the United Fresh Food Safety & Technology Council published a white paper on Microbiological Testing of Fresh Produce that lays out the value of product testing in several different scenarios including testing raw materials (including pre-harvest), finished product testing, and environmental testing, inclusive of pathogen and indicator testing.

This document was developed as a complement to the Microbiological Testing of Fresh Produce resource and to provide a more detailed and comprehensive discussion specifically on finished product testing for pathogens as applied to the produce category. As such, it is intended to enhance industry understanding of the critical considerations of a finished product testing program and to guide communication with all stakeholders, including customers, consumers (including those on a jury), regulators, and media who may unfairly assume product that was tested may provide perceived confidence even if the statistics illustrate that it does not guarantee product safety. Therefore, there is a need to provide guidance on how to construct a product testing program, including interpreting, communicating, and acting on the results.

This document is provided as a guide for food safety professionals to use as a reminder of the numerous factors that should be considered when developing any kind of sampling and testing program for pathogens. This includes the "how-tos" of a testing program, as well as how to interpret, act upon, and communicate a positive finding. Further, consideration should be given to managing supplier and customer expectations, including situations in which they are also testing product.

Components of a Product Pathogen Testing Program

The following must be included in a product testing program, and considerations are described in more detail for each of the following:

- The objective, the analyte (what you are testing for), details of how sampling is done, product matrix, lot definitions, and other mechanics of testing as described below
- Responses to a positive or negative result
    - Immediate actions regarding product disposition
    - Communication through the supply chain, and to regulators

The aspects that should be addressed in SOPs, developed in a policy, and/or communicated to customers, suppliers, and senior management, are listed below.

Mechanics of testing

The Objective

- How do you define a clear objective or intention for the product testing program?

- Should you consider testing to assure your process is under control?
- With the Preventive Controls rule in mind, how does finished product testing (FPT) relate to validation and verification? Is FPT used for those? Is FPT part of your food safety plan?

Determining the Analyte (what you are testing for)

- Which pathogen(s) should you test for (and how specifically, e.g., EHEC versus STEC)?
- Are you testing for presence/absence, or quantification of the analyte?
- When is it appropriate to test for indicators (and what is the appropriate indicator: aerobic plate count, coliforms, etc.)?
- Is there an index organism for the target pathogen (e.g. *Listeria* spp., generic *E. coli*, etc.)?

Establishing the Sampling Plan

- Frequency: How often should testing be conducted?
- Statistics: Is your sampling plan (sample size, number and frequency of sampling) intended to be statistically relevant? Does it need to be?
- Quantity: How many samples should be taken?
- Sample size: What is an appropriate sample size? Is there a minimum weight, volume, or number of pieces that should be targeted?
    - Should the sample size be expressed in terms of "pieces"? Weight? Packages?
- Sampling time/location: When and where in the process is a sample taken? At a defined time or over a time course?
- Sampling: How are samples collected? (auto samplers, grab randomly, composites, in-process, finished package, etc.)?
    - Do you have historical data that helps you understand if compositing samples will affect your ability to detect the analyte?

Implementation

- Training: Is the sampler trained in aseptic technique? Are SOPs and documentation developed or needed?
- Records: What information should be collected about that sample: date, lot, time, raw material lot(s), sampler, ways sample was taken, processing line, etc.?
- Sampling time: Is testing planned so as to coordinate the collection of different types of samples (e.g. swabbing for *Listeria* and doing product testing; should wash water be tested along side a product?)
- Sample management: When should you schedule sampling so that you are able to efficiently deliver the samples to the laboratory? How must the sample be packed, stored, and transported?
- Impact of other issues: How might your finished product testing plan change if there is an issue going on? For example, if your *Listeria* monitoring indicates an issue with a line, does your approach to finished product testing change? Can it demonstrate that corrective actions are appropriate?
- For multi-ingredient products:
    - Will you also test components individually?

        - If so, how does this impact the use of ingredients in other products/ blends or ingredients that have already been used to make finished products?
    - If you test a mix that has a masterpack does that get included in what is tested?

