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AUGUST/SEPTEMBER 2013

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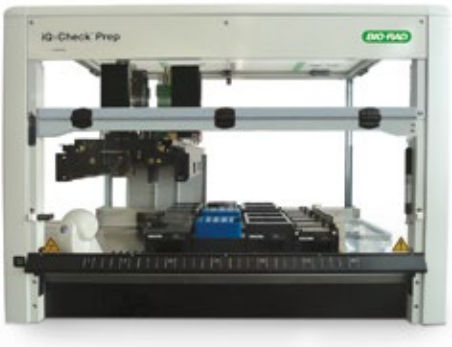

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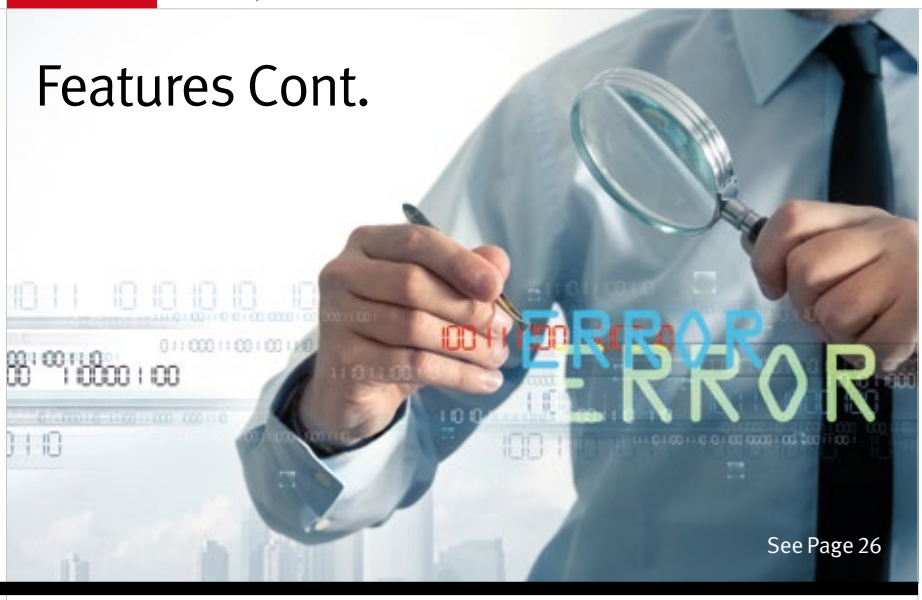

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From The Editor

At press time, the FDA finally released two new proposed rules under FSMA: The Proposed Rule on Food Supplier Verification Programs for Importers of Food for Humans and Animals and the Proposed Rule on Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.

While industry trade associations are applauding the safety rules on imported food (indicating the rules are long overdue), the release of these rules have shed some light for consumers who are now realizing how much the food they consume is in fact imported. According to the FDA, imported food comes into the U.S. from about 150 different countries and accounts for about 15 percent of the U.S. food supply, including about 50 percent of the fresh fruits and 20 percent of the fresh vegetables Americans consume. In addition, the FDA typically only manages to inspect 1 to 2 percent of all imports.

The new rules couldn't have come at a better time to help ease consumers' worries of the food supply. This year alone, there have been several import-related food scares. There was the *Salmonella* outbreak in 18 states from cucumbers that originated in Mexico. Then there were *Salmonella* strains that occurred in nine states from Tahini sesame paste from Turkey. And more recently, the Hepatitis A outbreak that occurred in nine states due to Turkish pomegranates in a frozen berry mix.

FDA's new rules would help eliminate contaminated products like these from finding their way into American households. According to the FDA, under the proposed rules, importers would be accountable for verifying that their foreign suppliers are using prevention-oriented food safety practices and that their food is meeting U.S. requirements. This means importers are required to have a plan for imported food, including identifying likely hazards and providing proof that these hazards are indeed being controlled.

However, there are already some questions surrounding these rules, such as the discrepancy regarding on-site inspections, which will have to be addressed in the coming months when the rules are available for public comment. In a time where consumers have the power to destroy a business due to a recall, importers should be making every effort to ensure the new rules truly make sense. In fact, industry professionals are urged to voice their opinions on all the proposed rules and not rely on Washington's lack of understanding of the food supply to decide their future.

Marian Zboraj
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FARM TO FORK SAFETY

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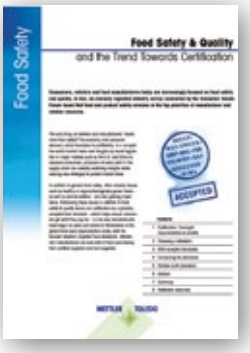
NEWS & NOTES



Guidance on Certification

Mettler Toledo's "Food Safety and Quality and the Trend Towards Certification" whitepaper gives an overview of the regulatory and consumer pressures behind increasing food safety certification. It looks at the GFSI benchmarks as well as the four accepted standards most widely used—the BRC Global Standard, FSSC 22000, International Featured Standard, and SQF 2000. The whitepaper helps manufactures find the standard that best suits their market needs and customer preferences. It also indicates parameters that can be used to evaluate the most appropriate certification standard to pursue. Go to www.mt.com/uk-foodsafetyquality for a copy.

New Traceability Readiness Programs

Two new readiness programs are available from GS1 US to help companies in the food industry implement and improve product traceability processes by leveraging GS1 Standards: The Seafood Traceability Readiness Program and the Dairy, Deli, Bakery Traceability Readiness Program. Companies that subscribe to these self-paced, online programs will learn how to establish or enhance an effective traceability program; identify, capture, and share product data along the supply chain with GS1 Standards; improve business efficiencies; and gain visibility into supply chains. Companies will also understand how to comply with traceability-related requirements of the Bioterrorism Act and the FSMA.

AUFSI Achieves 'Institute" Status

The Auburn University Food Systems Initiative (AUFSI) recently accomplished the goal of becoming an institute thanks in part to its multi-disciplinary faculty and successful ventures, including bringing in some $11 million in extramural funding. AUFSI is dedicated to improving the food system, which includes the growing, harvesting, processing, packaging, transporting, marketing, consumption, and disposal of food. The institute, jointly funded by the Alabama Agricultural Experiment Station and the Office of the Vice President for Research, brings experts from a variety of disciplines and departments together in order to collaborate on improving the safety and quality of the U.S. food supply.

Establishing a Food Defense Plan

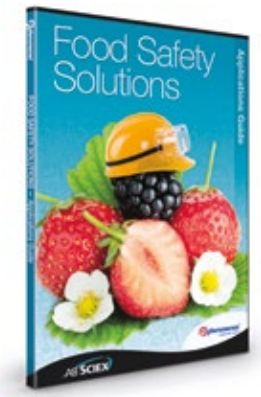
Available free of charge from the FDA, the Food Defense Plan Builder is a software program designed to assist owners and operators of food facilities in developing personalized food defense plans. This tool harnesses existing FDA tools, guidance, and resources into one single application in order to protect food products against intentional contamination incidents. To download, go to www.fda.gov/food/fooddefense.

Produce Recall Ready Program

United Fresh's expanded Recall Ready Program services now includes new training and education opportunities that leverage the expertise of the food industry's leading professionals in food safety, legal and regulatory counsel, and crisis communication. The Recall Ready Risk Management Webinar and Recall Ready Training Workshops are designed to help produce industry companies prepare for and respond to virtually any recall event.

AOCS Receives A2LA Accreditation

The A2LA (American Association for Laboratory Accreditation) Program accredits American Oil Chemists' Society (AOCS) for its Reference Material Producers. Formal accreditation ensures AOCS Certified Reference Materials (CRM) are produced and handled according to the criteria outlined in the *ISO Guide 34:2009*. The AOCS CRM program provides control materials for third-party qualitative testing of transformation events in agricultural commodities derived through modern biotechnology.



Food Safety Applications Guide

Phenomenex's 92-page *Food Safety Solutions* guide is available in print and digital format. It presents 41 complete applications for all of the frequently requested food compound classes and draws on all analytical techniques—sample preparation, HPLC, UHPLC, LC/MS, and GC/MS. The guide contains sections on analysis of contaminants, pesticide residues, allergens, and fraudulent practices. Requests for the guide can be made at www.phenomenex.com/FSguide.

Business Briefs

Thermo Fisher Scientific opens its Product Assurance Services and Solutions (PASS), a new product contamination evaluation facility in Sugar Land, Tex. to help food manufacturers address safety and quality issues. It provides packaged product evaluations due to foreign object contamination concerns and reviews products for processing anomalies and missing components.

InfinityQS International establishes a strategic partnership that enables **ATS International B.V.** to offer ProFicient, InfinityQS' enterprise quality hub, to manufacturers with facilities and suppliers around the world.

Terminix opens a new branch in Santa Barbara, Calif. to expand its pest control offerings to commercial customers while also lessening commute times for sales and service personnel.

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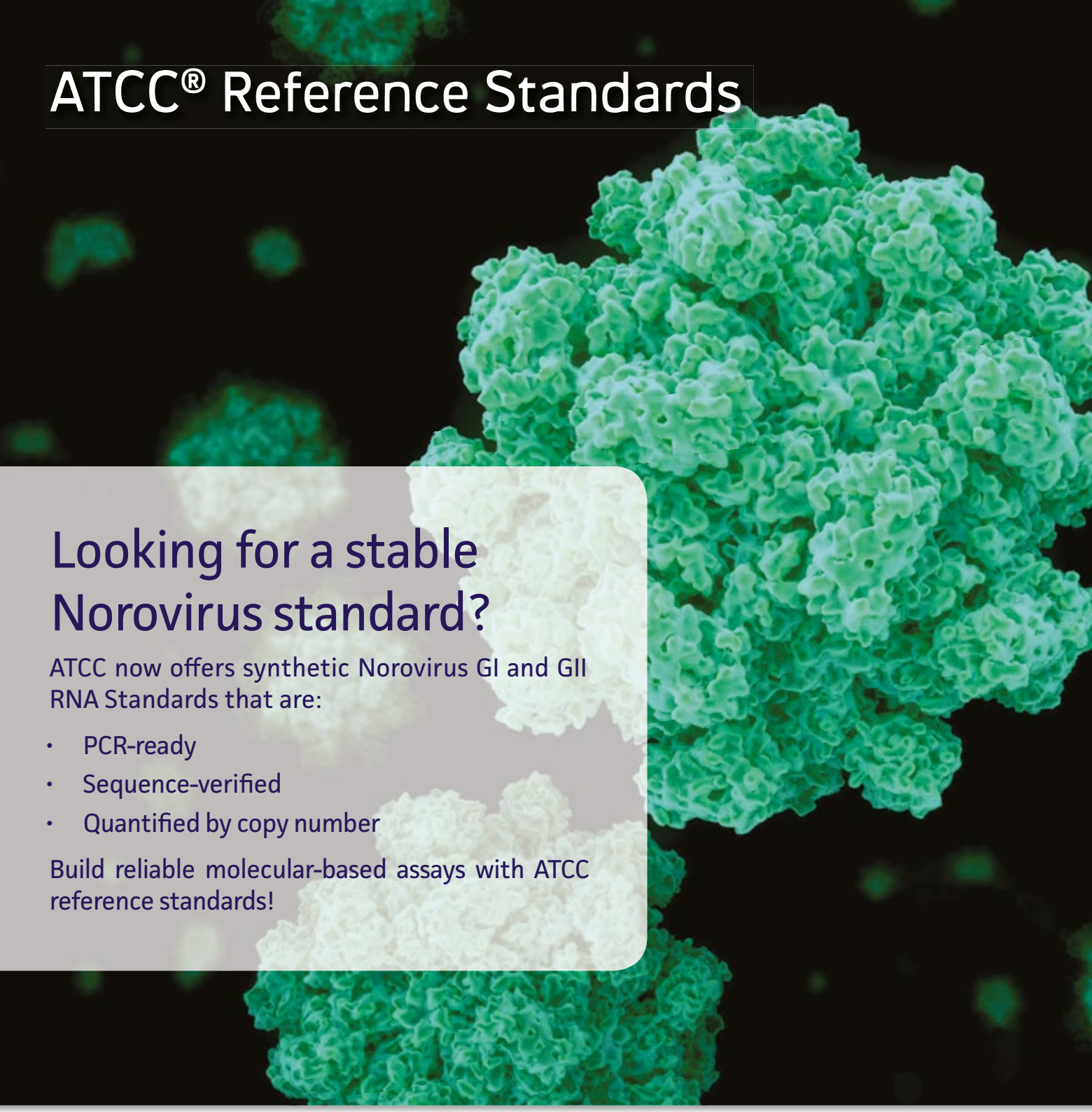

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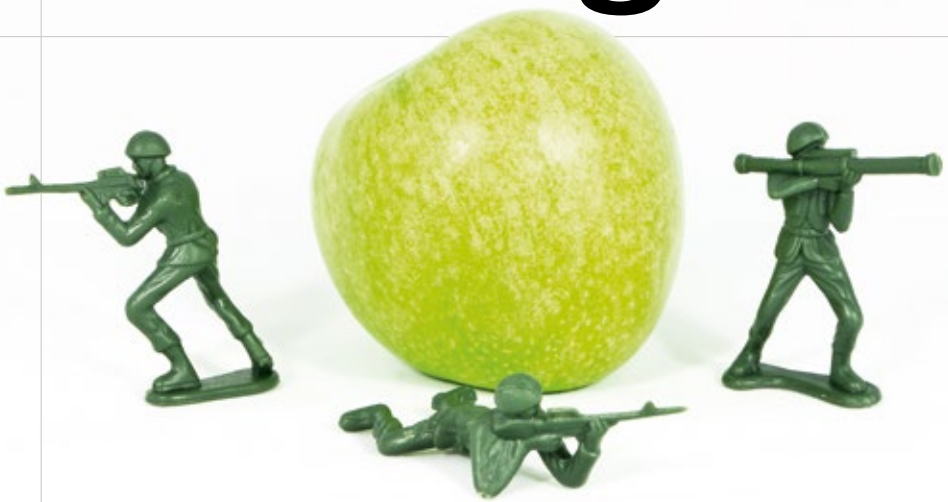
Washington Report



Food Defense and Protection

Exploring how to safeguard the nation's food system against intentional contamination and adulteration | BY **TED AGRES**

Much of the focus on food safety has been on preventing unintentional or accidental contamination of products and ingredients by bacteria and other naturally occurring pathogens and agents. But specialists in government, industry, and academia are quietly exploring ways to protect the nation's food supply against intentional contamination and adulteration from sabotage, terrorism, economic fraud, and other illegal actions.

In some ways, their task is made harder because intentional contamination can occur when insiders—company officials, disgruntled employees, or terrorists who have infiltrated the workforce—perpetrate their crimes as they go about everyday activities. "It's very difficult to prevent an employee at a company manufacturing high-risk foods from engaging in terrorism because they have access to the facility and adding ingredients may be part of their job," says David Acheson, director of the food and import safety practice at Leavitt Partners and a former FDA associate commissioner of foods.

The spectrum of intentional food contamination ranges from extremist groups (terrorism), to disgruntled employees (sabotage), to company officials engaged in economically motivated adulteration (counterfeiting and fraud). Examples of the latter include unapproved enhancements, such as the addition of melamine to milk to increase its apparent protein value; mislabeling, such as selling sunflower oil as olive oil; and substitution, such as using beet sugar in place of honey. A 2010 study by A.T. Kearney for the Grocery Manufacturers Association placed worldwide losses from economic adulteration and counterfeiting of food and consumer goods at $10 to $15 billion annually. One adulteration incident alone can slash a food company's annual revenue by 2 to 15 percent, the report said.

Devastating Food Terrorism

While counterfeiting and food fraud extract their economic and health tolls on consumers, an act of widespread food terrorism could be even more devastating and weaken confidence in the nation's overall food system. While FDA has had a long interest in food defense, the September 11, 2001 terrorist attacks "seriously ramped it up," Acheson says. "Food defense moved from being a slow-paced, low-priority project to a high-paced, high-priority one after 9-11," he says. During those years, the FDA explored ways to help companies understand the importance of identifying and eliminating vulnerabilities in their products and processes. But because a terrorist attack on the nation's food supply did not materialize, interest in food defense again began to wane—at least until recently.

Things changed with the enactment of the Food Safety Modernization Act (FSMA) in 2011. Section 106 of FSMA requires the FDA to conduct a vulnerability assessment of the nation's food system, determine the types of science-based mitigation strategies or measures to protect against intentional adulteration of high-risk food, and, in coordination with the Departments of Agriculture and Homeland Security, publish regulations and guidance to implement those strategies and measures.

"FDA will be requiring companies to pay attention to food defense and will be writing rules and regulations around that," Acheson tells *Food Quality & Safety* magazine. As with most other regulations required under FSMA, the FDA has not issued those food defense rules on schedule. In fact, they are not expected until after regulations on import safety and the foreign supplier verification program, preventive controls for animal food, and third-party audit certification are published this year. This means the food defense rules may not be issued until 2014.

Assessing Vulnerability

But the FDA has not been neglecting food defense either. In April, the agency met one of the FSMA's requirements by issuing a report assessing the vulnerability of the nation's food system. The analysis is based on vulnerability assessments conducted jointly with USDA, FBI, and the Department of Homeland Security of more than 50 food and agriculture products and processes during 2005 to 2008. The goal was to identify processing steps of highest concern, potential mitigation strategies to

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reduce these vulnerabilities, and gaps in research. A key concern was to do all this without disclosing sensitive information such as vulnerabilities in specific facilities, commodities, or processes.

