RAW MATERIALS: TEST OR NO TEST?

You can send incoming raw material samples out to a third-party lab, but plenty of easy-to-use, rapid test kits can more quickly provide the results you need—right at your own facility.

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A June 10, 2011 report on Deutsche Welle states "bean sprouts are the likely source of an E. coli outbreak in Germany that has killed 31 people and made nearly 3,000 ill since May [2011]." This information was attributed to Reinhard Burger, president of Germany's federal infectious disease laboratory, the Robert Koch Institute (RKI). (FE Tech Flash, June 13, 2011.)

"I am nothing short of outraged at the increasing number of outbreaks of foodborne illness in this country," said Senator Tom Harkin, chairman of the Senate Agricultural Committee in February 2009. "Everything from spinach and lettuce to beef products and, now, peanut products has been implicated. Within the last year, we had the biggest recall ever under USDA jurisdiction. And just in the last month, with the recall of peanut products from the Peanut Corporation of America [PCA], we had one of the largest recalls ever under FDA jurisdiction." (FE, March 2009.)

Although four senior officers of the now-defunct PCA were indicted on 76 counts of fraud and food adulteration, early facility inspections by FDA and a third-party auditor revealed no serious problems. In fact, the March 2008 third-party audit scored PCA's facility a 910 out of a possible 1,000. When FDA subsequently took samples from PCA, several tested positive for Salmonella, but the plant continued to ship known, defective product.

According to FDA's Form 483, dated February 5, 2009 (inspection carried out on January 9, 2009), "Peanut paste under lot #8278 was found contaminated with Salmonella Typhimurium by private laboratory testing conducted by the firm [PCA]. After the firm retested the product and received a negative status, the firm shipped (redacted) lbs. of the product in interstate commerce."

"No amount of testing will ever make a food safe. The sheer volume and variety of food produced, the distribution and state of microorganisms in the food, and industry resource limitations make it essential to ensure that food production systems are inherently safe. Microbiological testing should be regarded as a helpful tool in support of these systems," according to the authors of a 1997 article published in Food Science and Technology Today. The article, "Development and use of microbiological criteria for foods," also points out that microbiological testing should not be used just as an indicator (e.g., satisfactory or unsatisfactory) to demonstrate the

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safety of food.1

Inherent issues

Unless you cook your incoming raw materials, you have much to worry about. “All raw ingredients have inherent risks since they are potential sources of nutrients, habitats for microflora and carriers of toxins,” says Stuart Ray, Seward Ltd. technical director. In any risk assessment, an analysis of a raw material includes its source, water content, applied preservation or preparation technique and the potential consumer of the finished product.

A great deal of food microbiology has been concerned with the high-profile outbreaks of food poisoning caused by contaminated meat, leaving the impression meats are high risk, adds Ray. Of course, this risk should not be underestimated, but farming practices in the production of produce such as melons and tomatoes can also lead to serious food poisoning incidents. “The best approach to food safety is the constant vigilance and sampling regimes that maximize the confidence in your finished product. Even where a kill step such as cooking is involved, the problem of thermally stable toxins and hygiene must be considered,” adds Ray.

“The riskiest FDA-regulated foods are leafy greens, eggs, oysters, cheese, fresh tuna, potatoes, tomatoes and berries,” says Joe Scioscia, VAI (Vormittag Associates Inc.) vice president of sales. “In fact, leafy greens are the riskiest food of all. In 2012 alone, 363 outbreaks from leafy greens were reported by the Center for Science in the Public Interest.”

Leafy greens are problematic from the start, says John Surak, principal, Surak Associates. Many farms now use fences to keep larger animals out and set poisoned traps around the perimeter for rodents. Unfortunately, it’s next to impossible to avoid the bird flyover. And, though paracetic acid and acidified chlorine washes plus washes at the farm are all used, there is no way to get the 5-log reduction you might expect with other food products. So, it’s incumbent on the farm to follow good agricultural practices (GAPs) and for processors and packagers to run tests to verify leafy greens are consistently as clean of microbes as possible.

Another important issue is the use of clean irrigation water (or agricultural water), especially if it’s applied by spray. For more on this subject, see “FSMA Update: Staying ahead of the curve,” FE, January 2014.

Bacterial contamination is not the only microbiological problem that can crop up with certain ingredients. “Raw materials such as grains, tree nuts, peanuts, vine fruits, spices and even cocoa and coffee may be at risk throughout cultivation, storage and processing,” offers Patricia Jackson, VICAM market development manager. “These products continually face challenges from insects and weather conditions. They also may become compromised by mechanical damage during processing, which gives molds an opportunity to grow and potentially produce natural toxins, which are chemicals deposited on the surface or inside the product.” In fact, each step in the supply stream including commodity harvest, transport, processing and storage presents potential risks for mycotoxins.

While it’s generally assumed that raw protein foods and leafy greens are high-risk raw ingredients, and processed soy, corn, palm kernel and cottonseed oils are less risky, it’s not always a good idea to make generalizations. “The relative risk of different raw foods and ingredients cannot

always be based on the food type alone," says Tim Carmack, global marketing and product manager for DuPont Nutrition & Health. "For example, [risk] can also depend on factors such as the specific processing techniques used for each ingredient and the required food safety plans already in place. Because these factors can vary even among manufacturers of the same ingredients, it may not be accurate to generalize the riskiness of a particular food based on just its contents."

