

Testing Is More Than the Numbers

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ABSTRACT

Food safety is an integral element of doing business around the world. It is part of federal law in many countries, and these laws often are based on a HACCP (hazard analysis critical control point) management system. Because it is not possible to test safety into a product, safety must be built into the process and monitored. Testing has a role to play in verification of food safety but requires money and resources. As a result, it is imperative that companies not only design testing programs to meet quality and safety goals, but that the tests conducted are appropriate for the products manufactured. This article provides an overview of how an effective testing program can be created and some of the tools available for determining what tests to perform and how to perform them, including accepted test methodologies, published guides, and exchange programs for technicians, scientists, and managers.

Food safety is an integral element when it comes to doing business in the United States and around the world. It is part of federal law in many countries, and more often than not, the laws governing food safety are based on a HACCP (hazard analysis critical control point) management system. However, there are many countries that have not adopted HACCP-based food safety regulations and others who, whether they have adopted the system or not, simply do not grasp the basic concepts of the system. In many cases, implementing a HACCP-based system becomes a business decision for a processor: it must be done, or you will have no markets. So, there is definitely pressure to put a HACCP program in place. At the same time, however, there are many individuals in developing countries, both in industry and government, who feel that the emphasis on developing, implementing, and maintaining a world-class food safety management system as a prerequisite for doing business globally is a restraint or trade requirement imposed by others.

I participated in a meeting organized by the United Nations Food and Agriculture Organization (FAO [www.fao.org]) in the Middle East a few years ago that demonstrated this point and touched on the next issue to be discussed—the role of testing. The FAO is a specialized agency of the United Nations that includes 194 member nations and leads international efforts to defeat hunger. The goal of the agency is to achieve food security for all. The meeting was attended by representatives from the Middle East, Africa, and the Balkan nations, as well as a few representatives from southwestern Asia. The chair of the meeting was an FAO member from Rome. The opening session was devoted to explaining the commitment of the FAO, the European Union, and the world to HACCP-based food safety systems. The chair and other speakers carefully explained how HACCP works:

- 1) Determine hazards based on risk
- 2) Establish critical control points
- 3) Set limits
- 4) Monitor limits
- 5) Establish corrective actions
- 6) Verify that the system is working
- 7) Maintain records

The speakers emphasized that the key to ensuring food safety is building safety into the process and monitoring the established controls: process control technology. They also made it very clear that one of the factors that led to the development of HACCP was the fact that it is not possible to test safety into a product; safety must be built into the process. They also mentioned that testing does have a role to play, but only as a verification activity. As soon as there was a call for open discussion, the delegates began asking questions about how they could test products to ensure safety. They wanted to know about sampling plans, microbiological limits, and what tests need to be done on different types of products. It was clear the group did not understand the concept the speakers had elucidated and were married to the need for testing. The following pair of quotes from the 1985 National Academy of Sciences report that addressed the subject of process control was not in their playbook (1):

“HACCP provides a more specific and critical approach to the control of microbiological hazards than is achievable by traditional inspection and quality control.”

“Testing of finished products was not an effective means of protecting the consumer and assuring the foods were free of microorganisms of public health significance.”

Target Your Testing

Having had the opportunity to work with regulators in developing countries, I've observed the emphasis on testing, and only testing, again and again. Being able to attend a meeting of food regulators provided some interesting insights on the subject. One meeting I attended was a yearly joint meeting of different regulatory agencies in a nation that focused on what each agency had done over the past year. One of the speakers was from the government agency specifically responsible for monitoring imports. The whole presentation focused on how many samples they had collected over the course of the year. The audience learned how many samples of canned foods, sweets, grains, etc. were collected and tested. The presentation did not include the tests conducted on the different products, how many of the samples were rejected, or why they were rejected. The group was quite pleased that they had tested so many samples, rejected a specific percentage, and, thereby, protected consumers in their country.

When the speaker was asked for more specifics on what percentage of products failed to meet the standards or what the biggest problem observed was and which product posed the greatest concern, there were no answers. This individual was not the only speaker whose presentation moved along these lines. Another speaker, who was the head of the radiation laboratory, talked about their laboratory's work. The individual also proudly emphasized that they had tested thousands of imports for radiolytic entities and helped protect the nation's consumers. When asked if they had found any positive samples, the answer was no. When asked how long the agency had existed, the speaker informed the audience that it was established immediately after the Chernobyl incident in 1986. This was now more than 20 years later. The next question from the audience was, "Have you ever found a positive sample?" The speaker hesitated and said, "No, we never have." After 20 plus years of testing and something in the neighborhood of 100,000 samples tested, one might think this was a resource that could be better allocated.