The methodology used is called CARVER + Shock, a relative risk-ranking tool originally developed by the military and since used by the food industry to identify vulnerabilities. Six of the attributes include:

- ***C***riticality: The measure of public health and economic impact,
- ***A***ccessibility: The ability to physically access and egress from the target,
- ***R***ecuperability: The ability of a system to recover from an attack,
- ***V***ulnerability: The ease of accomplishing an attack,
- ***E***ffect: The amount of direct loss as measured by loss in production, and
- ***R***ecognizability: The ease of identifying the target.

The seventh attribute ("shock") was added to assess the combined health, economic, and psychological impacts of an attack within the food industry. CARVER + Shock "can determine the most vulnerable points in the infrastructure and focus resources on protecting the most susceptible points in the system," the FDA report says.

Because CARVER + Shock is a relative risk ranking tool, there is no equivalence between a score value for a processing step in one industry to the same score value for another processing step in a different industry. With support from the Battelle Memorial Institute, the FDA reevaluated the data to determine common attributes and activities between processing steps. It found that some processing steps repeatedly rose to the top. For example, 14 of the 47 most vulnerable processing steps involved mixing, grinding, or coating as the primary function and which could result in "probable homogeneous distribution of a threat agent into the product." Twelve of the 47 steps involved the staging, preparation, or addition of minor ingredients. Six involved receiving while five others involved storage. The rest were an assortment of other activities. "The processing steps where mixing occurs or secondary ingredients are staged, prepped, or added prove to be critical processing steps in many assessed products," the report said.

The FDA concluded that four processing steps trigger the highest concerns, and if present in a facility, should be given priority consideration:

- Coating, mixing, grinding, and rework activities,
- Ingredient staging, prep, and addition activities,
- Liquid receiving and loading activities, and
- Liquid storage, hold, and surge tank activities.

Processing steps involving liquids carry far greater risk than handling or storage of dry ingredients, the report noted. The FDA is encouraging facilities to perform their own private, custom assessments using CARVER + Shock or another software tool to determine the risk of intentional contamination. Toward this end, in May the FDA unveiled a free software program called the Food Defense Plan Builder, a tool companies can use to privately and confidentially perform their own vulnerability assessments. "The FDA is committed to providing best practices and resources to support industry as we pursue our shared goal of protecting our food supply," said Michael Taylor, FDA deputy commissioner for foods and veterinary medicine in a statement. "We strongly encourage companies to take full advantage of the Food Defense Plan Builder."

Software Controversy

Acheson says the FDA will eventually require companies to perform vulnerability risk assessments and implement a food defense plan. Companies hoping to get a head start on this process may choose to use the FDA's Food Defense Plan Builder, figuring that it has the agency's seal of approval, says Bruce H. Becker, president of FoodQuestTQ LLC, a small software development company in Frederick, Md. But Becker and John H. Hnatio, FoodQuestTQ's chief science officer (and president of Projectioneering LLC, another small software company), claim that the FDA stole their patented risk assessment technology and used it to develop Food Defense Plan Builder and four other software risk assessment applications, driving away potential customers.

In May, Becker and Hnatio circulated a 34-page "technical paper" outlining their dispute with the FDA. Included in it was a 10-page rebuttal from the Office of the General Counsel for the Department of Health and Human Services (HHS), FDA's parent agency. "We have uncovered no evidence that FDA or its contractors took or used any trade secrets that you might own," concluded Dale D. Buckley, intellectual property rights counsel for HHS. In June, Becker and Hnatio sent an email to various food companies advising them not to use any of the FDA's free programs if they wished to avoid future liability. "We believe that if the FDA had looked at the facts fairly and did the necessary comparison between the patent and how we implemented the patent to practice, that it was very apparent that it infringed on our intellectual property," Becker tells *Food Quality & Safety* magazine.

Independent of risk assessments, there are other steps that companies can take to ensure the integrity of their supply chain. "From a legal compliance and business risk management perspective, food companies may strengthen safeguards preventing economic adulteration from affecting the food and food ingredients they purchase from vendors by focusing on three key areas," says Sarah Roller, JD, RD, MPH, who heads the food and drug legal practice at Kelley Drye & Warren in Washington, D.C.

These safeguards include: 1) Making sure that vendor qualification programs are rigorous and selection criteria favor vendors whose regulatory compliance track record and supply chain management practices demonstrate a culture of compliance; 2) Ensuring that product purchasing specifications include technical criteria that can be used to detect signs of economic adulteration; 3) Ensuring that supply agreements with qualified vendors include performance standards that require products to meet all applicable legal requirements.

These agreements should "require suppliers to submit to audits and data reporting requirements that ensure the company is equipped with the data and information it needs to verify and substantiate that the products it receives from suppliers meet legal requirements and hold suppliers accountable when missteps occur," Roller tells *Food Quality & Safety*. ■

Agres is based in Laurel, Md. Reach him at tedagres@yahoo.com.

FSMA Update

Preparing for FSMA Compliance: Are You Ready?

Full implementation of the rules will be here before you know it, so make sure you have the necessary pieces in place that will optimize your compliance

BY **JIM BAIL**

By now, your organization has begun preparation to comply with the Food Safety Modernization Act or FSMA. This article provides background on FSMA and highlights some best practices that will help your organization with compliance.

Background

President Obama signed FSMA into law in 2011 and the FDA began publishing proposed rules in January 2013.

The Act makes extensive changes to U.S. food safety laws, most notably shifting focus from reacting to food safety problems to preventing them in the first place. By requiring a risk-based approach to identifying and implementing preventive controls, FSMA places new and more extensive requirements on food manufacturers, processors, growers, and importers. The Act focuses primarily on the following to minimize or prevent food safety hazards:

- Produce safety,
- Imported food safety,
- Mandated inspections on a risk-based schedule,
- Third-party laboratory testing,
- Farm-to-table responsibility, and
- Ability to require third-party certification for high-risk operations.

Another important component of the legislation provides for FDA recognition of accredited third-party audit and certification programs for imported foods—a category that has grown steadily over the years.

Regulatory Update

Currently, the FDA is holding meetings and receiving comments on how to best implement the new law and promulgate effective regulations. Additional updates can be found at www.fda.gov/fsma.

The FDA is required to publish several rules that will be the basis for compliance enforcement once they are made final. These rules are to be presented in draft form to the public for a specified comment period. To date, two of the five proposed FSMA rules related to produce and processing have been published. The public comment period for the two proposed rules has already been extended, but a word of advice: Don't wait.

Start preparing for FSMA now by reassessing your prerequisite programs and Hazard Analysis and Critical Control Points (HACCP) plans. Are SOPs or standard operating procedures current and adequate for their purpose? Has employee training been conducted and documented? The following are some key steps to keep in mind.

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Identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility and food.

1. Develop your Food Safety Plan.

2. Identify, train, and qualify the experienced individual who is responsible for developing the facility's Food Safety Plan.

3. Identify and evaluate the hazards that could affect food manufactured, processed, packed, or held by your facility.

4. Identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that the food you make is not adulterated.

5. Monitor the performance of those established controls.

6. Maintain records of monitoring as a matter of routine practice.

7. If you are importing foods, you are responsible for compliance to FSMA by your foreign suppliers.

Once the basic food safety elements are developed and implemented for your operations, you may not have as much to modify once the final rules are published.

Action Plan

Where to start? It can be summed up in two words: Plan ahead. Companies can begin by performing a basic hazard analysis.

Prepare a written Food Safety plan that documents and describes the procedures used by your facility to comply with the requirements of the Act, including analyzing the hazards and identifying the preventive controls adopted to address those hazards. Your written plan, together with the documentation must be made promptly available to a duly authorized representative of the FDA upon oral or written request.

Identify, train, and qualify your skilled individual who is responsible for developing your facility's Food Safety Plan. Establish your team with clearly defined roles and responsibilities.

Perform a hazard analysis. Identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility and food including:

- Biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives;
- Hazards that occur naturally, or may be unintentionally introduced;
- Hazards that may be intentionally introduced, including by acts of terrorism; and
- Develop a written analysis of the established hazards.

Identify and implement preventive controls, including any critical control points, to provide assurance that:

- Validate your HACCP plan, control points, and limits using objective, scientific, and defensible data;
- The hazards identified in the hazard analysis will be prevented, eliminated, or significantly minimized; and
- The food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 or misbranded under section 403(w) of the Food Drug and Cosmetic Act.

Monitor the effectiveness of the preventive controls you have implemented.

Establish corrective action procedures to ensure that if the preventive are not properly implemented or are found to be ineffective:

- Appropriate action is taken to reduce the likelihood of recurrence of the failure;
- All affected food is evaluated for safety; and
- All affected food is prevented from entering into commerce if the owner, operator, or agent in charge of your facility cannot ensure that the affected food is not adulterated under section 402 or misbranded under section 403(w) of the Food Drug and Cosmetic Act.

Verify that:

- The preventive controls implemented are adequate to control the hazards identified;
- You are making appropriate decisions about corrective actions;
- The preventive controls implemented are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means; and
- There is documented, periodic reanalysis of the plan to ensure the plan is still relevant to the raw materials, conditions, and processes in the facility, and new and emerging threats.

Maintain records for not less than two years, documenting:

- The monitoring of the preventive controls implemented;
- Instances of nonconformance material to food safety;
- The results of testing and other appropriate means of verification instances when corrective actions were implemented; and
- The effectiveness of preventive controls and corrective actions.

Conduct a reanalysis of your preventive controls whenever a significant change is made in the activities conducted at your facility if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard, or not less frequently than once every three years, whichever is earlier. This reanalysis must be completed and additional preventive controls needed to address the hazard identified, if any, must be implemented before the change in activities at the facility is operative. You must revise the written plan if such a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed.

Completing these steps will help companies prepare for FSMA and be ready once the final rules are passed. ■

Additional Assistance

NSF International has developed a free online tool (www.nsf.org/extranet/fsma) to determine compliance readiness and identify areas needing improvement. The 10-minute assessment tool helps identify potential gaps in food safety management systems and provides practical steps to develop and implement an effective control program. Participants receive a customized report upon completion.

Bail is the director of supply chain food safety technical services for NSF International. He can be reached at foodsafetysolutions@nsf.org or 734-827-6844.

GLOBAL FOOD PARTNERSHIPS

How appetizing will FSMA's impact be on international policies and trade?

BY **TED AGRES**

www.foodquality.com

While the FDA and the White House Office of Management and Budget (OMB) slowly roll out regulations to implement the Food Safety Modernization Act (FSMA), regulators in other countries are pushing ahead with standards for such key areas as product traceability, potentially outpacing the U.S. Meanwhile, concern is growing among many food safety experts that expanded FSMA requirements for foreign facility inspections and certifications may trigger a backlash from other nations requiring their own expanded inspections and certifications of U.S. firms and growers.

"If FDA starts to ramp up requirements for imported foods, which they clearly said they are going to, we may see reciprocal challenges or requirements from other foreign countries that will affect U.S. exporters," says David Acheson, MD, director of the food and import safety practice at Leavitt Partners and a former FDA associate commissioner of foods. "I see that as a potential area for U.S. companies to look at."

And as major exporting countries review their food production and certification mechanisms in light of expected FSMA requirements, the desirability of global food safety standards is becoming apparent. "Companies would prefer to understand one set of rules and requirements that are good everywhere. But that's a long way from happening," Acheson tells *Food Quality & Safety* magazine. It would be a "big thing" if global standards were established, adds Wayne Ellefson, senior program manager, Covance. "It's an interesting concept but it will take awhile before it happens. In the current day it may not be practical, but in the future, it may come to exist," Ellefson tells *Food Quality & Safety*.

Facing Reality

As pleasant as speculation about global standards may be, the reality is that many countries are struggling to formulate national standards that will comply with expected FSMA requirements while also fitting within their own political and business environments.

"We have a deep commitment to work with the U.S. to achieve the least-burdensome approach of achieving compliance with the Food Safety Modernization Act and all other U.S. import requirements," says Chris Parker, agriculture minister-counselor for the Embassy of Australia in Washington, D.C. "Given that there are equivalent food safety outcomes contained in Australia's food export systems, we believe that Australia is already in strong compliance with the Food Safety Modernization Act. The only significant effect we see is increased audit frequency," Parker said during a four-hour panel discussion on FSMA at the Food Safety Summit in Baltimore in April.

His concerns were echoed by Hugo Fragoso, director general of animal health at SENASICA, Mexico's agency for National Health Service, Food Safety, and Quality. "We need to comply with regulations of food safety not only with FSMA but we are trying to establish a national program to comply with every country in the world," Fragoso told the gathering. "Mexico is working to educate our people to know about FSMA. We understand it's very, very important for us to comply with FSMA. FDA and SENASICA should work better and coordinate on food safety," he said.

Craig Henry, a director at Deloitte & Touche LLP and panel moderator, noted

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that "the diversity of approaches among the different countries to food safety is very evident, but there are also many commonalities." Among the latter is the need for food traceability standards. Currently, the FDA is evaluating comments submitted to recommendations made by the Institute of Food Technologists (IFT). In a recently released report, the IFT recommended that FDA establish a uniform set of recordkeeping requirements for all regulated foods and not allow exemptions based on risk categories or the size of the firm involved.

After considering public comments, the FDA will submit recommendations to Congress on traceability standards and prepare proposed regulations—steps required by Section 204 of FSMA. While the law requires FDA to establish recordkeeping requirements only for "high-risk" foods, the IFT recommended that these requirements be extended to all food categories because "low-risk" products quickly become "high-risk" when an unexpected outbreak occurs.

Canada appears to be outpacing the U.S. in terms of implementing traceability. On June 2, the Canadian Food Inspection Agency (CFIA) published a discussion document outlining in general terms proposed regulatory mechanisms for product traceability as well as for licensing, preventive control measures, foreign inspections, and foreign regulatory systems equivalency. According to "A New Regulatory Framework for Federal Food Inspection," Canada will implement "at a minimum" the international standard for traceability established by the *Codex Alimentarius Commission*—namely recordkeeping to identify product movement one step forward and one step back in the supply chain. Retailers who are covered by the regulation would not be required to trace food products sold to the final consumer, however.

"The question is whether Canada can draw the rest of the world in traceability."

—**DAVID ACHESON**, *MD, director of the food and import safety practice, Leavitt Partners*

"There is a big opportunity for Canada under the Safe Food for Canadians Act to move forward more quickly than the U.S. on traceability standards," Henry says. "They can put a stake in the ground and state, 'This is what we will require from anyone moving product into my country or [from product that is] domestically produced.'"

Cameron Prince, vice president for inspection modernization at the CFIA, says implementation of the traceability regulation is "fairly imminent in terms of how bureaucracy goes" with a final regulation expected by the end of 2014 or in early 2015. "It would be naïve to say this will be nice and smooth because there are many perspectives on this," Prince told the Food Safety Summit. "Some industry players say they don't want the long arm of the government involved directly with information like that and prefer the government to have just an oversight role. Others want to see more rigorous traceability standards in place. So the debate is just beginning." Combined with an already established identification framework for beef and pork, the traceability mechanism would create a "farm-to-fork approach," according to Prince. "It's a broad vision and many countries share that vision. The question is how to get there."

But whether Canada's traceability mechanism will become the *de facto* international standard remains to be seen. "The question is whether Canada can draw the rest of the world in traceability," says Acheson. "Typically, they haven't been able to [influence the world] because they are too small. Europe and the U.S. could, but for Canada, maybe, maybe not."

Mutual Recognition

Australia's Parker ties growth in world food trade with the way governments cooperate and recognize each other's food safety systems. "This is no small body of work by any stretch of the imagination. But we see the Food Safety Modernization Act as an opportunity for us to work with FDA and, through some of those issues, work out exactly what each of our systems should be doing to provide confidence in both countries over their food safety systems," he says.

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"The additional audits mandated by FSMA may be viewed by some in industry as regulatory duplication," Parker explains. "Accordingly, Australia is working with the FDA and the outcome we are hoping for is for simplified compliance arrangements under which Australia's regulatory system is recognized, similar to how New Zealand's regulatory system is recognized by the FDA."

This is in reference to the fact that, in December 2012, the FDA and New Zealand regulators signed a voluntary "systems recognition agreement" acknowledging that each other's food safety system provides "comparable" levels of safety assurances. Expected benefits from this first-ever arrangement will include enhanced information sharing to allow food products to be imported without duplicated inspections.

Under such a comparability agreement, "nations can concentrate more resources, including inspections, on foods that present a greater risk, providing for improved food safety overall," wrote Deborah M. Autor, deputy FDA commissioner for global regulatory operations and policy, and Michael R. Taylor, deputy

"Hundreds of customs brokers have served notice that they will no longer act as U.S. agents for any foreign food facility."

—**MARK FEDUKE**, *director of trade compliance, VLM Foods*

FDA commissioner for foods and veterinary medicine in a Dec. 13, 2012 blog posting. While comparability certification is not required for countries to export food into the U.S., "any country that believes it can meet the very high bar will have the option of seeking recognition."