Setting up a sampling program

Whether you're testing incoming ingredients or checking the safety of a process, there are tools that can help, and consistency goes a long way in achieving accurate results. "Sampling regimes and sample preparation for testing are critical steps in preserving food manufacturers' reputations," says Seward's Ray. "Regimes that are not statistically representative or sample preparation techniques that are not effective and reproducible all lead to vulnerability."

"Common test regimes are based on HACCP," says Ron Wacker, global business development manager food testing, SGS Consumer Testing Services. "The strategy is to define the critical points in your production process and set appropriate measures to reduce the risks. Guidance is published by FDA." Wacker recommends regularly reviewing all HACCP plans, which should include the facility's water quality and employee training. Improving food safety testing and enforcing regulations with respect to developing markets also are critical factors in reducing potential contamination since global supply chains mean contamination issues in one part of the world can quickly spread, according to Wacker.

"The first place to start with a risk-based sampling/testing program is supplier verification—particularly if imported food is involved," says VAI's Scioscia. "Before testing begins, make sure the supplier in question is compliant with all food safety regulations." After that, "high-risk products" and "suspect products" should always be tested first. If the food processor has proper lot tracing technology in place, then its degree of confidence should be high, according to Scioscia.

Under the Food Safety Modernization Act (FSMA), FDA-regulated food processors must "comply with the requirements for hazard analysis and risk-based preventive controls [HARPC]." HARPC includes a series of preventative steps and intervention measures such as antimicrobial usage, according to DuPont's Carmack. Therefore, sampling and testing should be set up in a way that most accurately verifies all processes are working smoothly and identifies any gaps in the overall food safety program.

"To help identify best practices for mitigating risk associated with raw foods and ingredients, certification organizations establish working groups that combine the expertise of industry, academics, regulators and test kit manufacturers to establish statistically justified sampling plans, such as the Standard Method Performance Requirements [SMPRs] being created by AOAC International [www.aoac.org]," says Carmack. These requirements help ensure the safety of products based on key findings from the creation of best practices for more established areas such as the beef industry. For example, investigations suggest that, due to the sporadic nature of contamination, increasing the standard sample size for food testing from 25 grams may help detect pathogenic organisms. "Based on the requirements developed, we as test manufacturers can design and validate test methods that match

the mandated regulations and also fit well into the current food safety plans of food producers," states Carmack.

How many samples should you take? That is the question. Surak points to the beef trim industry. The N60 plan (where n = 60 samples) is the basis for the International Commission on Microbiological Specifications for Foods (ICMSF) Case 15 sampling plan.3 For instance, many beef trimmings weigh in at 10,000 lbs. or less, depending on the number of units in the lot, and are usually collected and transported in 2,000-lb. totes; the totes are often grouped into a five-combo lot or whatever size a process requires. Typically, 60 samples from a lot are combined into a 375-gram unit for analytical testing.4

"N60 sampling gives you a 95 percent assurance that 5 percent of your lot is contaminated. That's a very high contamination rate for the pathogen," says Surak. With E. coli, of course, no processor wants any of the bacteria reaching the public. Surak points to an example of an incoming lot of trim in 20 totes of 2,000 lbs. each—40,000 lbs. total. Considering one hot spot might represent two to five lbs. of beef, what number of samples should be taken? The N60 sampling program specifies that for a 95 percent assurance that 0.1 percent of the beef is contaminated, a processor would have to test 3,000 or more samples. But who can afford to do this number of tests?

The above situation can be partially remedied by passing this responsibility up the supply chain. "You must have your suppliers do testing as well," says Surak. This is why there are programs like GFSI schemes, which provide some confidence suppliers are doing their part to reduce risk with proper cleaning and sanitizing. Still, processors must ask suppliers how they measure their effectiveness in controlling pathogens and allergens—what their key indicators are.

More rapid today than yesterday

It wasn't too many years ago that rapid test kits for Salmonella and other bacteria took several days to get results, and some processors shipped product to distribution centers while they waited for test results. Today, many rapid test kits can provide results in much shorter time periods (e.g., 12.5 hours for Neogen Listeria and Salmonella spp. tests). The advantage is that the samples don't have to go out to the lab, especially when processors don't have their own internally staffed labs.

Most rapid protocols require the same kind of preparation of a food sample as traditional (slower) tests, but they do not need further preparation such as serial dilution (often needed in traditional culture methods to be able to read plate counts), says Alan Traylor, MOCON business manager-microbial detection. With the oxygen depletion method, the initial sample is diluted only once before being placed in a special sensor vial. Then software drives the instrument to determine the result without further operator involvement.

Rapid tests tend to be extremely reliable, says VAI's Scioscia. "The rapid test for Salmonella has been AOAC certified to detect one cell in 25 grams in various products, such as meat, poultry and processed foods. Rapid testing is inexpensive and easy to use and requires minimal training, so it offers several key benefits to processors that want accurate testing while reducing overall costs."

