GAP's, Food Safety, and Third-Party Audits

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Over the past several months, major retailers have communicated their requirement that all suppliers of non-processed fruits and vegetables must participate in grower/shipper certification programs that are overseen by approved third-party auditors. Some vocal members of the produce industry view this development as a case in which a federal guidance document (Department of Human Health Services, FDA. 1998. Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. http://www.fda.gov) has emerged as *de facto* regulation and enforcement in the market place. This has been made possible, in part, by the strong leverage created by recent retail consolidation.

Major Questions Arise

While the scientific justification and relevance to food safety for specific aspects of these programs may be vigorously questioned, parties on both sides of the issue agree that the broader spirit of the initiative will benefit everyone. Proactive measures to protect the consumer and to retain or enhance public confidence in an already substantially safe food supply are supportable by the produce industry. However, in an effort to satisfy the expectations of diverse receivers, suppliers have called for greater clarification of several key issues:

1. Are there qualified auditors to provide timely and accurate coverage? Yearly and quarterly third-party audits are being required down to the ranch level. For some packer/shippers, this may involve more than 3,000 separate locations. The cost, at this time, is projected to be close to $800.00 per location. There is concern that unless retailers express increased flexibility, grower/shippers may not be able to qualify within the timelines required for 2000, due to the absence of complete coverage by auditors. Those with existing programs in place and contracts with approved third-party auditors will clearly have an advantage.

2. How will the inspections and audits be standardized? Retailers have called for a science-based audit system for microbial food safety that uses objective standards. While the goals are clear, the path forward is fairly murky at this time. Science is not at the point of providing unambiguous standards for all production environment and postharvest situations, pathogens and produce items. The design and implementation of Good Agricultural Practices, as suggested in the FDA Guide, are a combination of long-standing good hygiene and sanitation practices and newer information on hazard identification and risk assessment coming from fairly recent (or recently rediscovered) scientific studies that were applied to fresh produce, production and postharvest water, and manure-based soil amendments. Significant gaps in our definition and knowledge related to critical limits (How much, How many, How long?) for microbial contamination remain to be filled. From a practical perspective, audits are based, primarily, on the quality of record-keeping and documentation of practices that are defined in a grower's or company's food safety plan. However, monitoring for microbial contamination, a common required element of the plan, has as yet unresolved limitations in sampling method, sensitivity, and accuracy. In addition, critical limits or even standardized limits for microbial indicators on produce are unavailable. Suppliers are faced with multiple microbial test requirements and standards from buyers. It is not uncommon for a single packer/shipper to have multiple auditors inspecting several different types of records of performance practices using varying standards of stringency on the same product from the same fields. All of this may occur on the same day. Clearly, efficiency and economics would be served by establishing a standardized system with uniform criteria and formatting that will function smoothly between approved third-party auditors. As the cost burden for food safety is essentially borne by the grower/shipper, avoiding redundant record-keeping will help the bottom-line.

3. What microbial standards will be used and applied to global sourcing? There are very few uniformly accepted criteria for microbial standards or limits for most situations involving agricultural inputs and outputs. Retailers and large food service buyers have widely varying performance standards. Shippers are faced with having to provide documentation of routine microbial testing of packed product that may be entirely generic (total aerobic plate count), superficially predictive (total or fecal coliform counts), potentially informative for exposure to gross contamination (*E. coli* counts), or bear a high cost with limited liability reduction

(pathogen specific tests for Salmonella, *E. coli* O157:H7, Shigella, Listeria, and others). Certain buyers have erected a Zero Tolerance for generic *E. coli* in fresh produce. The microbial standards that third-party auditors are verifying must be set by agreement between the supplier and buyer. It should not be a function of varying standards developed by the auditing company. One key problem that arises is what action is triggered if a set of tests exceed the establish limits. For example, standards specify a total aerobic plate count of log 3.0 CFU per gram (essentially equivalent to 1,000 bacteria per gram fresh weight of plant tissue), but test results recorded for a given lot might average log 3.2 per gram (approx 1,580 bacteria). Is this an actionable event triggering a notification to the buyer (data is almost always retrospective)? Is this the basis for a cautionary notation on an audit? With experience, some have approached this problem by using monthly averages of microbial testing which may help prevent marginal triggering events but may disguise useful data that would help understand sources of microbial variation during production or harvest. In an area related to microbial standards, product shipping and arrival temperature standards have been incorporated into audited food safety plans. Here again, what if the standard is 42°F (5.6°C) and the measured temperature is 43°F? Do you measure again looking for a colder set of replicated spots, re-cool the load, dump the load or sell it to someone else? If the product has historically been free of documented pathogens or association with known illness, does it matter? There are no easy answers.