An FDA systems recognition pilot project is currently underway in Canada. "Canada and the United States are working in parallel towards strong food safety systems. Enhancements over the next couple of years will mean a stronger food safety culture, safer food supply, better trade opportunities, and better regulatory cooperation," says Prince.

According to Katherine Bond, director of FDA's Office of Strategy, Partnerships, and Analytics, the agency has many approaches to facilitate increased collaboration. "Local, state, federal, and international regulators should ultimately form one network protecting our respective consumers to build one global product safety net. FDA is committed to working with specific countries to identify which approaches make the most sense," she told the Food Safety Summit.

Partnering with food agencies in other countries is one of four "pillars" the FDA has established to improve product safety. The others are:

- Building global information systems and networks and proactively share data with peers,
- Expanding intelligence gathering with an emphasis on risk analytics, and
- Allocating agency resources based on risk leveraging the combined efforts of government, industry, and public and private third parties.

FSMA includes several provisions intended to improve imported food safety, including the Foreign Supplier Verification Program, third-party auditor accreditation, and the voluntary qualified importer program, among others. The White House OMB is still reviewing these regulations and some of them are expected to be released this year for public comment. Under the expected rules, imported foods will be held to the same safety standards as domestic foods, and importers and foreign suppliers must have controls in place to ensure product safety. Over the next several years, assuming adequate funding, the FDA will spend nearly $1.4 billion to hire hundreds of new staff and pay third-party private contractors to inspect foreign food suppliers, especially for high-risk foods.

Under the law, the FDA must establish offices in foreign countries and enter into agreements with foreign countries to facilitate inspections of their facilities. This expanded inspection and verification regime has the potential to trigger reciprocal requirements from other countries. As Mexico's Fragoso puts it, "We need to recognize Mexico [will be] having third parties in the U.S. and the U.S. having third parties in Mexico." In South Korea, lawmakers have introduced legislation that would allow Korean authorities to inspect food manufacturing facilities in foreign countries and require all food importers to supply the addresses of foreign manufacturing facilities before filing an import declaration.

"While FSMA will surely lead to improved food safety outcomes, one has to consider the potential for unintended consequences such as the impact on America's export food supply chain when our trading partners create their own FSMA-like administrative requirements," says Mark FeDuke, director of trade compliance at VLM Foods Inc., an international supplier of processed foods. FSMA will require U.S. importers to certify that foreign products meet all domestic food safety standards. In many cases, this means a U.S. agent or representative of a foreign company may be held liable for FDA reinspection fees and product recall-related fees and fines, he says.

"Given the potential for open-ended liabilities, hundreds of customs brokers have served notice that they will no longer act as U.S. agents for any foreign food facility," FeDuke tells *Food Quality & Safety* magazine. "Meanwhile, surety providers are hawking their coverage with premiums to be paid by those entities that have sufficient risk appetite to continue acting as U.S. agents for foreign food facilities." If a Korean food facility ends up paying a U.S. agent as a condition of market access in the U.S., "why wouldn't they, and all the dozens if not scores of other countries buying American food exports, impose the same requirements on U.S. food facilities?" FeDuke adds.

"To me, harmonizing the test methods on a global basis is an issue of concern."

—**WAYNE ELLEFSON**,
senior program manager, Covance

Quest for Global Standards

It's possible that these and many other issues would be more easily addressed if countries adopted a uniform set of food safety standards established not by any particular private certifying organization but by an international body such as the United Nations, says Covance's Ellefson, who is coauthor of a recent book, *Improving Import Food Safety,* that examines the differing approaches to food safety problems taken by the U.S., Latin America, Europe, and Asia.

While such an outcome is unlikely to happen anytime soon, Ellefson says there is an immediate need to standardize laboratory testing not only internationally but within single countries, including the U.S. "How do you know if you will get the same test result from laboratory to laboratory?" Ellefson asks. "How do you know if they are using the same harmonized methods? Expand that to the whole world–Canada, Europe, Asia, South America–how do you know the quality of the methods they are using for testing is equivalent in all locations? To me, harmonizing the test methods on a global basis is an issue of concern."

The issue is being addressed. For example, AOAC International (formerly the Association of Analytical Communities) is one of several groups developing analytical and other standards for global acceptance. AOAC has assembled an expert stakeholder panel on infant formula and adult nutritionals and, with industry funding, is developing standard method performance requirements for nutrients and analytical methods for validation studies. "They are working on getting global buy-in. They are trying to carry this to food items other than infant formula, but you have to start somewhere," Ellefson says.

As Acheson puts it, the global food supply situation is "already critical and is becoming increasingly more so."

"It's also becoming increasingly challenging and complicated through these regulatory requirements and hurdles and potentially reciprocal arrangements. Unquestionably, this is a very complex field that needs to be watched carefully over the coming months and years," Acheson says. ■

Looking for more information on global food trends?
Then check out this issue's online exclusive, "Is Europe Outpacing the U.S. in Traceability?" The article explores how Europe's strict testing has potential to affect the flow of information and research results across multiple locations. Available at www.foodquality.com under the August/September issue.

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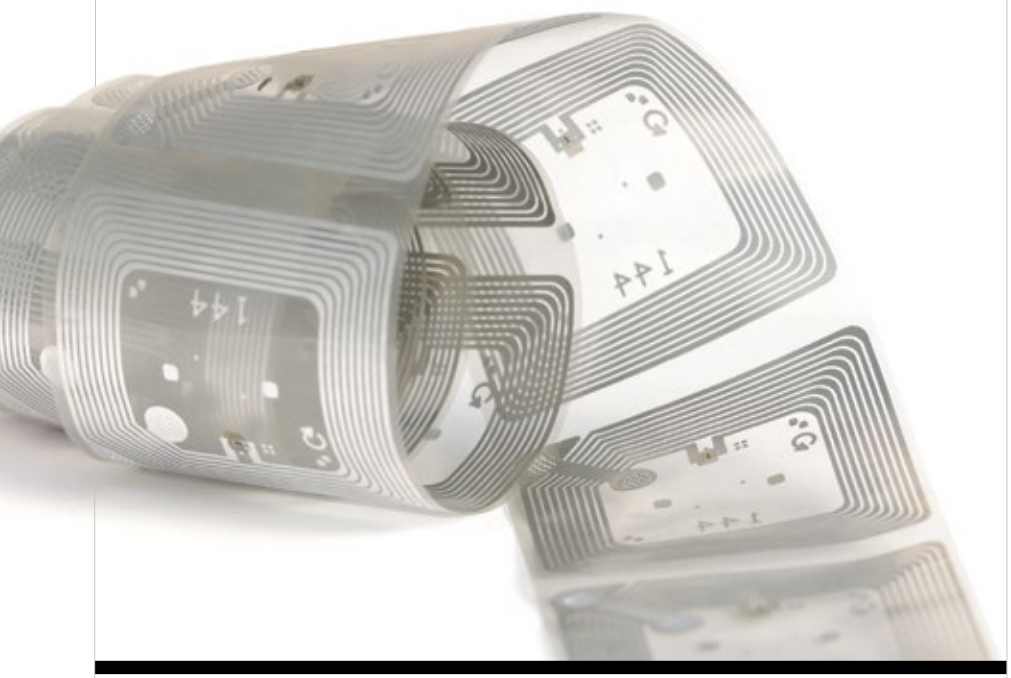
RFID Sanitation Monitoring Meets Demands of Digitized World

Using RFID technology can simplify ATP test data plan creation and test data collection and interpretation

BY **JAMES TOPPER**



For those of us old enough to remember when they were initially available, those first clunky mobile phones were mind-blowingly amazing. They were absolutely magical—you could actually make a call from the middle of a field a mile from your house without a mile-long phone cord. The technology was immediately a must-have for those with the means. But looking back at those days now, sitting with our do-everything smartphones in our pockets, the technology of the first mobile phones seems stone-age primitive. If you asked it a question, it responded with a stony silence.

Parallels can be drawn to a similar technological revolution that has occurred with the adenosine triphosphate (ATP) sanitation monitoring systems designed for use in the food industry. When they first became available in the 1990s they were simply astonishing. In just seconds, ATP systems could determine if food contact surfaces were microscopically clean. They provided an instant solution to verify the effectiveness of critical sanitation protocols needed to help ensure the safety and quality of food products. However, nowadays the methodology used in the early ATP systems seems pretty primitive.

The earliest ATP units were bulky and big, and while certainly not bad when compared to other alternatives for monitoring surface cleanliness, including growing cultures, their features were limited compared to today's options.

Rob Soule, sanitation product manager, Neogen Corp., sees the evolution as being, "all about the information" the ATP systems provide. Where in the past the immediate pass/fail determination for a site was enough, today's more sophisticated managers want to look at trends and deeply analyze their test results to better understand the effectiveness of their sanitation efforts. They also want to improve sampling programs to ensure that sites provide a representative sampling of the facility and get the attention each one deserves.

"RFID technology has many uses and we applied it to sanitation monitoring to help our customers develop their sanitation monitoring programs. We didn't invent RFID technology," states Soule. "We simply took this terrific technology that's been used in everything from inventory tracking to cattle identification to toll booth access and figured out a way to automate some of the things that our customers were telling us take up too much of their time."

Easing Test Plan Creation

As in the early days of ATP system usage, each facility is still required to develop a sanitation monitoring program that is unique to that facility. Whether the program is part of the operation's Hazard Analysis and Critical Control Points (HACCP) program, sanitation standard operating procedures (SSOP), Food Safety Modernization Act (FSMA) compliance, or similar sanitation monitoring initiative, the goal is the same: Identify critical control points in the facility that are the

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The addition of an objective for a specific test site displayed in a line graph (e.g., 195 relative light units in orange above) provides an easy comparison between actual test site results and the cleanliness objective for the site.

toughest to sanitize effectively, and the likeliest to pose risks of contamination to that facility's food products.

Once the higher-risk points are identified, a daily test plan can be developed to monitor the effectiveness of the facility's sanitation program by testing any or all of the points. Because most facilities have more critical control points than can be realistically tested on a daily basis, in the past supervisors had no other choice but to take the time to attempt to tailor daily test plans to best ensure the overall cleanliness of the facility.

With today's ATP sanitation monitoring systems, all a supervisor has to do is identify test sites just once as either being mandatory, meaning they are tested every day, or as being of lower risk, which means the sites are among those that are tested on a random basis. With this information, a test plan can be automatically created on a daily basis—completely eliminating the supervisor's once daily responsibility.

RFID Improves Daily Testing

The newest advancement in ATP sanitation monitoring is the use of RFID technology, which typically involves two components: An antenna and RFID tags. The tags are passive, which means they give off no signal on their own. They simply reflect the RFID signal back to the instrument with their specific code, which is linked to the appropriate test site grouping. To keep from being a potential point of contamination, the RFID tags, which are about the size of a quarter, have been inserted into a 6-inch by 6-inch, brightly colored sign.

The user simply swipes the instrument near the tag and the site group is read automatically. From there, the instrument picks test sites within the site group automatically at random. And if the facility has chosen to designate some test sites as mandatory, meaning they're "hot spots" or sites that need to be tested each time, those are presented first and appear in red on the instrument's display.

"The RFID technology is the 'wow' factor of the newest ATP systems. We've tried to move the design of the day's test plan from the manager's computer to the instrument," says Soule. "In the past, you would have to create a daily test plan on a computer and upload it to the instrument, then toggle and scroll, and toggle and scroll some more to get to the appropriate test site before you could test the site—for every site you tested. We've eliminated all that. With just one swipe, the instrument can be ready to test."

Analyzing and Interpreting Test Data

Not only have the latest ATP sanitation monitoring systems greatly improved upon the creation of test plans and the actual testing, but the analyzing of the collected data has seen numerous advancements since ATP technology was first used.

"We are in the information age and it's really about how or what we do with the information that is important. Whether that information is used to comply with the seemingly endless global food safety regulatory initiatives, or simply finding a way to better produce your products," says Soule. "The goal is to make sense of the data that is collected. Data collected through an ATP program is meaningless unless it can be interpreted, and used to help modify sanitation programs to produce unerringly effective results—the ultimate goal of sanitation efforts."

The newest ATP sanitation monitoring systems can easily produce results that display:

- Results by test sites,
- Results by test site groups,
- Results ranked by highest percentage of fails,
- Results by date ranges, and
- Trends by monthly averages.

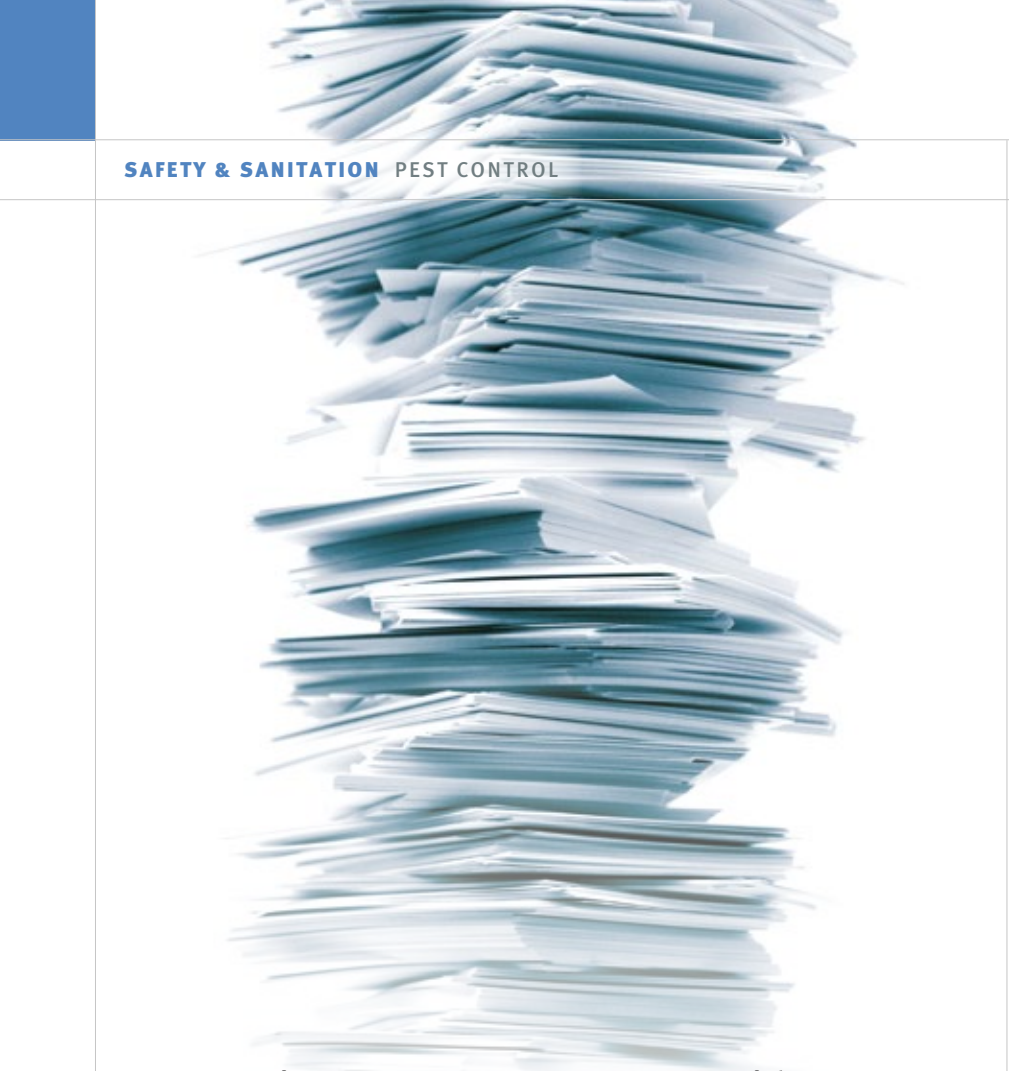
"We've even been able to automate the selection of which test sites should or should not be designated as mandatory," says Soule. "The software has a filter for the manager to enter some predetermined criteria, such as a test site failing more than 20 percent of the time in the past 60 days, and then highlights those test sites that have met the criteria in red and places a check-mark in the 'mandatory' column. The other side of that is a facility for removing test sites that have met certain criteria, such as having passed each time in the past 90 days, from the mandatory designation.

"I have worked with sanitation supervisors who thought some areas in their facilities were the highest risk control points, but repeatedly testing showed otherwise," Soule adds. "Seeing test site results presented in a concise manner can make it very easy to see which test sites are actually giving the sanitation crews the most trouble. Many times, it's not as obvious as some may think. With the latest generation of software, a supervisor can easily adapt his facility's sanitation plan, if it is ever needed, to reflect those evolving test results. It may be what he thought should be a mandatory daily test site can be tested on a random basis, or vice versa."

With the new systems, performance objectives for sanitation can be established, and then results can be tracked against that objective. A manager could learn from the data that a certain test site needs more focus. By implementing a performance improvement objective, the software tracks that test site and compares it to the designated goal—such as reducing ATP test scores to less than 150, and plots it in the graph.