Put Your Numbers to Work for You

This last point leads to the next concern—putting your numbers to work for you. It is surprising how few companies and regulators actually do something with their data. Of course, this is not just an issue for laboratories in developing countries. There are many companies in the United States and elsewhere who suffer from the same problem. I once worked for a person who wrote a proposal, the objective of which was "to gather data." Gather data for what purpose?

Putting data to work is much easier in this age of computers, because the computer does much of the work. If you look back at how food science and technology has evolved and read some of the old papers, you have to marvel at the perseverance, patience, and level of commitment of some of our predecessors. The work performed by Dr. C. Olin Ball in developing the formulae for thermal process determination in the 1920s is astounding.

Food processors and regulators around the world have file cabinets full of old test results that have never been compiled into databases so they can actually be used in decision-making processes. This is especially important with the global emphasis on risk-based food safety programs. A company's historical data is an important tool for evaluating product, process, and ingredient risks. For example, a company may be manufacturing a product or ingredient that would be deemed sensitive (e.g., a dairy ingredient), but if the test data from the past few years were put into a database, the company could demonstrate that the product has never tested positive for a pathogen and has a very low microbial load. The end results can not only be utilized in an overall risk assessment, but they could be used as a means for reducing overall operating costs. These findings could lead to a reduction in the amount of testing that is done. Another route that processors in developing countries often fail to follow is to incorporate testing into their HACCP plan. Pathogen test results can be incorporated into an operation's verification activities to support the safety of a product. Because so many processors must generate certificates of analysis (COA), which include pathogen testing, there are many ways to put test data to work.

Are You Performing the Proper Tests?

Testing requires money and resources, so it is imperative that companies not only design their testing programs to meet their quality and safety goals, but that the tests that are conducted are appropriate for the products being manufactured. Sadly, this is not always the case. I have observed many situations in which companies have spent a great deal of money on tests that are both unnecessary and unrealistic given the products the company is producing. Here are two examples. One of the products manufactured in Southeast Asia is vinegar, which is produced in huge tanks from industrial alcohol. Vinegar is a very safe product. It inhibits a wide range of microorganisms and, in fact, is used by some as a sanitizer. A manufacturer was testing every lot they produced for coliforms, *Escherichia coli*, and aerobic plate counts (APC). When asked why, the answer was, "It is a government requirement." The suggestion was made that they confirm this with the regulators. The next two questions were, "How long have you been doing these tests, and have you ever had a positive test for coliforms and *E. coli*?" The answers to both were, "For many years, and no, we have never obtained a positive result."

In the second example, a processor of low-acid foods, including some meat items, in the Middle East had a well-equipped microbiology laboratory that was quite busy. When asked what tests were done on the canned products, the answer was quite long. They were running total counts and were testing for coliforms, *E. coli*, yeasts, and molds, as well as for *Clostridium botulinum*. Containers were being tested on the day of production, so there was no incubation period. They also did not check vacuums and pH values on the cans as part of their testing regimen. The laboratory technicians informed us that these were the test procedures mandated by the government. The bottom line is that this testing regimen was way off target. If they had obtained positive results when testing for coliforms, *E. coli*, yeasts, and molds, it would have indicated either gross underprocessing or postprocessing contamination (leakage). If this was the case, in all likelihood, the container would have been swollen and obviously defective. The proper procedures for evaluating canned foods may be found in the U.S. Food and Drug Administration's (FDA) *Bacteriological Analytical Manual* (www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm), as well as other sources such as the *Codex Alimentarius*.

Finished product testing, including microbiological testing must be based on potential risk and the characteristics of the product. The objective of the low-acid canning industry is to control *C. botulinum*, but again, you cannot test safety into such products. The controls are the process times and temperatures, as well as adherence to the critical factors established for each product, and ensuring that seal integrity is properly maintained during processing operations. Testing canned foods for coliforms, *E. coli*, yeasts, and molds is a waste of time and money.