Selecting the Method

- How do you select a method? What are its pros and cons?
- Should you use a validated method? (e.g., AOAC PTM, AOAC OMA, AFNOR, etc.)
    - If not, how do you establish that the method is valid?
- Is the method validated for the produce item you are sampling (your matrix) and the sample size you are using?
- Can you apply indicator tests as a replacement for pathogen testing?
- What is the test method's accuracy and sensitivity?
- Should you verify the method for your chosen sampling plan and other variables?
- When might you use a "rapid" test? How long will it take to get results for a traditional or a rapid method?
- What research data are available on viable but nonculturable cells (VBNC) and are those data relevant to your product, conditions, etc.
    - How effectively will your method detect stressed or VBNC?

Selecting the Laboratory

- Is the lab accredited, including for the method you wish to use?
    - Do they have a 3rd party audit that verifies the laboratory capability for the method and the matrix?
    - Does the laboratory have a proficiency testing program? Is it appropriate?
- Does the individual lab location and staff performing the test have experience handling your product and the analyte?
- Have you verified the lab's proficiency?
- Should you or a third party audit the laboratory and their results?

Executing a Testing Program

Holding Product, and Defending "Lot" Definition

- What defines a lot, both in the production and growing environments?
- What about other products run on the same line?
- How does your facility define a raw material lot?
    - How does this definition compare with the field lot from the growing environment?
    - How is a raw material lot incorporated into your production lot?
    - What does a finished product positive mean relative to the greater raw material lot?
- How does your raw material supplier define their lot?
- How do you define a production or finished goods lot? What about raw material lots that are used in multiple finished goods lots?

- What is your approach to holding product until results are received versus letting it ship/transport, while retaining control?
- What data are available to support your lot definition, including historical data, sanitation verification data, management of cross-contamination points, etc.?

Interpreting Test Results

- If the test method provides 'presumptive' or 'suspect' or 'initial reactive' results, what do these terms mean for that particular test method?
- Certificate of Analysis (COA): How do you apply a finished product test result to a COA process? How do you define the upper limits on a specification for an indicator?
    - If a result for an indicator exceeds a specification, under what circumstances could exceptions be made?
- What do you consider "presumptive" versus "confirmatory" results?
    - When should you conduct confirmatory testing?
- What if it's suspect/ presumptive, and then confirms negative?
    - How does method selection/sensitivity impact your decisions?
- If a raw material lot tested ok once, and it will be used again (e.g., on a different day), should it be retested? Can/should it be considered a different lot?
- How does testing conducted on a finished product correlate with testing completed on the incoming raw material?
    - To what extent can you consider that production variables contributed to the positive result?
    - What do multiple positives on different finished product lots mean if the finished product contains material from same raw material lot)?
- When might you apply Whole Genome Sequencing (WGS) or other typing?

Planning for a positive?

- What is the immediate corrective action?
    - Immediate: What do I hold, who do I notify, when do I clean, what other parts of the operation need to be evaluated?
    - What if the positive is still within your control but you already released another part of that raw material lot based on a negative result. Is the raw material implicated?
        - What additional information can help inform this decision (production/ processing information, other sampling data, etc.)?
- How quickly should senior management know about a pathogen positive test result?
- Should you initiate a recall and submit an RFR?
- If the product is out of your control (e.g., in distribution), when do you let the customer(s) know?
    - For the purpose of the Reportable Food Registry[1], what does it mean for a product to be "in your control"?

Determining Root Cause

- How does the sample design direct you to the likelihood of the pathogen coming from raw product or the processing environment?
- What near term actions should be taken with respect to sanitation, preventive maintenance, equipment, etc.?
    - What are the steps to conduct a root cause analysis on a product positive?
    - What would more testing tell me (at different points); how would this test result be interpreted in the context of other test results?
    - Should vector sampling be used for further investigation?
    - Should you increase your frequency of testing? Do lot separation and "clean breaks" impact the handling of product produced immediately before, after, or in close physical proximity to the product that tested positive?
- How are trends in positives (including presumptives) analyzed? Can an association be made with a certain shift? Line? Day of the week? Season? Supplier?

Business Considerations

Product testing has ramifications up and down the supply chain. In addition to an SOP related to how to sample product and what to sample for, it is critical to plan for communication of results, internally, through the supply chain, and potentially to regulators and the media.