"The newest generation of sanitation monitoring systems makes data collection and interpretation easier than it's ever been for sanitation supervisors," comments Soule. "Like I've been telling my older friends and relatives who have been slow to switch to the newest smartphone technology, food operations using the older ATP systems are missing out on some pretty amazing stuff. The world has changed and ATP systems have changed too." ■

Topper is a market development manager for Neogen Corp., specializing in sanitation monitoring solutions. He has worked with companies, both large and small, on developing, implementing, and maintaining sanitation monitoring programs with very diverse protocols. Topper can be reached at 517-372-9200 or jtopper@neogen.com.



Leaving a Paper Trail...

Keeping pest management documentation on hand is integral to a facility's food safety audit score

BY **ZIA SIDDIQI, PHD, BCE**

Editor's Note: *This is the third in a five-part series of articles that provide a practical approach to various pest control topics.*

Paper trails. They don't have a great reputation, do they? In fact, during most scenarios when paper trails are mentioned in conversation, the general consensus is the group doesn't want a paper trail to be left. The group simply doesn't want to allow any evidence to exist that would track its steps and actions.

However, when it comes to pest management and food safety, you undoubtedly need to have a paper trail. Documentation is the key to proving to an auditor that your facility has an efficient and effective pest management program. The pest control portion of your facility's third-party food safety audit can account for up to 20 percent of the final score, and without proper documentation, your facility doesn't stand a chance.

Food processing plants are governed by several third-party audit standards, with the most common being the Global Food Safety Initiative (GFSI), Safe Quality Food (SQF), the British Retail Consortium (BRC), and other food safety certification criteria. Other third-party food safety auditors like American Institute of Baking (AIB), NSF, Silliker, and YUM! Brands use similar standards to make sure the facilities they audit are compliant with the food safety requirements.

These auditors inspect pest management programs to ensure that no pests—no matter how big or small—can put your company's products in danger of contamination. Auditors like AIB, Silliker, and YUM! Brands actually consider pest control to be so important that they will give a failing score (for the pest control section) to a facility without even the slightest hesitation if they find significant problems with the pest management program. With that in mind, it is essential to thoroughly prepare your team and facility for third-party audits.

The Need for Documentation

Although auditors inspect your facility for proper placement of pest management devices and storage of pest management materials, documentation cannot be overlooked. Documentation is the only piece of evidence that demonstrates your facility's adherence to a formal pest management program. Without documentation, there is no way to verify the proper processes are being carried out, and as a result, you may end up with a mediocre audit score.

What Documentation Includes

The first piece of documentation required by auditors is the scope of service of the pest management program. This document outlines the roles and responsibilities of the pest management professional, as well as the facility staff. It also details the kinds of pests that will be targeted by the program and how their activity will be managed.

At the end of every service visit, your pest management professional should fill out a signed service report that includes comprehensive details on the tasks that were executed and the date completed. These service reports are extremely important to your facility, as third-party auditors review them to confirm your facility and pest management professional are following the guidelines set forth in the scope of service by taking necessary corrective and preventive actions.

On-site documentation should also include a pesticide usage log. Improper pesticide application can pose a massive threat to food safety because products can be contaminated as a result, so the pesticide usage log exists to assure the third-party auditor that your pest management professional is using these materials appropriately. The pesticide usage

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log should detail all pest management materials that have been used, in addition to the trade name and active ingredients in each product. Dates, times, and sites of applications, as well as the targeted pests and frequency of applications, are also key details to include in the pesticide usage log. The pest management professional must sign the log to validate its authenticity.

Another major part of pest management documentation is the map of the pest control devices utilized at your facility. Every single device the pest management professional uses—glueboards, insect light traps, mechanical traps, bait stations, pheromone traps, among others—both inside and outside the plant must be included in the map. Third-party auditors compare the device map with the actual placement of those devices in the facility, and if the two do not match, audit scores often decline. Avoid this by ensuring your map is updated whenever a new device is installed or an old device is removed.

In addition to these items, your documentation must also include pest sighting logs, pest trend logs, and corrective action reports.

Pest sighting logs. Every time you or a member of your staff see a pest, it is imperative to fill out a pest sighting report to record when and where the pest was spotted.

Pest trend logs. Once you've filled out enough pest sighting reports, you can establish pest activity trends over time. The pest trend log should document these trends, which is why it's important to fill out pest sighting reports every single time.

Corrective action reports. Whenever the pest management professional makes recommendations for improvements to your pest management program, you should follow through on the instructions. The corrective action reports detail each recommendation made by the pest professional and whether the facility complied with the recommendations. If your facility does not comply, points could be taken from the final audit score.

In addition, auditors will check for copies of the pest management professional's liability insurance, license, and the training certification of the individual who is actually conducting the service at your facility.

To make it easy for your pest management professional to keep all of this information updated after each service, place all of these documents into a logbook that is kept on-site for the auditors to access easily. In the event of unplanned or unannounced audits, this logbook is instrumental in helping the facility achieve a high score, even if you are not able to prepare fully.

For added security, hold monthly or quarterly meetings with your pest management professional to review and update the documentation and pest management program. With all of these documents in place, a high audit score can be ensured for your facility no matter when the auditor comes knocking. ■

Dr. Siddiqi is director of quality systems for Orkin, LLC. A board certified entomologist with more than 30 years in the industry, he is an acknowledged leader in the field of pest management. Dr. Siddiqi can be reached at zsiddiqi@orkin.com.

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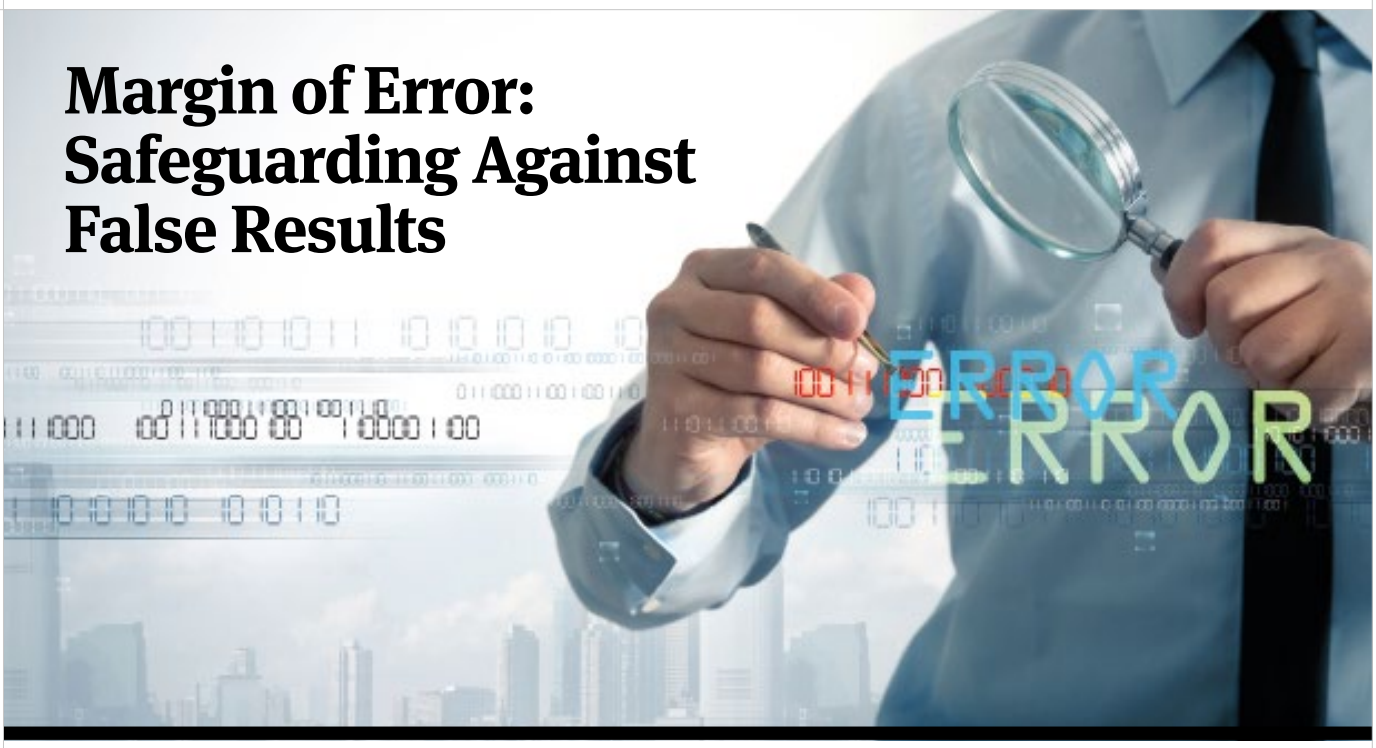

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Among the most frequently reported foodborne pathogens worldwide, *Salmonella* and *Campylobacter* impact a number of large food industries, forcing the need to deploy testing solutions that ensure the safety of products and the well-being of consumers

BY **MAYBELLE COWAN-LINCOLN**

The larger the area we source our food from, the more we encounter the threat posed by a microscopic enemy: Foodborne pathogens. Good safety practices demand stringent, broad-spectrum testing to identify potentially dangerous microbes, but are the current testing products and procedures doing an adequate job? According to a recent report from the American Proficiency Institute, an independent agency that measures the accuracy of laboratories, there is significant room for improvement. New technology and new iterations of existing technologies hope to fill that need.

The food supply is becoming more and more global. Much of the produce, meat, and seafood found in U.S. markets and restaurants come from other countries. In fact, more than half of the food consumed on the planet is eaten in a different geography than it is grown or produced in. This opens our food supply to not only pathogens found locally, but also to microorganisms from all over the world.

Problematic Pathogens

Two of the most problematic pathogens are *Salmonella* and *Campylobacter*. As few as one to 10 *Salmonella* cells can cause disease, while 1,000 *Campylobacter* cells in contaminated poultry, raw milk, or produce can make a consumer ill. Of course, cooking does eliminate these pathogens, but food may still be handled between the time it is cooked and when it is served, opening up the possibility of bacteria being introduced by food handlers or servers.

Salmonella is the leading cause of foodborne illness according to FoodNet, the Centers for Disease Control and Prevention system for tracking foodborne infections. The number of *Salmonella* infections has remained relatively steady since 1996; however, there has been a shift in the strains sickening consumers. Wendy Lauer, senior sales product manager of Bio-Rad Industries, a San Francisco-based lab equipment provider, states, "Organisms continue to change and adapt." Infections from the most common strain have decreased, while illnesses caused by rising new strains, especially antibiotic-resistant strains,

have increased. Infections from *Campylobacter*, the pathogen responsible for the third largest number of foodborne infections, are up 14 percent from the period between 2006 and 2008.

Mistakes in the Lab?

In May 2013, a report issued by the American Proficiency Institute and presented at the 113th General Meeting of the American Society for Microbiology revealed that over the past 14 years, the laboratories it has tested have shown significant gaps in accuracy when testing for disease-causing bacteria including *Salmonella* and *Campylobacter*. On average, participating labs had a false negative result rate (meaning bacteria was present when the test showed no pathogens) of 4.9 for *Salmonella* and 9.1 for *Campylobacter*. False positives (indicating bacteria was present when it was not) occurred at a rate of 3.9 percent for *Salmonella*.

Christopher Snabes, food technical specialist with the American Proficiency Institute, explains that it is unrealistic to expect that all labs would be error-free. No testing method and no testing facility is foolproof, and the largest variable is the human factor. According to Snabes, a number of errors can produce false negatives or false positives. For one thing, the lab technician can test for the wrong bacteria, or confuse samples and their target bacteria. A sample infected with *Campylobacter* will appear clean if only tested for *Salmonella*. Sometimes a recently emerged strain of bacteria has not yet been included in a lab's pathogen database, or a technician makes a mathematical or transcription error. In proficiency testing, these mistakes result in a black mark, but in real life, the consequences can be deadly if a disease-causing pathogen finds its way into the food supply and sickens consumers.

Beyond human error, equipment problems can cause wrong incorrect results. Instrument failure can skew test results. Also, the reliability of test kits varies from manufacturer to manufacturer, and faulty kits produce incorrect results. Garbage in, garbage out.

Conventional Testing Methods

There are three main detection paradigms used to test for *Salmonella* and *Campylobacter*: Culture, ELISA, and PCR.

Culture. A pathogen test in which a sample of the food in question is placed on traditional selective culture media to allow the target microorganism to grow while simultaneously preventing the growth of other organisms. Culturing is the oldest method of pathogen detection as well as the gold standard because of its clear, visible endpoint. However, cultures are time consuming, taking several days to produce results depending on the target organism, which can be prohibitive when dealing with perishable food with a short shelf life. It also requires trained laboratory staff following Good Laboratory Procedures and, even when technicians take

(Continued on p. 28)

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the utmost care, cultures are vulnerable to the interference of background flora.

ELISA. Enzyme-Linked Immuno-Sorbant Assay determines if a pathogen is present by detecting the presence of an antibody that has linked to it. An enriched sample solution is placed in a 96-well plate coated with a protein that will bind to an antibody to the target microbe. The solution is removed and a second antibody, linked to an enzyme, is added that will bind to the first antibody, making an antibody-antigen-antibody sandwich that will cling to the side of the well. The solution is washed away and a substrate is added to the well that will cause the colorless antibodies to become colored products, thus signaling the presence of the target bacteria. A detraction from ELISA is its cost. A different test kit is needed for each unique strain of bacteria, and this can impact the reliability of results. Companies will do a cost-benefit analysis and test for usually two or three strains that are the most likely to appear in the products, potentially overlooking a harmful microorganism.

Proficiency Testing Process

Pathogen testing is what stands between consumers and potentially deadly outbreaks of foodborne illnesses, so accuracy in the lab is paramount. Proficiency testing is an objective means of testing lab accuracy, or as Christopher Snabes of the American Proficiency Institute puts it, "We...test the labs that test the food." Unless a lab is ISO17025 certified, in which case annual proficiency testing is mandated, laboratories voluntarily submit to this analysis as part of quality control. American Proficiency Institute sends client labs two samples of food to test, each infected with different bacteria in varying concentrations. The lab tests it for pathogens using any method it choose—culture, ELISA, or PCR—and sends its findings to the Institute to check it against what was added. The Institute then posts its report on the lab's accuracy on a secure area of its website, accessible only to the client laboratory. Clients log onto their own secure page to find out how this test rates their exactitude.

PCR. Polymerase chain reaction is arguably the most sensitive of the three methods because it looks for the actual DNA of *Salmonella* or *Campylobacter* strains. A sample is heated in a thermocycling instrument, splitting the double-helix DNA into a single strand. An enzyme called "Taq polymerase" is added which builds two new strands of DNA using the originals as templates, and then proceeds to amplify the DNA exponentially, creating a large enough sample of DNA for pathogen detection.

False negatives allow dangerous pathogens to be released into commerce, sickening consumers.

What's New?

One example of a platform that claims to lower the risk of technician mistakes is the Molecular Detection Assay (MDA). Launched by 3M in 2011, MDA uses BART (Bioluminescent Assay in Real Time) technology to recognize distinct sections of a bacteria's genome. In an email, 3M's food safety division explained that MDA involves two processes: Isothermal DNA amplification, meaning it is done without a thermocycling instrument, and bioluminescence which uses luciferase, the enzyme that causes fireflies' abdomens to light up. An enzymatic process in the enriched sample produces ATP which reacts to luciferase, causing the target pathogen DNA to glow. MDA reduces the risk of human error by requiring only a single instrument and preparation protocol across most assays. The technician does not have to match the protocol to the pathogen, thereby lowering the opportunity for confusion. Additionally, MDA uses color-coded assay tubes to differentiate pathogen assays to help shrink the margin of error.

Safeguarding against instrument failure is another way to improve testing accuracy. MDA does not require calibration and features an automatic diagnostic program that runs on startup.

Accuracy is paramount in pathogen testing, but speed is an important consideration as well. If a supplier has perishable food sitting in a climate-controlled warehouse, the shorter the time to results the better, and 3M claims that MDA delivers molecular level accuracy in real time. The process still requires enrichment time of anywhere between 18 to 24 hours depending on the target pathogen. But once the enriched sample is placed in the instrument, a presumptive positive can be seen in as little as 15 minutes, and a negative result takes 75 minutes.

Life Technologies, providers of a PCR test, is currently developing a technology that improves upon the conventional PCR platform. The company believes its new assay will increase accuracy and shorten time to results. The confirmation test, run after the presumptive positive, adds time to pathogen testing. In the interests of accuracy and consumer safety, it is a good idea to confirm negative results as well. However, some food processing companies skip the confirmation assay if the initial results turn up negative, although this is a risk because a false negative can allow a potentially deadly pathogen to slip into commerce. According to Nir Nimrodi, director of Life Technologies' food safety division, the technology now under development will allow the confirmation assay to run simultaneously with the initial test, using the same sample, saving time and improving accuracy for testing laboratories.

Both false negatives and false positives of *Salmonella* and *Campylobacter* have an impact: False positives have an economic impact and false negatives lead to a health impact and potentially, an economic one as well. In the case of a false positive, pristine meat, dairy, produce, etc. will either be destroyed and thereby become a total loss, or be cooked before sale, which results in a smaller profit margin. False negatives allow dangerous pathogens to be released into commerce, sickening consumers. Many brands cannot recover from the damage that resulting recalls and lawsuits bring about–emphasizing that the importance of precision in pathogen detection cannot be overestimated. ■

Cowan-Lincoln is a science/technical writer based in New Jersey. She is a frequent Wiley-Blackwell contributor who has been featured in numerous publications.