How to Do Better

Helping processors and regulators enhance the economies and efficiencies of laboratory operations is a challenge. Part of the challenge is that the managers and decision makers are often “old school,” i.e., they are still of the mind-set that testing is the best means for ensuring food quality and safety. Unfortunately, this mind-set is particularly prevalent in developed countries, including the United States. Many consumer groups in the United States and elsewhere also seem to believe that testing is essential for safety and quality and have condemned government and industry for their commitment to HACCP-based food safety management systems.

Overcoming this mind-set requires tact, diplomacy, and education. People need to be taught the whys and wherefores of building an effective testing program. Easy access to internationally accepted test methodologies through AOAC International, IUPAC (International Union of Pure and Applied Chemistry), AACC International, Codex, and ISO (International Organization for Standardization) is essential to ensuring operations personnel are all on the same page. The FDA provides easy access to the *Bacteriological Analytical Manual* and the *Bad Bug Book*. Both are useful tools for determining what tests to perform and how to perform them. Another option that should be pursued is exchange programs. Sending laboratory technicians and managers abroad to work in laboratories in Europe, the United States, Australia, New Zealand, or Japan can help improve their skills and offset the “testing is the answer” mind-set. An American Field Service (AFS) for scientists and technologists might be a good idea (<https://afs.org>). It has certainly helped young people connect for many years.

Perhaps the biggest challenge is redirecting the efforts of existing laboratory operations. The radiolytic testing operation cited earlier had outlived its usefulness, but how many managers are wise enough or brave enough to tell their bosses that the time has come to redirect their efforts? Very few.

Better directing of resources when it comes to laboratory testing and analysis is something that will benefit everyone, but it takes a commitment from all.

Reference

1. National Academy of Sciences. *An Evaluation of the Role of Microbiological Criteria for Food and Food Ingredients*. National Academy Press, Washington, DC, 1985.

Richard Stier is a consulting food scientist with international experience in food safety (HACCP), food plant sanitation, quality systems, process optimization, GMP compliance, and food microbiology. He has worked with a wide range of processing systems and products and with companies at all levels to understand, develop, and implement systems to enhance operations. Rick has been instrumental in helping processors develop quality, food safety, and sanitation systems. He is also a food safety, GMP, and quality systems auditor; is certified as a seafood HACCP instructor (AFDO) and by the International HACCP Alliance; is a preventive controls qualified individual (PCQI) instructor; and has received instruction in the Foreign Supplier Verification Program (FSVP). Rick has a B.S. degree in food science (Rutgers University) and an M.S. degree in food science and technology (University of California at Davis). He is a member of the IFT, IAFF, and NCAACC and has served as chair of the IFT Northern California Section, Refrigerated and Frozen Foods Executive Committee, and Continuing Education Committee. He is a contributing editor to *Baking & Snack* and *Food Engineering* and serves on the editorial board of *Food Safety Magazine*. He is also a member of the U.S. delegation for TC-34, the technical committee charged with developing and updating the ISO 22000 standard. In 2012, Rick received the Bor S. Luh International Award from IFT for his international work.



27 have also started testing more than 210,000 members of the Shincheonji religious group in Daegu. United States. On March. 2, Dr. Stephen Hahn, FDA Commissioner, announced that the US will have, by the end of the week, the ability to perform 1 million tests. The US CDC initially declined to test the patient who on Feb. California Governor Gavin Newsom characterized the number of test kits available in the state as "remarkably inadequate." As of Feb. 26, CDC had performed a total of 445 tests. For comparison, the UK, with a population five times smaller than the US, had conducted over 7,000 tests. March 2, 2020 Dr. Matt McCarthy, a staff physician at New York-Presbyterian The number of tests does not refer to the same in each country "one difference is that some countries report the number of people tested, while others report the number of tests (which can be higher if the same person is tested more than once). And other countries report their testing data in a way that leaves it unclear what the test count refers to exactly." The reason for this is that it is common for COVID-19 testing that the same person is tested more than once. Some countries report tests performed, while others report the number of individuals tested. Start studying Test 1: Numbers. Learn vocabulary, terms and more with flashcards, games and other study tools. In 1955, close to _____ people lived in public mental institutions across the United States, while today the number is less than _____. 600,000; 40,000. What percentage of psychiatrists are female? 25. It is estimated that more than _____ percent of people with obsessive-compulsive disorder seek treatment. 40. In a number of international studies, _____ percent of participants given cognitive treatments have been found to be free of panic. 80. The ratio of men to women who have obsessive-compulsive disorder is: 1 to 1. In some studies, African Americans and Hispanic Americans report having at