Communicating Internally

- What does senior management need to know about product testing?
    - In the event of a positive?
    - On an ongoing basis?
    - About the test plan and potential results/impact?
- How are business risks communicated? (especially when dealing with priority customers)
    - How is the decision to hold product, definition of being "in your control" and RFR implications, communicated internally?

Relationship with Suppliers

- What are the best practices for communicating within the supply chain (end customers and distributors in between)?
- Do you need to tell your raw material supplier that you are testing their product?
    - What if the grower/processor is not your immediate supplier, but is further back in the supply chain?
- If a raw material tested positive, when do you let the supplier know?
    - Who is the "supplier": the grower, harvest company, cooler, storage entity, broker, etc.?
- How will you handle a situation in which your downstream customer is testing the supply you sent them?
- If your customer requires you to test product, should you require that your supplier test what they are sending you?
- What if your supplier gets a positive on something they have already sent to you?
    - And you have no result, or a negative test result?
    - How do you AND they define their lot?

    - Farms are not subject to reporting through the Reportable Food Registry; if your supplier is a farm who will handle regulatory communications?
    - What did they get the positive for- pathogen vs indicator?
- Is testing by suppliers part of your supplier approval program?

Relationship with Customers

When your customer questions your testing plan

- How do you manage your sampling plan when different customers have different requirements, or their requirements differ from your program?
    - The extent to which you modify or amend your program may depend on the customer. As staff change you may need to provide continued education; documenting your thought process, using the questions in this document as a guide, can be helpful.
    - What are the key points to raise in these discussions?
- What is your policy for a customer request for testing data (e.g., positive rate report; individual results, etc.)

When a customer or downstream recipient tests your product

- Someone downstream of you tests your product. What can you do to avoid or reduce potentially confusing situations in the marketplace?

Third Party testing

- What if a regulator tests product?
    - If a sample is taken at retail do you require your customer to notify you?
    - How do you handle/hold related product?
- Facilities under dual jurisdiction may be subject to USDA testing. What are the policies around that program?
- If a retailer says they got a positive test result on your product, but they did not get it directly from you (because there were several handlers in between)…
    - What questions should you ask them? (who tested it, what did they test for, what method did they use (method validated for this matrix?), who did you get it from etc.)

Closing

Having a well-thought out testing program is part of an overall food safety management system. Testing can also be applied as verification or monitoring within a food safety plan. However, limitations in time to result and statistical power hamper its utility. No matter how statistically valid the plan is, and how good the method is, if there is an outbreak or a regulatory positive is associated with your product, your test results cannot “undo” this. If a regulatory positive contradicts your data, it may trigger a reevaluation of what your sampling plan does and doesn’t tell you. Still, this due diligence can help manage relationships with regulators, customers, limit the scope of a recall, etc. Companies should always plan for the “worst case” and be prepared to act, and communicate, around unfavorable test results. As much thought should be given to the management of test results as is given to the mechanics of testing.

Citations

[1] FDA RFR Guidance (edition 2, May 2010): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food

[2]FDA BAM Appendix 3 (2nd edition, May 19, 2015): Guidance for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Food and Feed, Section 4: https://www.fda.gov/media/83812/download

Other helpful resources

ICMSF. Microorganisms in Foods 8: Use of data for assessing process control and product acceptance. 2011. Springer. https://www.springer.com/gp/book/9781441993731

Includes chapters specific to testing vegetables and fruits

ICMSF. Microorganisms in Foods 7. Microbiological testing in food safety management. 2018. Springer. https://www.springer.com/us/book/9783319684581

Includes details of statistics and sampling plans

NACMCF. 2015. Response to questions posed by the Department of Defense regarding microbiological criteria as indicators of process control or insanitary conditions. https://www.fsis.usda.gov/wps/wcm/connect/2ea3f473-cd12-4333-a28e-b2385454c967/NACMCF-Report-Process-Control-061015.pdf?MOD=AJPERES

Appendix J includes tables with micro limits for RACs, fresh-cut, mushrooms and sprouts; Appendix K discusses lot acceptance/ statistics

Xu A and Buchanan R. 2019. Evaluation of sampling methods for the detection of pathogenic bacteria on pre-harvest leafy greens. Food Microbiol. 77:137-145 https://www.ncbi.nlm.nih.gov/pubmed/30297044

Evaluates different preharvest sampling patterns