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Food Allergies on the Rise

The challenge for business and the opportunity to build trust

BY **NEIL CANAVAN**

Food allergy is a serious and growing public health issue. Recent data suggest that approximately 15 million Americans have food allergies, including one in every 13 children. Every three minutes, a food allergy reaction sends someone to the emergency room. The U.S. Centers for Disease Control report that food allergies result in more than 300,000 ambulatory-care visits a year among children under the age of 18.

The most serious reaction to a food allergy is anaphylaxis, an exaggerated immune response that can lead to severe rashes, pronounced swelling, particularly of the throat and tongue, and a precipitous drop in blood pressure that can be fatal. Teenagers and young adults with food allergies are at the highest risk of fatal food-induced anaphylaxis.

Eight foods account for 90 percent of all reactions: Milk, eggs, peanuts, tree nuts, soy, wheat, fish, and shellfish. Even trace amounts of a food allergen can cause a reaction.

Regulatory Action

"Currently, the FDA is weighing the issue of preventive controls and food allergen thresholds—matters of great importance to the food allergy community," says John Lehr, CEO of the nonprofit advocacy organization, Food Allergy Research & Education (FARE), McLean, Va. "In January, the FDA requested public comment on a new proposed rule on preventive controls called Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food. It would improve safety across the food system by reducing the risks from all hazards in manufactured foods."

Even trace amounts of a food allergen can cause a reaction.

The regulations would include specific requirements for preventing the unintended presence of allergens, generally referred to cross-contact, including requiring companies to identify areas of concern and to implement plans to prevent cross-contact.

Another major issue of concern is the mislabeling of food. "Prior to 2004, there was no requirement in the law specifically requiring that food allergens be labeled," says Lehr. "Then with the passage of the Food Allergen and Labeling Consumer Protection Act (FALCPA) by Congress, companies were required to declare the eight major allergens." However, Lehr points out, even though the legislation has been in place for several years, there are still recalls for undeclared allergens, "So there is still a significant problem."

Helping to address the problem, FARE offers a website with a list of resources for industry, and for members of the food allergy community. "We also have staff members who address industry groups on a regular basis, speaking to employees about the food allergic consumer's perspective," says Lehr. "We also host the annual meeting of the Food Allergy & Anaphylaxis Alliance, a group of advocacy organizations around the world." This year's meeting, which will be held in early October, includes an industry day that brings together regulatory officials, representatives of the food industry, and allergy advocates to discuss issues in food allergy safety.

Establishment of Thresholds Key

"There is a large range in individual threshold doses," says Steve Taylor, PhD,

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director of the Food Allergy Research and Resource Program, University of Nebraska-Lincoln. "If you just look at peanut allergy alone, some people have to eat several peanuts, or a hand full to get sick. Other people would react to small specks." For specific measures of what induces an allergic reaction there is enough published data out there, Dr. Taylor thinks, to get a consensus on how much is too much—insofar as food production is concerned—and how that threshold, or reference dose should be the industry standard for the detection and prevention of cross-contact.

> The biggest risk of allergen cross-contact is at your local restaurant.

Yet, precise regulatory guidelines are lacking. "None of the public health agencies have established regulatory reference doses so, in the absence of official action, everybody continues to work towards zero, which of course you can never achieve."

The big questions remaining for the food and beverage industry are, how do I effectively clean, and further, how can I validate cleaning efficacy? Dr. Taylor points out that the FDA is working on it, and he hopes some standards will be set soon. "The FDA published a threshold notice in the federal register as part of the FALCPA in December of last year, and they sought public input. So, they are certainly seriously considering it."

Of course some sectors of the food and beverage industry and some types of facilities have a greater risk profile. "Any situation where you have a clean-in-place system, say like, dairy processing, that's the ideal way to clean up because you can use copious amounts of aqueous fluids to do the cleaning," says Dr. Taylor. Standards can be programmed in—all you have to do is push the button. "It's much harder to do in any situation where you have to rely upon dry cleaning. Bakeries are a good example. Baking ovens are only partially accessible, and not easily cleaned." Ensuring an allergy-free environment in such a case would likely involve the use of laboratory test kits, which are now widely available.

The biggest risk of allergen cross-contact is at your local restaurant. "That's where most of the more serious reactions occur," Dr. Taylor says. Foods are not labeled, as they would be in a grocery store, and the server may not really know all the ingredients of a certain dish.

"It's pretty hectic in those kitchens during the dinner hour—could peanut residue from your entrée end up in mine? Probably. And because of that I know any number of peanut-allergic people who won't eat in certain kinds of restaurants because they know that the risk is there."

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Rapid Test Kits

Due to the rising prevalence of allergies to certain foods, and the relatively certainty of new regulatory standards, business in the testing sector is brisk.

"We have different diagnostic kits that you could use yourself in-house," says Jennifer Baker, a product manager for Neogen, headquartered in Lansing, Mich.

Kits are based on antibody technology, such as enzyme-linked immunosorbent assay, commonly known as ELISAs—these are quantitative. For more "yes or no" type testing there are swipe tests. "These can be done in five minutes, and it lets you know if you cleaned your surface well enough."

As for the threshold of detection, "the tests have always been sensitive," says Baker. "In many cases I think the kits are more sensitive than they need to be (since the FDA has yet to set the standards) but that provides an additional layer of security for the food manufacturers."

While interest in allergen testing has been relatively constant of late, what Baker has noticed is a much greater interest in testing for gluten—a problem not described as an allergy per se, but a sensitivity. "We're getting inquiries about kits for wheat seed allergen, and also barley and rye. That's definitely been on the increase since the establishment of the gluten-free market."

Neogen has also recently developed an assay for mustard. "A Canadian law recently went into effect that states that mustard must be included in labeling, so in the last year we introduced both a quantitative assay and a lateral flow test, we also added a new lateral flow test for sesame, also on the Canadian list."

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Restaurant Rescue

Necessity is sometimes the mother of re-invention—take the case of Lara Holland, a certified food allergy and gluten consultant for commercial kitchens based in southern California.

"I grew up with the belief that people with food allergies were just picky eaters," recalls Holland. All through childhood she could eat anything, but then a serious illness in her twenties changed all that, and the average meal became a minefield.

"I became acutely embarrassed about my food allergies—I didn't want to talk about it." It seemed few understood, and fewer still were willing to accommodate what could easily be a life-threatening allergic sensitivity.

In self-defense, Holland set out to get an education. Training as a nutritionist, and then working in commercial kitchens, Holland came to understand the product, and the production line, and became an expert on where the hazards lie. Her focus now is on food service.

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"Often times people's most serious reactions happen inside a restaurant—they encounter the allergen where they have no control." And hazards can be commonplace. "You tell the server, 'no nuts' and the server forgets to write it down, or worse, the line cook doesn't see it or ignores it, or the dish is premade and the server picks off the nuts and brings it to your table." An hour later you're in the hospital.

A second offense is ignorance of ingredients. "You may think the soy sauce is gluten free but often it is not, you may think there's no garlic in the condiment, but there is..."

For the first offense, Holland can offer an allergy audit of an operation, followed by staff training, online or in person. "For the most part, servers really do care; it's just that sometimes they have no idea."

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As to the second offense, Holland has, with her nutritionist and restaurant background and the help of a software designer, put together a program tailor-made to each restaurant client, a program that provides an allergy-free menu to the customer and alerts to the kitchen.

The AllerSmart program works like this: All the ingredients for all menu items are input into the program. When the customer says, "I'm allergic to shellfish," the server enters that information, the program then generates a list of shellfish-free options. Further, the kitchen receives an alert that table six has a shellfish sensitivity, so be extra careful to avoid cross-contact on the prep line.

Holland says reactions to the program are positive. "They tell us that it will save them money on training (staff turnover is generally high) and moreover, minimizes their liability regarding law suits."

And it's just plain good for business. "Once you've served that person with special needs, they will be forever loyal. We see increases from 8 to 25 percent in revenue with food allergic diners," comments Holland. ■

Canavan is a freelance writer based in Brooklyn, N.Y. Reach him at ncanavan@hotmail.com.

In the Lab

GOOD LABORATORY PRACTICES

Sample Preparation Selection

Typically regarded as the bottleneck in the analytical laboratory, sample preparation can be conducted more smoothly by assessing the strengths and drawbacks of three common used approaches in food safety—LLE, QuEChERS, and SPE

BY **SUEKI LEUNG** AND **ALLEN MISA**

With the increasing awareness of food safety in both developed and developing countries, analysis of a variety of imported and exported commodities is a priority concern for the national competent authorities. Sample preparation of foods such as vegetables, fruits, dairy, and meats followed by downstream high-pressure liquid chromatography (HPLC), liquid chromatography with tandem mass spectrometry (LC/MS/MS), or gas chromatography with mass spectrometry (GC/MS) analysis is a practice that helps ensure the safety of consumers. Sample preparation is a huge challenge in this analytical process for two primary reasons. First, typical food testing assays can include many analytes with widely varying chemical properties, and second, sample matrices are complex and often contain compounds that can interfere with analysis. For instance, the avocado matrix is rich in lipids that cause ion suppression in mass spectrometry (MS) analysis, leading to inaccurate results when tested for a particular set of analytes.

All analysis begins with sample preparation, whether it's a simple dilution or filtration or uses more targeted techniques such as LLE (liquid-liquid extraction), QuEChERS (quick easy, cheap, effective, rugged, and safe), or SPE (solid phase extraction). Because accurate analysis is required in food safety testing, sample preparation plays an integral role and directly affects downstream analytical results.

Sample preparation helps ensure that accurate and reproducible results are produced across a wide variety of food sample matrices. As regulations change and become more strict, analysts are challenged to develop robust analytical methods that reach even lower detection and quantitation levels. More selective sample preparation methods are employed in some cases; while in other situations, a less specific technique focusing on simple matrix removal may be more effective.

Matrix interferences such as lipids, proteins, and carbohydrates have become a limiting factor because they can cause ion suppression or enhancement, making it difficult to accurately identify and quantify the target analytes. Further, without adequate cleanup, these troublesome components can damage or shorten the lifetime of laboratory instrumentation. Thus, sample preparation for matrix interference removal in food samples is extremely important in order to achieve proper performance requirements and to improve the "shelf life" of instrument systems.

Selecting the most effective sample preparation technique to achieve your overall analysis goals saves time that would otherwise be spent on trying different techniques based on trial and error.

Sample preparation can also represent a major bottleneck in the analytical laboratory. It's estimated that the sample preparation step can make up 60 to 70 percent of the total time required for analysis. Estimates also show that 30 percent of analytical errors originate from the sample preparation step. Most food testing labs follow approved official/standard methods that often specify a validated sample preparation procedure. In some cases, when special needs must be met, analysts are granted flexibility to deviate from the official method and select a more appropriate sample preparation technique.

Straightforward, non-specific sample preparation techniques such as weighing, dilution, or filtration typically work well and can adequately achieve the goals of sample preparation for simple sample matrices.

For more complex and dirty sample matrices, more intricate and selective extraction/cleanup methods such as

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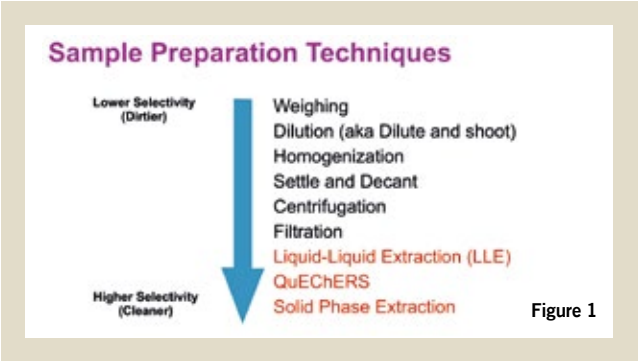

Figure 1

LLE, QuEChERS, and SPE are required to transform samples into compatible formats for GC/MS and LC/MS/MS analyses. (See Figure 1.)

Each approach has its own benefits, drawbacks, and specific uses and no one approach is superior to the other. However, choosing the correct approach can significantly help in analysis goals.

LLE

Probably the simplest and most typical sample preparation approach for a variety of sample matrices is LLE. In LLE, homogenized sample is added to a biphasic system containing an aqueous phase and an organic phase. The target analytes will partition into either layer, which can then be isolated for further analysis.

LLE is cheap, relatively quick to perform, and fairly simple. It also provides short method development times and is easily transferable to other labs because it is a simple approach that requires no special equipment or consumable products. When developing a LLE extraction, a few simple considerations are: In what solvents will the targets most likely solubilize (i.e. what is the log P of my target analytes?); and are the extraction solvents compatible with the analytical approach?

Although LLE is known to be simple, quick, and cheap, the major tradeoff is that LLE is not analyte specific. Co-extraction of interferences with the target compounds is a very common problem, leading to inaccurate results caused by ion suppression/enhancement. Another common problem is that LLE often requires large volumes of hazardous solvents such as petroleum ether, dichloromethane, and other organic solvents, which raise undesired environmental and health concerns. Because two immiscible solvents must be used to create a biphasic system, the choice of solvent is often limited. Additionally, the formation of emulsion from the biphasic system can produce inconsistent data.

Thus an example where LLE would be a preferred option is when a wide range of organic-soluble compounds must be analyzed from a small volume of aqueous-based sample.

QuEChERS

A widely used method, QuEChERS was first introduced in 2002 at the European Pesticide Residues Workshop in Rome. It was developed by Lehotay, et al. to extract and analyze multi-residue pesticides from food samples and was published in the Journal of AOAC in 2003. In 2005, the USDA reported a validation study for 229 analytes of varying polarities. In 2007, QuEChERS was designated as an official AOAC Method 2007.01 for pesticide residues. The main advantage of QuEChERS is its ability to remove a large quantity of unwanted interferences from a large variety of food matrices in a quick, easy, cheap, effective, rugged, and safe process. Since its creation, QuEChERS has been used with a variety of food matrices and is slowly being evaluated for other uses.

The QuEChERS method is broken down into two main steps.

Step 1: Extraction. The purpose of the extraction step is to extract analytes from any given sample matrix by using a combination of solvents, magnesium sulfate (to induce phase separation and LLE partitioning), and buffering salts (to stabilize base sensitive analytes). Analytes of interest will partition into the organic solvent, and physical matrix interferences are eliminated during this extraction step. Sample matrices can be solids, semisolids, small volumes of liquid, or viscous liquids. To summarize, the following events take place during the extraction step:

- Sample is homogenized;
- Sample is transferred to an extraction tube and organic solvent and salts are added, the sample is then shook by hand;
- Extraction tube is centrifuged to pellet homogenate; and
- Top layer of solvent is extracted and is further cleaned up during Step 2.

Step 2: Dispersive Solid Phase Extraction (dSPE). The main purpose of the dSPE step is to remove from the sample undesired

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chemical matrix interferences such as lipids, organic acids, sugars, and pigments. These chemical matrix interferences are damaging to instrumentation and can lead to inaccurate results. Typically, end-capped C18 (C18E), primary secondary amine (PSA), and graphitized carbon black (GCB) SPE sorbents are used to remove these interferences. To summarize, the following events take place during the dSPE step:

- Solvent extracted from Step 1 is added to a dSPE tube that contains a combination of dSPE sorbents and salts;
- Tube is shaken by hand and centrifuged; and
- Supernatant is ready for analysis by GC and LC/MS/MS.

Although QuEChERS is a quick multi-matrix solution, it still has its drawbacks in covering specific single-class analytes that are difficult to extract or clean up from persistent interferences. In addition, because QuEChERS is mainly a manual process, automation of the procedure is not very effective. Because QuEChERS does make use of SPE sorbents, some method development to determine the best sorbent combinations is required, which can take additional time.

SPE

One of the most selective sample preparation techniques employed in food safety testing, SPE is a technique in which intermolecular interactions between a solid stationary phase and the target analyte results in the removal of contaminant and the concentration of the analyte. SPE addresses the three primary goals of sample preparation including analyte extraction, concentration, and solvent switching. It is used in a wide variety of industries and can be utilized to clean up a multitude of sample matrices and target analytes.

The flexibility and strength of SPE comes from the users' ability to choose the sorbent that selectively interacts with the analyte(s) of interest or with the matrix interferences that could affect the recovery. Thus, SPE cartridges can also be used in a nonretentive approach as a "chemical filter" that removes interference from the sample while target analytes pass through the sorbent and are collected for further analysis. Unwanted matrix interferences will remain in the SPE cartridge while the analytes of interest are collected.

SPE is performed by using a tube filled/packed with a chemically derivitized sorbent. By varying the chemical nature of the sorbent and the buffer conditions used during the loading, washing, and elution stages, a method can be developed that can be very selective to clean and isolate the target analytes from complex sample matrices.

The steps for SPE include:

- Pretreat sample (via LLE, homogenization, buffering, etc.);
- Choose appropriate SPE sorbent and protocol;
- Condition sorbent to prepare for interaction with sample;
- Load pretreated sample onto SPE sorbent (target analyte will be retained on sorbent);
- Wash sorbent to remove unwanted interferences that are not retained on the sorbent;
- Elute target analytes (using a combination of organic strengths and buffers); and
- Analyze clean eluent by GC or HPLC.