"Different types of rapid tests are available to detect specific foodborne pathogens, and these methods can vary in accuracy,

simplicity, cost, speed, etc.," says DuPont's Carmack. "Some rapid screening methods are based on bacterial traits or behavior, such as antibody response; however, these tests can cross-react with nonpathogenic bacteria exhibiting a similar response, affecting the test's specificity."

Other rapid methods are based on molecular technology such as the polymerase chain reaction (PCR), which addresses the unique genetic structure of the bacteria and produces highly accurate results, according to Carmack. "For example, the DuPont BAX system, which pioneered the use of PCR in commercial food safety testing, includes a wide portfolio of certified assays to detect Salmonella, Listeria, E. coli O157:H7 and STEC, Campylobacter, Staphylococcus aureus and other organisms of interest to the food industry." This DNA-based detection system performs as well as or better than standard culture methods, but with a significantly faster time to results. PCR technology also allows the development of tests that can detect different bacteria or different species of the same bacteria in a single process, providing additional time savings, according to Carmack.

For nonspecific bacteria, other molecular methods that identify and characterize unknown isolates can be used. For example, the automated DuPont RiboPrinter system not only provides a genus and species identification, it also creates a genetic "fingerprint" for strain-level comparisons to help control the microbial environment in a food production facility. This type of technology is highly useful for advanced applications such as epidemiology tracking and controlling unwanted bacteria.

"There are multiple test methods for different pathogenic bacteria," says Joe Heinzelmann, Neogen market development manager. "For example, Neogen's assays for Salmonella species range from dehydrated culture media to DNA-hybridization technology, antibody-based lateral flows and isothermal nucleic acid amplification. These different technologies allow for different levels of specificity, accuracy, time to results or ease of use. For instance, the lateral flow devices can be appropriate for environmental Salmonella spp. tests, but a more accurate and specific assay would be needed for the pathogenic STECs in beef trim." Neogen offers a range of products from NeoSeek (rapid confirmation of STECs) to the easy-to-use Reveal 2.0 devices.

Different technologies have nuances, making them more suitable for different applications based on the needs of the user.

Sometimes, processors can use a more general rapid test to get a handle on potentially larger issues, such as E. coli. "The rapid tests that identify total viable counts [TVCs], also known as aerobic plate counts [APCs], give you an estimate of the total aerobic bacteria, without specifics," says Traylor. "There are also other screening tests that can identify a class of bacteria such as total coliforms [bacteria that live in human and animal guts]. These tests are worthwhile because they allow the processor to focus on the few lots that may have a high level of contamination and do further, more detailed tests on those." However, identifying tests are still very expensive and time consuming to prepare, so screen tests are necessary to save time and money.

"Rapid testing kits in the food industry should be fully validated against classical methods," says James Cook, SGS food scientific and regulatory affairs manager. If properly validated, the rapid tests are reliable. Testing scope and maximum limits are defined for product groups and can vary

according to the country in which they are used, he adds.

3M Food Safety's 3M Molecular Detection Assay Salmonella was recently validated through AOAC International as a First Action Official Method of Analysis (OMA method number 2013.09) for the detection of Salmonella in selected foods. A complete review of the study conducted for this AOAC-OMA validation will be published by the Official Methods of Analysis of AOAC International in an upcoming edition of the Journal of AOAC International. 3M's Molecular Detection Assay Salmonella was introduced in December 2011 at the same time as its Molecular Detection system.

In addition to test kits for bacteria, there are rapid mycotoxin test kits that are capable of producing results in as little as three minutes. Some quantitative methods may require from seven to 10 minutes depending on sample type and the range of detection needed, according to VICAM's Jackson. Simple lateral flow strip tests, such as the company's Vertu Afla-V, allow nontechnical users to obtain actionable data in minutes. AflaTest with a fluorometer has a six-minute test time and carries AOAC and USDA-GIPSA approvals, which are desirable for facilities where HACCP or quality management systems specify a method must have this type of validation. For more detailed results, processors can send samples to third-party labs that use liquid chromatography methods to simultaneously analyze multiple mycotoxins in a single sample run.

Where's the ROI?

With FSMA in place, FDA can hold food companies accountable for preventing contamination, testing and proving their processes are safe and keeping records, says Scioscia. Fortunately, there are software systems that can help processors record the results of their test procedures and have the data available at a moment's notice when FDA requests it.

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"Recalls can be devastating for food companies in terms of significant revenue loss, remedial costs and brand damage," says Carmack. "Some estimate the impact of the recent peanut butter recalls at $1 billion in lost production and sales for US peanut producers. Many of these recall cases were determined to have been post-process contamination events, suggesting standardized environmental monitoring programs for Salmonella, similar to the programs currently in place for Listeria, can be used to mitigate this risk in the future. These outbreaks also emphasized that even where operations have not been considered at high risk for Salmonella contamination, a routine environmental and finished product testing program is still necessary."

"The ROI is really a risk reduction process," says MOCON's Traylor. "What is the cost of a recall or destroying the lot? For rapid tests, what is the value of a speedy answer?"

Priceless.