4. How do the third-party audits contribute to improving food safety? Third-party audits of a well-designed food safety program will significantly enhance the overall safety of fresh produce by helping grower/shippers formalize recognized preventive practices to minimize contamination. Audits are also a tool to formalize and provide oversight to the critical aspects of employee and produce handler training and education in general food safety awareness and personal hygiene. However, current microbial food safety audits too often appear to focus on minutia related to aspects of produce production and handling that are easy to score on a sheet but have dubious impact on real (or realistic) food safety concerns. For example, a field packing crew for bulk produce may receive negative marks for inconsistent use of hairnets and disposable gloves. From an extension scientist's perspective, what is the justification for hairnets and gloves in the field? Why was this in the food safety program to begin with? While there are too many aspects of this issue to engage in this brief overview, the main point is that the development of an on-farm and shipping point food safety plan and program should focus on areas where control can be exercised and the documented activities have some recognized bearing on minimizing food safety risks. In the absence of hard data for a specific crop or situation, reasonable and non-burdensome approaches must be taken to promote credibility and support for the system as a whole. To achieve this employee support, the general experience of companies with operational on-farm food safety programs for the past several years has led them to streamline the areas of routine record-keeping and monitoring. The focus is heavily weighted to water quality, waste and fecal contamination, sanitation routines in key areas, and worker hygiene. Third-party audits can verify these good practices for all potential buyers.

The Race to Disclosure

One primary outcome of all of the documentation, record-keeping, and auditing programs that are in place or in development is to win the Race to Disclosure, a program promoted by industry organizations such as the California Tree Fruit Agreement, the California Strawberry Commission, the California Cantaloupe Advisory Board, and others. Emergency Preparedness and a Crisis Response Plan are integral components of the Trace Back criteria mentioned in the FDA Guide. Rapid positive lot identification and audited farm, harvest crew, and shipping point record-keeping help reduce or eliminate the economic consequences of any food borne illness investigation. The efforts of health investigators are greatly aided by the availability of production flow diagrams and shipping schedules, organized records of locations, dates, inputs, secondary suppliers, lot identifications, harvest crew identification, sanitation programs, training programs, and general audit performance results.

The goal is to provide timely, if not rapid, response and disclosure to segregate implicated commodities, or specific sources of a commodity, from all others. In a trial of the traceback system, the California Tree Fruit Agreement reports that it took less than five minutes, from selection of a random fruit sample at retail, to identify the specific orchard and date of harvest. Typically the timeframe is a few to several hours in most systems. In a very recent outbreak of Salmonella on

cantaloupes that affected consumers in several states—once channels of communication between regulators, health investigators, and the melon industry were established—it took very little time to determine that the melons on the market could not have come from the suspected source. Rapid dissemination of this information prevented buyers from rejecting the purchase of cantaloupes and greatly limited the economic impact of the media coverage of the outbreak. In other cases, unfortunately, due to the lack of organized and thorough record keeping, together with the complexity of produce handling systems, health officials may be faced with weeks of investigative work and may feel compelled to release blanket consumer warnings that will severely impact a whole category until resolved.

Final Thoughts

It seems premature and unsubstantiated to require a long list of audited records and documents ostensibly designed to ensure food safety. More science-based information is needed to address the hazard potential, risk potential, and actual risk exposure of practices related to produce production and handling. At that point, uniform and standardized third-party audits will provide meaningful information and increased confidence for all parties.