Although SPE is highly selective, produces high recoveries, and provides repeatable results, there are a few drawbacks that prevent labs from implementing the technique. SPE requires method development, special equipment, and is much more expensive than its alternatives due to sorbent packing and media costs. When the analysis of complex sample is required, SPE would be the ideal choice of sample preparation technique because it reliably and repeatedly provides high recovery.

Real-World Instances

The following are some real-world examples on how each approach was chosen as the most effective technique.

Example 1: Multiresidue Pesticide Analysis in Spinach using QuEChERS AOAC Kits. With the strong presence of pesticides in the food cycle, the purpose of this analysis is to detect concentrations of pesticides below the maximum residue limits because global legislations are quickly becoming more concerned. It is imperative that sensitive and efficient analytical techniques are used to detect low levels of the variety of pesticides.

The primary challenge in this analysis is to eliminate the naturally occurring pigments, fatty acids, nutrients, and fats that are present in spinach samples in order to achieve lower limits of detections (LOD) of pesticides. Although a traditional technique such as LLE can be used, it employs the use of hazardous solvents and cannot remove all matrix interferences that can prevent reaching the desired LOD.

roQ QuEChERS Kits (Phenomenex) were employed. The combination of buffering salts, magnesium sulfate, and organic solvent induced delivered clean separation and extracted all pesticides, while PSA and GCB dSPE sorbents were used to remove the remaining matrix interferences

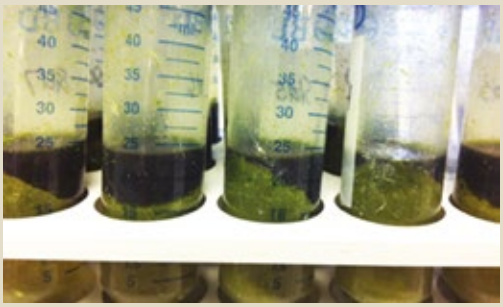

Figure 2. Spinach extracts after liquid partitioning step with 1 percent acetic acid in acetonitrile and magnesium sulfate. The organic phase was heavily pigmented in dark green.

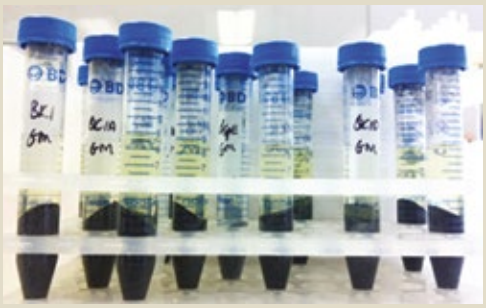

Figure 3. Spinach extracts after dSPE cleanup. GCB removed a majority of the pigment from the sample matrix and the extracts were clear with a light green tint.

PHENOMENEX

Sample preparation helps ensure that accurate and reproducible results are produced across a wide variety of food sample matrices.

(Figure 2 and Figure 3). Because the AOAC 2007.01 method had already been validated and established, this procedure was the best alternative to achieve a combination of low limits of detection, easy and quick processing, and analysis of a wide range of pesticides. SPE would also be an acceptable cleanup option for this work, however, because pesticides are of varying polarities, SPE method development would have been quite intensive and may not have produced the high recoveries of all of the varying pesticides that can be achieved with QuEChERS, which provides a wide analyte screening.

Example 2: Sulfonamides Extraction from Honey Using Strata-X-C Polymeric SPE Sorbent. Two bacterial species, *Paenibacillus* larvae and *Melissococcus* pluton are known to cause American and European Foulbrood from honey bees. Honey is a widely used sweetener and is highly produced and tested. Although antibacterial agents such as sulfa drugs (sulfonamides) are effective in controlling their growth, high residues of these antibacterial agents found in consumers' honey have become a huge concern. A reproducible and highly selective method is required for their analysis.

A strong cation-exchange polymeric SPE sorbent, Strata-X-C (Phenomenex) was chosen to perform sample cleanup due to its specificity to extract sulfonamides from honey. Honey is saturated with a variety of classes of compounds including carbohydrates, aliphatic acids, amino acids, proteins, and minerals. Simpler extraction methods such as LLE or QuEChERS are not specific enough for the extraction and concentration of sulfonamides without co-extracting matrix interferences.

Using SPE allowed target of sulfonamides based on their basic properties, which formed interactions with the strong cation-exchange sorbent. A strong organic wash could then be used to rinse off all interferences from the cartridge prior to elution, producing the cleanest and most concentrated extract of the target drug residues.

Sample preparation is an integral step in any analysis. The lack of proper sample preparation in food testing can lead to instrumentation and analytical challenges. It also adds substantial effort and time to the complete analysis. Knowing which sample preparation technique to use for the goals at hand is quite beneficial in achieving the desired outcome. In foods, LLE, QuEChERS, and SPE are the three most commonly used approaches to sample preparation. No one approach is better than another; rather each approach has its own strengths in achieving the desired outcome of the analysis. ■

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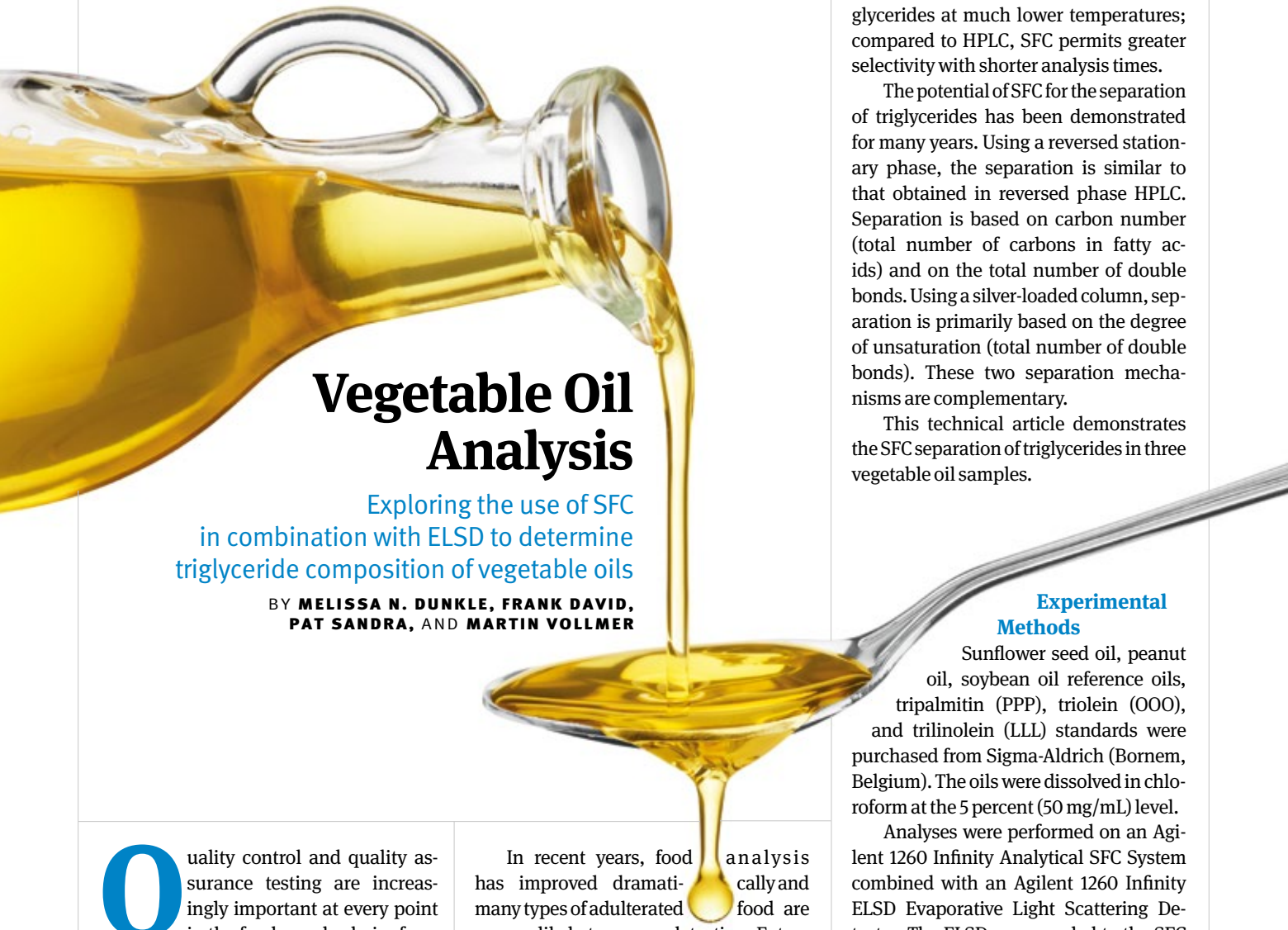

Vegetable Oil Analysis

Exploring the use of SFC in combination with ELSD to determine triglyceride composition of vegetable oils

BY **MELISSA N. DUNKLE, FRANK DAVID, PAT SANDRA,** AND **MARTIN VOLLMER**

Quality control and quality assurance testing are increasingly important at every point in the food supply chain, from manufacturing and packaging to distribution and retail sale. The focus on efficient and reliable food analysis has become more acute over the past few years, as high-profile cases of food fraud and adulteration have come to light.

Food fraud is a decades-old problem. According to researchers at the U.S. Pharmacopeial Convention (USP), an independent scientific non-profit organization, vegetable oils—especially olive oil—have a high vulnerability to adulteration and represent the most documented cases of food fraud, with dilution being the most common cause of problems. Over the past 30 years, more than 270 studies and articles have been published on the adulteration of olive oil alone.

In recent years, food analysis has improved dramatically and many types of adulterated food are now unlikely to escape detection. Extensive research has been done in the field of vegetable oil analysis to test for authenticity and chemical properties. For example, gas chromatography (GC) and high-performance liquid chromatography (HPLC) have frequently been used to evaluate triglyceride content in vegetable oil samples. The physical and chemical properties of vegetable oils are closely related to the type and relative amount of each constituent triglyceride in the sample.

A New Technique

Supercritical fluid chromatography (SFC) in combination with evaporative light scattering detection (ELSD) is a valuable technique for the determination of triglyceride composition of vegetable oils. Compared to GC, SFC separates triglycerides at much lower temperatures; compared to HPLC, SFC permits greater selectivity with shorter analysis times.

The potential of SFC for the separation of triglycerides has been demonstrated for many years. Using a reversed stationary phase, the separation is similar to that obtained in reversed phase HPLC. Separation is based on carbon number (total number of carbons in fatty acids) and on the total number of double bonds. Using a silver-loaded column, separation is primarily based on the degree of unsaturation (total number of double bonds). These two separation mechanisms are complementary.

This technical article demonstrates the SFC separation of triglycerides in three vegetable oil samples.

Experimental Methods

Sunflower seed oil, peanut oil, soybean oil reference oils, tripalmitin (PPP), triolein (OOO), and trilinolein (LLL) standards were purchased from Sigma-Aldrich (Bornem, Belgium). The oils were dissolved in chloroform at the 5 percent (50 mg/mL) level.

Analyses were performed on an Agilent 1260 Infinity Analytical SFC System combined with an Agilent 1260 Infinity ELSD Evaporative Light Scattering Detector. The ELSD was coupled to the SFC module using a procedure similar to the one used for SFC-MS 4.

The addition of a make-up flow before the backpressure regulator, together with additional heating at the entrance of the ELSD, was found necessary to obtain good sensitivity, reproducibility, and avoid solute deposition in the transfer capillary. Experiments show that switching off make-flow or heating immediately results in low sensitivity and unstable baseline in ELSD detection.

Analyses were performed on two different stationary phases: ZORBAX SB-C18 and Chromspher 5 Lipids silver loaded column. For the reversed phase separation, three ZORBAX SB-C18 columns were coupled in series.

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Reversed Phase Separation

Figure 1 shows the UV and ELSD chromatograms for the separation of triglycerides in sunflower seed oil. As seen, the ELSD detector is more sensitive than UV detection, giving S/N ratios approximately five times better than in UV detection. In addition, the baseline is more stable than in the UV signal at this low wavelength. Moreover, the response in ELSD is more universal and less dependent on the number of double bonds in the lipid molecule.

In SFC, using a reversed phase C18 column, triglycerides are separated according to the carbon number and the total number of double bonds. By approximation, the elution order is set according to:

PN = CN – NDB

Where:

PN = partition number

CN = carbon number (sum of carbons in fatty acid chains)

NDB = sum of number of double bonds

Therefore, the PN for OOO is (18+18+18)–(1+1+1) = 51, and this compound elutes later than OLO with a PN = (18+18+18)-(1+2+1) = 50. Within a group of triglycerides with an equal PN number, additional separation can be obtained. For example, LLL and PLL (PN = 48), OLL and PLO (PN = 49), and OLO and POO (PN = 50) are separated.

Three different vegetable oil samples were analyzed in another experiment (see Figure 2). In all cases, distinct profiles and ideal separation were obtained for all oil types when using SFC with ELSD detection.

Separation on a Silver-Loaded Stationary Phase

The separation of the vegetable oils on the silver loaded column is shown in Figure 3. On this column, separation is mainly based on the number of double bonds, resulting in a group type separation of lipids. Within a group of triglycerides with the same number of double bonds, some partial separation could be observed but to a lower degree as compared with separation on C18 (for example, PLL/OLO).

> Some of the methods... could easily be applied to quality-control protocols for other types of food oils, including fish oils.

Retention time and peak area repeatability was tested on both columns for a test mixture containing PPP, OOO, and LLL. The RSDs percent on retention times were below 0.2 percent on ODS and around 1 percent on the silver loaded column. Peak area repeatability was around 2 percent on ODS and around 4 percent on the ChromSpher lipid column.

In Closing

This experiment demonstrated the separation of triglycerides in vegetable oil samples using the Agilent 1260 Infinity Analytical SFC System coupled to ELSD. The ELSD results were reproducible and provided enhanced sensitivity compared to UV detection. The separations obtained on octadecyl silicagel (reversed phase) and on a silver-loaded stationary phase (ChromSpher Lipid) were complementary. Analyzing the three vegetable oils on both column types demonstrated that the combination of both SFC methods creates an ideal quality-control tool for vegetable oil samples.

International standards for the analysis of vegetable oils are evolving. The methods described open the door for continued advances in the assurance of food quality and the fight against food fraud, particularly in regards to vegetable oils like olive oil. In addition, some of the methods, such as SFC separation on a silver-loaded column, could easily be applied to quality-control protocols for other types of food oils, including fish oils. ■

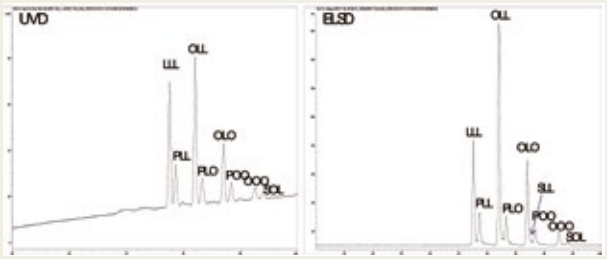

Figure 1: Separation of sunflower seed oil triglycerides with UV detection at 210 nm (left) and ELSD detection (right).

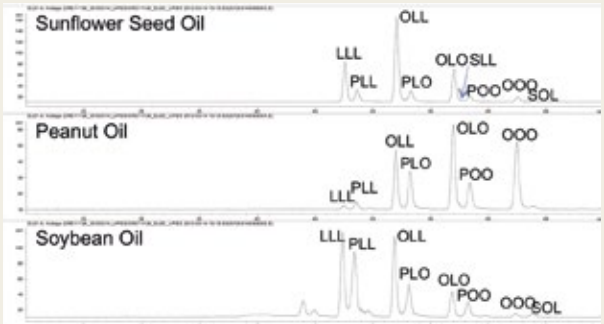

Figure 2: 3x C18 column vegetable oils 50mg/mL (5 percent) (CHCl3)

Separation Conditions:
Column = 3X Zorbax SB-C18 (4.6 x 250mm, 5µm), Injection = 5µL, Flow Rate = 2.5 mL/min, Outlet P = 150 bar, SF = CO2, Mod = 9:1 ACN/MeOH, Gradient = 0 – 90min: 2-10%, Column T = 25°C, Make-up = IPA at 0.6mL/min, Caloratherm = 60°C, UV = 210/4nm REF 360/100nm, ELSD: Evap = Neb = 30°C, 1.60 SLM, Gain = 1, Smoothing = 5s, 10Hz.

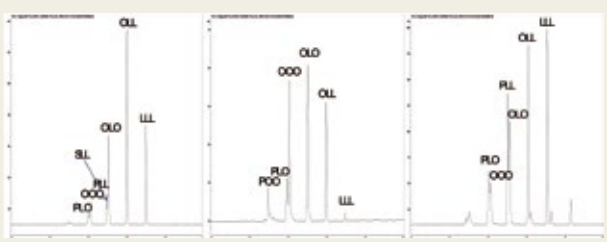

Figure 3: Separation of triglycerides of sunflower seed oil (right), peanut oil (center), and soybean oil (left) on silver loaded column.

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Getting a Handle on Foreign Materials

Risk assessments of raw materials, process, and finished product, and analysis of customer complaints can help identify control measures | BY **BETH DRISCOLL**

The Hazard Analysis and Critical Control Points (HACCP) system classifies risks to consumers into three categories—biological, chemical, and physical—and it emphasizes preventing, reducing, or eliminating high-risk biological hazards. Food safety professionals, as a result of years of education, experience, and audits to the HACCP system, often relegate physical hazards to lower risk status, primarily controlled through the metal detector and supplier approval programs. When focusing on microorganisms, it is easy for the food safety professional to forget that the "illness" in "food borne illnesses" encompasses injuries as well as disease.

The general public, however, has a different perspective on food safety hazards. Consider a salad with fresh, crisp lettuce, crunchy cucumbers, and juicy tomatoes. Food safety professionals see a salad as a bowl potentially brimming with *E. coli* O157:H7, pesticides, and insects. Consumers, however, won't notice the *E. coli* O157:H7 and are unlikely to be concerned about chemicals, unless it's a question about the organic status of the vegetables. But they will notice a grasshopper nestled under the lettuce at the bottom of the dish. Where food safety professionals focus their actions on the intangible risks of biological and chemical hazards, consumers focus on the material risks of physical hazards.

This example illustrates the importance of foreign material control. Though *Salmonella* and hepatitis A may keep the food industry awake at night, consumers remember, and tell their neighbors, about the grasshopper in their salad or glass in their spaghetti sauce.

Health Hazards

Foreign material is defined as foreign bodies that may cause illness or injury to the consumer, or are perceived by the consumer to be alien to the food. While not all foreign material is harmful, it is a physical hazard and its potential to cause injury or illness must be considered. The Canadian Food Inspection Agency (CFIA) recognizes three risks to the consumer from foreign materials—physical injury to the consumer, choking, and product tampering.

Customer Complaints

Foreign material in foods (glass, plastic, metal, etc.) is the major single cause of customer complaints received by many food manufactsurers, retailers, and enforcement authorities. In Canada, 42 percent of consumer food safety investigations conducted by the CFIA between April 2011 and March 2012 were the result of consumer complaints of extraneous materials, whereas only 11 percent of the 496 recalls issued in 2012 were caused by extraneous materials.

(Continued on p. 40)

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(Continued from p. 38)

It's not hard to understand why foreign materials account for such a high percentage of customer complaints; physical hazards are easily identified by the consumer. Physical hazards can often be seen in the food item before consumption whereas biological and chemical hazards are rarely identified by sight. Consumers can also feel the presence of a physical hazard in their food; biting into a piece of wood, chipping a tooth on a date pit, or choking on a piece of plastic are all dramatic incidents. They also have an emotional reaction to foreign material. While a grasshopper may stimulate disgust, it's not likely to be seen as hazardous. Other materials, however, such as glass, metal, or plastic, are seen as dangerous and the consumer will likely notify the manufacturer or the government.

Sources of Foreign Material

To prevent injury to the consumer, it is necessary to understand what types of foreign material can contaminate food and where this contamination occurs. Foreign materials are classified as either intrinsic (a component of the food such as bones, stems, or pits) or extrinsic (materials not normally found in food, such as stones, insects, plastic, glass, or metal). These categories indicate that physical hazards may contaminate food at any stage of production, from the farmer's field, e.g. stones in grain, to the consumer's kitchen, e.g. glassware.

Risk Assessments

Raw Materials and Process. Controlling foreign materials requires understanding three items: First, are there physical hazards intrinsic to your raw materials? Second, are there physical hazards inherent in your process? Third, are there hazards commonly associated with the food product when it's consumed? A well-documented hazard analysis can help the producer, from the field to the manufacturer, focus its resources on the highest risk sources of foreign materials. The identification of physical hazards (FSEP Form 7) associated with raw materials (FSEP Form 2) and process (FSEP Form 3) facilitates the hazard analysis (FSEP Form 8). Once the high-risk items and processes have been identified, effective control and monitoring strategies can be developed and implemented. As a result, virtually every HACCP plan has some form of foreign material control as a critical control point.

Mitigating the risk completely, however, is impossible. Therefore, the CFIA has also developed *Guidelines for the General Cleanliness of Food—an Overview*, which provides maximum limits for the amount of foreign matter in some foods. Two examples include an allowance for magnetic metal particle size and presence in chocolate and pits or pit fragments in pitted dates. This is a valuable resource for determining acceptable amounts of foreign materials in food and can guide both your HACCP program and your response to customer complaints.

Finished Product and Intended Use. Hazards commonly associated with a food product are often overlooked. For example, if you are producing spaghetti sauce packaged in glass jars, your company has an elevated risk for glass complaints and should have good processes in place to control glass and respond to glass complaints. However, if your finished product is grated cheese, you are also at an elevated risk for glass complaints because your product is often served with spaghetti sauce. If the glass from the jar is eaten with the cheese, your company could receive the complaint. In this case, your company should recognize this risk and have a procedure to handle these complaints. This extra risk assessment is invaluable to determining what type of customer complaints a manufacturer may expect and how the company can direct its investigations accordingly.

Controlling Foreign Material

A HACCP plan is the foundation of effective foreign material control as it identifies the raw materials and process steps where contamination is likely to occur. Using the HACCP risk assessment, as well as industry standards, guidelines, regulations, and scientific studies, the facility can identify the steps in the process where foreign material control is needed. At the manufacturing level, devices commonly used to control foreign material include metal detection, X-ray, optical sorting equipment, mechanical sorting equipment (sieves, screens, filters, and magnets), bone separators, and visual inspection. Farm processing may include destoners, gravity tables, air separation, and visual inspection. This list is not exhaustive, and the devices needed in each facility will de-

Importance of Foreign Material Expertise

The appearance of unexpected particulate in foods raises questions about their origin and evokes safety concerns. Foreign particulate may be introduced via raw materials, or during the manufacturing process. Quality control laboratories can catch problems before products ship, but they do not always have the facilities to identify foreign material—a critical step in determining the problem's origin. Working in partnership with quality control groups, contract analytical laboratories can help establish the source of the problem by identifying the nature of foreign material.

For instance, particulate floating in one beverage had been identified by a lab as erucamide, a common slip agent, while particulate in another beverage were identified as amorphous carbon, similar to activated charcoal. Both of these foreign materials are used in manufacturing environments, do not represent a health hazard, and can often be traced to a particular plant location.

Metal particles are common contaminants. Scientists at contract analytical labs can identify a variety of metal particles in products, most commonly aluminum, galvanized steel, and 316 and 304 stainless steels. Because these metals are found in multiple manufacturing areas, their exact source may be difficult to trace. Less common metals, such as nickel phosphide—a type of electroless nickel plating, or specialty steels associated with tools or moving parts, may be easier to trace to a specific source.

Aggregated ingredients can be mistaken for foreign material. In a documented instance, brown particulate in one sample were identified as poorly-dispersed cocoa, which resulted in an unacceptably grainy texture, but no foreign materials were found.

In any case, effective communication between quality labs and contract analytical labs is critical to satisfactory resolution of the problem and helps to minimize recurrence.

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Mettler Toledo's Safeline R Series Profile Metal Detector.

Eriez E-Z Tec XR-Clean X-Ray Inspection System.

pend on the product being made and the manufacturing process.

Once you have identified the required devices, a strong program to control foreign material is necessary. Components of this program include standard operating procedures for activities, corrective action procedures for any deviations that occur, and employee training. Also essential for critical control points is the validation of the system.

Customer Complaints

When possible, customer complaints should be handled through the customer service department of the organization. These professionals will mitigate the risk from an upset customer, particularly if the consumer was harmed by the foreign material. First, determine if there has been an injury or illness associated with the incident. In this case, advise the consumer to contact a physician or seek medical treatment immediately. The usual consumer and product information should be documented, e.g. lot code or best before date, brand, package size, etc. Second, if the consumer mentions contacting the local or federal public health authority, encourage doing so. This transparency on your part will help to alleviate the consumer's fears and provides an independent, credible authority to supply information to the consumer. If the customer is particularly difficult, provide this information directly so that a recognized authority can be involved as quickly as possible.

Also, request the object from the customer. While consumers may not want to release it directly to the facility, they will likely release it to a government authority for testing, which is another benefit of involving the government as soon as possible. Once the object has been retrieved from the customer, the investigation can continue. Access to a forensic laboratory is useful to help determine if the material was from your process (e.g. glass baked into bread) or from the consumer's kitchen (e.g. rock salt that looks like glass).

Next, the production facility should be notified of the complaint details and begin the investigation. It is important that a thorough inspection be conducted because it's easy for the facility to believe it does not have that source of foreign material in the plant. For example, if the complaint is a piece of metal, the investigation may conclude that the plant was not responsible because of its metal detector. This equipment, however, is not infallible and there are many factors that could allow a contaminated product to not be detected or rejected. As a result, the facility should presume that the food was contaminated by their process. Factors affecting the metal detector can include vibrations from the floor, position near other equipment, or the size, shape, or location of the metal piece in the product. Furthermore, this investigation should begin as soon as the complaint is received, whether or not the object is available. Root cause analysis is critical to determining both where the foreign material entered the process and what caused the system failure that resulted in the contamination.

An investigation should also consider an unpleasant alternative—tampering. This is particularly important if the complaint is serious, such as a needle or blade in the product, or if the incidents are numerous and sudden. Tampering is unusual, but possible, and it is a criminal activity so consider involving the police early in the investigation.

When the root cause is determined, a corrective action should be implemented and documented. Follow up is necessary to ensure the corrective action is effective and, finally, the consumer should be contacted to close the complaint. Consumers are looking for transparency and honesty; letting them know what went wrong and what corrective actions were taken to prevent the issue from occurring again will build good will with the community.

Using Complaints Effectively

To begin, assemble and analyze your customer complaints and your supplier non-conformance reports using a Pareto chart. A Pareto chart is used to prioritize problems, providing information for the 80/20 rule. In most situations, a few problem categories (20 percent) will present the most opportunity for improvement (80 percent). This valuable quality tool will provide you with data to focus your efforts, both internally and externally.

Despite the best efforts of food safety professionals, foreign materials can enter the food supply at a variety of stages. A comprehensive risk assessment of the raw materials, process, and finished product, as well as a thorough analysis of customer complaints and supplier non-conformances, can assist the facility with identifying and implementing control measures for foreign materials. These preventative measures will reduce the risk of injury and illness to the consumers of their product. ■

Driscoll is senior project manager for NSF-GFTC. With experience both in the private and public sectors of the food and beverage industry, her background includes quality assurance, auditing, and inspection as well as education in nutrition and public health. Driscoll's knowledge of regulatory issues and her certification as a HACCP auditor with ASQ add value to NSF-GFTC's consulting services. Reach her at bdriscoll@gftc.ca.

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Detection Technologies: What Works, What Doesn't

The inner workings of establishing a foreign object control program with metal detection or X-ray inspection | BY **BOB RIES**

Metal detection and X-ray inspection traditionally have been the first line of defense to identify the presence of physical contaminants in food products before they leave the processing plant.

For food safety and quality professionals, process engineers, and others who decide which technology will best protect against contaminants, choosing a detection system is typically based on three things: The optimum detection point, overall application capability, and total cost/benefit.

However, even though detection systems have been used by food processors for decades, engineering and software improvements continue to set new standards. This has led to confusion regarding which technology to employ and why.

The Basics

In security applications, such as airport screening, metal detectors use radio frequency signals to react to moving metal (i.e. coins in your pocket). X-ray systems produce density images for specific elements that are analyzed for irregularities.

Deploying these technologies for food applications is more complex. The size and type of anomaly being detected is more challenging and the rapid speed in which the detection needs to take place makes the process more difficult. In fact, in many cases, the real challenge isn't finding the contaminant; it's ignoring the product, packaging, or environment. False detections add up to big costs and high frustrations.

Metal detectors and X-ray systems for food applications must be very sensitive, easy-to-use, fully automatic, fast, robust, reliable, and cost effective. This is a tall order for any automated system that must run for many years in a harsh factory environment, and make reliable pass/fail decisions on literally millions of products.

Foreign object detection performance is determined in three ways: Detectable contaminant types, minimum contaminant size, and probability of detection.

The best practice prior to deployment is always to test many samples with different contaminants. This helps you understand how the product and contaminant react when in the detection system. Minimum contaminant size depends on the system design/technology and the product effect (how much the food itself "looks like" a contaminant to the system). Probability of detection means the chance of missing a contaminant in real production with real products running at real speeds. Typically, the larger the contaminant the higher the probability of detection.

This fundamental trade-off is addressed by building in margin for error, setting periodic mandatory audits, and performing preventative maintenance.

Selecting the Detection Point

Companies typically use Hazard Analysis and Critical Control Point (HACCP) methodology to manage food safety. The first part of the process (HA) identifies which contaminants are most likely to occur as part of the process or ingredients used. Next is the determination of the CCP, or in the case of contaminants, the best detection point. CCPs can occur in multiple places—at beginning of the process; after cutting, sifting or mixing; immediately after a bag/box is filled; or at end of the line.

Ideally, the goal is to find problems early in the process to reduce the cost of rework or scrap while still ensuring the final product is safe. Inspecting large cases immediately prior to shipment is not always the right decision.

(Continued on p. 44)

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(Continued from p. 42)

The optimum detection point can influence which technology should be employed. Metal detectors can be installed almost anywhere, but their performance depends on the size of the aperture (hole) the product passes through. In general, they work best for bulk conveyed or piped product or products in small packages.

X-ray systems are also dependent on product size but have greater sensitivity with large products than metal detectors. Due to the basic detector sensor scanning rate, X-ray systems are limited by speed. They are typically found closer to the end of the line. Because X-ray systems need a constant known speed to construct images, they cannot be used in gravity flow applications. Metal detectors are ideal for these types of products.

Decision-Making Check List

Determine what contaminants you want to find and where do they come from.

Given all the factors that affect application performance, the best way to select a technology and specific system is to run a test. Try everything to make the system fail. Strive for near 100% probability of detection with no false readings. Make sure you have enough detection margin so the system can run trouble free for hours without false rejects or the need for calibration.

Guidelines for X-Rays

X-ray systems create grayscale images corresponding to density. To detect a contaminant in those images, the contaminant must have significant contrast compared to the product the contaminant is inside.

Table 2 shows some typical contaminant material densities compared to water (i.e water density = 1.0).

The only way to definitively determine what can and cannot be detected (material and contaminant size) is have an application specialist run a test.

Metal Detection Capacity

Sensitivity decreases for wet/variable products due to their product effect. Table 3 is for dry products that aren't conductive. Note X-ray systems also can detect metals—typically in 0.5 mm to 2 mm range.

Table 1: Overview of Detection Technologies

Metal Detection	X-Ray Inspection
Detects metal including aluminum and wires.	Detects most metals and many other solid contaminants. Can also inspect a product by measuring shape, counting objects, or estimating weight from density image.
Can be used almost anywhere in a process; conveyors, drop through, and pipelines.	Conveyor, bulk, and pipeline; not for gravity applications.
Operates over a wide range of speeds.	Speed must be constant and range may be limited.
Conductive (wet/salty) products are the most difficult to ignore.	Dense products with a lot of texture are the most difficult to achieve good performance.
Performance dependent on aperture size, coil configuration, and software.	Performance dependent on X-ray source, receiver, power, and software.
Long life in even the most harsh environments.	Moderate life in harsh environments. Controlled environments are best.
Metal only usually > 1 mm in size.	Typically can find smaller contaminants than metal detectors and also nonmetallic contaminants.
Dry products, small products, and piped or bulk products have best sensitivity.	Large packaged products and cases can be inspected; cans and bottles too.
Sensitive to metallic packaging so detection performance is poor.	Ideal for metalized film and foil packages.

Table 3: Metal Detection Capability

	Aperture Height*		
	2 to 6 in.	6 to 12 in.	12 to 20 in.
Ferrous	0.9 mm	1.4 mm	1.9 mm
Non-ferrous	1.0 mm	1.6 mm	2.2 mm
Non-magnetic stainless steel	1.4 mm	1.9 mm	2.5 mm

Aperture width varies from 8 to 24 in.

Table 2: X-Ray Detection Capability

Contaminant	Density
Detectable	
Iron	7.15
Steel	7.86
Stainless steel	7.93
Possibly Detectable	
Nylon	1.15
PVC	1.38
Teflon	2.19
Calcified bone	2.2
Stone	2.5*
Glass	2.5
Aluminum	2.71
Dense rubber	1.52
Not Detectable	
Hair	0.32
Fruit pits	0.56
Insects	0.59
Fish bones	0.6
Wood	0.65
HDPE	0.92
UHMW	0.94
Ice	0.92

Average

Capability is dependent on density and texture of the product, not aperture size.

Package Material Trends

The need to market products in packaging materials which cost-effectively enhance shelf life has led many brand owners to convert to metalized film or foil-based structures. These materials not only provide better oxygen, moisture, and UV-light barriers, but also improve shelf presence. However, metal-based packages are not compatible with metal detectors. On the other hand, X-ray systems have no problem seeing through these packages and can detect very small contaminants inside.

Packaging material trends will continue to be a critical factor in contamination detection choices.

Last but not least, fully educate staff on the use and operation of whichever technology you employ. Audit the system regularly to assure policies and procedures are being followed. A thorough and thoughtful analysis prior to selecting a detection system will ensure many years of trouble-free operation and fundamentally safer products. ■

Reis is the lead product manager, metal detection and X-ray inspection, at Thermo Fisher Scientific. Reach him at 763-783-2500.

The Produce Industry's 'Barcode' of Approval

The Produce Traceability Initiative is spearheading efforts toward whole chain traceability by incorporating technology and common standards | BY **DAN VACHÉ**

The U.S. has a tremendous ability to produce and distribute healthy and nutritious fresh produce in an efficient and safe manner. It is recognized that there is always a risk for a pathogen to slip past the many checks and balances currently in place to ensure food safety. Even with dedicated industry efforts, events do occur. During the last six months of 2012, there were 16 documented recalls of produce involving apples, cantaloupes, mangoes, romaine lettuce, cherry tomatoes, and bagged salads.

While most companies engaged in the growing, packing, processing, and distribution of our nation's fruits and vegetables have had some sort of internal traceability program in place since the Bio Terrorism Act of 2002 (one step up—one step back with subsequent records), the produce industry realized this was not good enough in the event of a food safety issue impacting its complex supply chain. In 2007, the fruit and vegetable industry took on the task of developing an external traceability program, the Produce Traceability Initiative (PTI), to complement the Bioterrorism Act. The initiative aims to assist governmental agencies in quickly identifying the location of specific implicated products by lot or batch number for removal from the supply chain. Its mission is to create an action plan to adopt an effective whole chain traceability program for the produce industry by incorporating the use of technology and common standards that serve as linkages between internal traceability programs.

As with any initiative involving process change and technology, there are challenges for early adopters. The PTI is no exception. The recommendation to apply a barcode on each case of produce is a whole new adventure for produce growers and shippers. The use of barcode technology is not new to the packaged food industry, it was first introduced to the retail trade in 1974 when a pack of Wrigley's Spearmint chewing gum was the first UPC scanned at Marsh's Supermarket in Troy, Ohio. But for bulk produce, it was indeed an undertaking.

In order to coordinate this produce industry-wide traceability initiative, 53 companies, including grower-shippers, wholesalers, retailers, food service distributors, and technology providers, volunteered to participate in 10 various working groups. Each working group of experts created guidance and best practice documents to pave the way for the use of standards.

The PTI Technology Working Group (one of nine PTI working groups) consists of a broad spectrum of technology companies who provide software, hardware, and technical consulting services. The group worked collectively to develop best practices for the industry, and to date have compiled and vetted best practices for Formatting Case Labels, Private Label/Brand, Direct Print, Product Substitutions, Cross Docking, Labeling Hybrid Pallets, and Best Practices for Repacking/Commingling.

Reading Between the Barcode Lines

The supply side began to pilot the different methods of attaching the Global Trade Idem Number, which includes the brand owner identification and item reference number, and the lot or batch number to each case of produce. The industry's initial reaction centered around the potential disruption of current processes and the cost of labeling, whether it occurred in the field at point of harvest, in the facility on packing lines, or at time of shipment. All of these methods were tested multiple times by various solution providers and their supply side clients. The solution providers were able to successfully limit the impact to the current process efficiencies and keep the cost down.

A huge challenge was labeling at time of harvest for those produce items packaged immediately in the field to be sent

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VIPERAGP - FOTOLIA

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down the supply chain, bypassing a packing facility. Should labels be preprinted in the office and delivered to the field, or printed in the field? Would it be feasible to label at the point of shipment, even if it impacted established processes and required additional handling of highly perishable produce? The additional challenge of unpredictable field conditions, including heat, wind, rain, dust, and mud, and factor in the fast pace at which the professional harvest crews work, and the situation becomes even more difficult. However, the best results were found when the harvest crews were asked to help design a solution to meet the objective that would be best integrated with their process. The employees came up with methods to have the PTI-compliant labels accessible on the field harvest equipment for immediate placement on each case. Field managers were surprised by how quickly they were able to train harvest crews, with many being unfamiliar with the technology, and the gains in efficiencies the crews discovered.

To bring the labels to the field, new designs for portable printers rugged enough to withstand field conditions were designed with ease of operation and low maintenance in mind. The ability to print and apply labels in the field was also a benefit to the operations in other ways—it provided real-time harvest information to the cooling facilities and sales teams by providing pack-out information that was not previously available on a real-time basis. And productivity increased by eliminating manual labeling, pen marking, and downstream guesswork.

With the engagement of the harvest crews, field managers and employees alike quickly developed a greater appreciation for the accuracy required for the products they handle in the field. They realized they are at the front end of traceability efforts and became more conscious of the requirements and expectations placed on them daily.

Packing within the four walls of a facility mostly eliminates the challenges of labeling from Mother Nature, but companies using either hand packing or high-speed packing lines face other obstacles. For example, many companies use pen and paper to document and track the movement of product, which can lead to inaccuracy of records and potential mismarking of cases. Implementing a new system of labeling can be initially disruptive to the process, considering the learning curve and audit period to ensure proper label application is occurring. The industry acknowledges how much easier it is to use technology-driven systems compared to those that are paper-based, but even if an operation is already fully automated, some operations fear that installing new hardware for labeling could decrease efficiency and add functional complexity to the line.

Pictured from right to left is Dan Vaché from the United Fresh Produce Association and Casey Precourt, the WMS/traceability project manager for Charlie's Produce Company in Seattle, Wash.

Regardless of the operation's strategy in applying a PTI label, it's all made possible by an integration of software and hardware to maximize control over material handling, box and size recognition, and label application. When controls are put into place, the technology is able to direct cartons that have been labeled to designated pallet stations or mechanical palletizers via electronic carton controls. This enhances the use of previously installed conveyor systems and provides a granular level of product information to route the right carton to the right place for shipping to the right customer. These established processes have proven to reduce labeling errors to nearly zero.

Direct print on cases is also a challenge with many suppliers using corrugated brown, white bleached, and white printed material. These suppliers have found it difficult to establish enough contrast to print an acceptable barcode that will withstand temperature and humidity fluctuations throughout the supply chain. It has been tested and confirmed that suppliers using bleached or white printed areas on brown kraft can provide enough contrast for PTI compliant direct print GS1-128 barcodes, assuming high-resolution, well-maintained, and monitored direct print equipment is used. There is a continuous drive to use direct print to reduce costs by eliminating the use of a label. Methods currently being piloted include Drop on Demand High Resolution Inkjet, Thermal Inkjet, Industrial Laser Coding, and Digital Tissue Stencil Process. The real test of direct print will come when the entire supply chain is engaged and the direct print barcode is scanned multiple times.

Moving Forward

The produce industry has been referred to as the poster child for all other perishable commodities preparing to attain a level of whole chain traceability to meet the needs and demands of government agencies and ultimately the consumer. With millions of cases of fresh produce moving through the supply chain annually, it is imperative to have visibility of the movement of fresh produce should a situation arise where it must be removed from the marketplace. With industry demands and concerned consumers, whole chain traceability is on the near horizon.

Multiple regional retailers and several food service distributors have announced to their suppliers their expectations regarding case labeling compliance. However, their buying power is limited and adoption has been slow without a critical mass in the market requiring PTI compliant labels on each case of produce. The tipping point is near for the wide adoption of the PTI with the recent announcement by WalMart/Sam's Club indicating that on January 1, 2014, product received at their distribution centers without a PTI compliant label will be rejected unless an active exception has been issued prior to delivery.

This move significantly strengthens the momentum for the entire supply chain to implement whole chain traceability. The common goal is to have a system in place that when produce is implicated in a food safety event, the specific product can be contained and removed from the marketplace quickly while safe products continue to be available to the consumer. ■

Vaché is vice president of supply chain management at United Fresh Produce Association. He can be reached at DVache@unitedfresh.org.

NEW PRODUCTS

Tube 5.0 mL

The Eppendorf Tube 5.0 mL features a convenient snap cap for single-hand operation and a compact conical design, removing the contamination risks associated with manipulating small volumes in large tubes. Tube is designed for centrifugation up to 25,000 x g, eliminating the risk of sample loss when using rapid protocols. Protein LoBind and DNA LoBind variants of the tubes reduce sample loss by minimizing surface binding of the samples. **Eppendorf North America, Inc., 800-645-3050, www.eppendorfna.com/5mL.**

Optical Sorter

The SORTEX A MultiVision is suited for various dry commodity food applications. Blighted product from a range of foodstuffs can be targeted, including such mycotoxins as sclerotia from sunflower seeds, vomitoxin from wheat, fusarium from barely, ergot from rye, and aflatoxins from peanuts. The Advanced Multivision Inspection System is a key element with its four wavelength technology (visible and infrared) and PROfile (shape) detection technology. Enhanced InGaAs camera component enables the unit to identify the subtlest of color defects. The five chute design offers maximum sort configuration flexibility, providing both re-sort and simultaneous sort on the same machine. **Bühler Group, www.buhlergroup.com.**

Ractopamine Testing

Bioo Scientific's Ractopamine Testing Services provide screening for ractopamine, a potent ß-agonist, in meat, animal tissue, milk, feed, etc. Services include extraction methods optimized for high recovery rates from a wide variety of sample types, and have reportable detection limits as low as 0.2 ppb for pork samples. Test results are available in less than one week from receipt of samples. Kits are also available for quantitative assessment of ractopamine for labs that wish to perform rapid screening in-house. **Bioo Scientific Corp., 888-208-2246, www.biooscientific.com.**

Business Intelligence Solution

TrackWise Analytics enterprise business intelligence solution helps redefine the benchmark for quality systems. It introduces real-time analytics and ad hoc reporting capabilities to the core quality management functionality of Sparta's TrackWise product. TrackWise Analytics is released as part of TrackWise 8.5, the latest version of the enterprise quality management software. Organizations can identify emerging trends and implement proactive quality management strategies that address the cost of poor quality. The TrackWise drag-and-drop reporting and charting capabilities deliver real-time intelligence. **Sparta Systems, Inc., 888-261-5948, www.spartasystems.com.**

Managed Sanitation Program

The SanitationCheck program uses a three-pronged approach to ensure proper cleaning and sanitation: Training, Validation, and Documentation. CleanCheck trains, tests, and certifies staff on HAZCOM, GHS, and OSHA Blood Borne Pathogen standards. Food Processing Training cards reinforce training and provide a framework for adherence to the standard going forward. This process is supported by ATP validation tools. ATP swabs and meter allow sanitation managers to objectively train and assess staff cleaning operations while minimizing risk of transfer of harmful pathogens. Data can then be loaded into CompuClean CMMS to document and monitor established CCP limits and verify program progress. **Spartan Chemical Co., 800-537-8990, www.spartanchemical.com.**

HACCP and Hygiene Program Management

The MVP ICON monitors key HACCP parameters including ATP, pH, temperature, conductivity, and chemical concentration. The software dashboard serves as a control panel, providing quality assurance professionals a quick overview of key control metrics, assuring their HACCP plans and sanitation protocols are being properly executed. The dashboard offers such insights as the amount of ATP swabs used in comparison to a set target, whether failed results have been adequately recleaned and retested, and when the MVP ICON's next calibration is due. Also features original print-and-present HACCP reports. **BioControl, 800-245-0113, www.biocontrolsys.com.**

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X-Ray Inspection System

The Ishida IX-GA Series X-ray inspection system can be used to check product integrity, package quality, and weight accuracy. It is capable of identifying and rejecting packages with broken or missing product pieces. System detects products caught in packaging seals and verifies that products' weight and size meet specifications. Setup is automatic and no routine calibration is required. Machine warm-up takes only 90 seconds. Stainless steel construction conforms to HACCP. Waterproof conveyor is designed to IP66 and is removed without using tools. **Heat and Control, 800 227 5980, www.heatandcontrol.com.**

Microfiber Disposable Towel

The Quatguard XL is a Quat and Chlorine compatible disposable towel designed for the foodservice market. Microfiber technology adsorbs sanitizer (rather than releasing it back to the wiping area), leaving surface tops properly disinfected. Provides up to 99.9 percent bacteria removal. **ITW Professional Brands, 800-242-7374, www.itwprofessionalbrands.com.**

Sliding Friction Testing

The TA-SFJ Sliding Friction Jig measures the coefficient of friction between two materials by sliding them against each other. It utilizes the Brookfield CT3 Tester to pull weight in a horizontal direction so sliding friction between the two materials is measured accurately over a distance that is sufficient to verify steady state behavior. The jig can be used to measure smoothness, slipperiness, or stickiness qualities. **Brookfield Engineering, 800-628-8139, www.brookfieldengineering.com.**

Food-Grade Sanitizers

KEEPER Professional products are FDA-approved, fast-acting, broad-spectrum anti-microbial agents using ClO2 technology for microbial control without altering or destroying the taste, color, nutritional value, or odor of food products. They are effective against *Salmonella, E. coli* 0157:H7, *Listeria monocytogenes, Campylobacter jejuni*, and other pathogens in red meats, poultry, seafood, and fresh produce. They also prevent formation of biofilm. **Zep Inc., 877-428-9937, www.zepfooddivision.com.**

Markers for Horse Meat

AB SCIEX's new method for detecting horse tissue present in meat samples is based on LC/MS/MS. It detects the protein markers distinct to specific meat species and confirms the presence of a particular species in a sample by direct detection. The method also enables labs to detect veterinary drug residues in the same analysis. While the method was optimized to identify horse tissue contamination in beef samples, it can also be adapted to detect peptide markers of numerous different animal types simultaneously. **AB SCIEX, 800-343-1346, www.absciex.com.**

Thermal Shock-Resistant Metal Detector

The APEX HD washdown metal detector withstands extreme temperature cycling typically experienced in fresh food processing and sanitation environments. Validated by a third-party laboratory, detector has a projected operating life of 10 years or more in these environments. It utilizes a new case design and a proprietary aperture filling technique that gives it additional robustness and stability. The control panel also has a one-way vent allowing any trapped humidity to escape. **Thermo Fisher Scientific Inc., 800-445-3503, www.thermoscientific.com/productinspection.**

Allergen Analysis & Extraction Buffers

The AgraStrip Total Milk LFD and AgraStrip b-Lactoglobulin LFD have been validated for a variety of milk products and soft drinks. Both LFDs ensure the correct labeling of products according to E.U. Directive 2007/68/EC. In addition, AgraStrip Wine extraction buffer egg and Casein both allow for the testing of low levels of egg white and milk proteins in wine samples, together with the respective AgraStrip kits for Egg and Casein. **Romer Labs, 636-583-8600, www.romerlabs.com.**

In Other Product News

Microbiologics receives ISO 13485: 2003 certification—the principal standard for manufacturers of medical products, devices, and components. In addition, the company adds a new strain of Shiga-toxin producing *Escherichia coli* (STEC) to their line of ready-to-use QC microorganism products.

3M Food Safety's Molecular Detection Assay for *E.coli* O157 (including H7) has been granted a NF Validation certification from AFNOR Certification for its ability to detect the bacteria in raw beef, fruit, vegetable, and dairy products.

Neogen's ANSR system for *Salmonella* receives AFNOR validation (NF Validation by AFNOR certification NEO 35/02-0513).

Microbac Laboratories adds GC/MS/MS and LC/MS/MS instrumentation to support food pesticide residue and multi-residue pesticide analyses.

bioMérieux receives two First Action Official Methods of Analysis approvals from AOAC International for VIDAS UP Listeria (LPT) and VIDAS Listeria monocytogenes xpress (LMX) testing methods.

Events

AUGUST

25-28
AOAC's Annual Meeting & Exposition
Chicago
Visit www.aoac.org
or call 301-924-7077 x 170.

26-30
FSSC 22000 Lead Auditor
Chicago/Toronto, Canada
Visit www.lrqausa.com/services-we-offer/training
or call 888-877-8001.

SEPTEMBER

3-4
FSSC 22000 Appreciation & Interpretation for Food Manufacturers
San Diego/San Francisco/Las Vegas
Visit www.lrqausa.com/services-we-offer/training
or call 888-877-8001.

10-12
Penn State HACCP for Meat and Poultry Processors
West Chester, Pa.
Visit www.foodscience.psu.edu/workshops.

16-17
Nevada Food Safety Task Force Conference
Reno, Nev.
Visit www.nfstf.com.

18-19
2013 HACCP Certification Course
Dallas
Visit www.food-safetynet.com
or email info@FSNS.com.

18-20
BRC Global Standard for Food Safety Implementation
Columbus, Ohio
Visit www.food-safetynet.com
or email info@FSNS.com.

19-21
FSSC 22000 Appreciation & Interpretation for Food Packaging
Houston/Ft. Lauderdale, Fla. /Orlando, Fla.
Visit www.lrqausa.com/services-we-offer/training
or call 888-877-8001.

23-25
Pack Expo
Las Vegas
Visit www.packexpo.com
or email expo@pmmi.org.

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Silliker	52	silliker.com
T&D Corp.	2	tandd.com
Waters Corp.	7	waters.com

Events cont.

OCTOBER

16-18
BRC Global Standard for Food Safety Implementation
Fresno, Calif.
Visit www.food-safetynet.com
or email info@FSNS.com.

NOVEMBER

6-7
China International Food Safety & Quality Conference + Expo
Beijing, China
Visit www.chinafoodsafety.com
or email info@infoexws.com.

Innovators

IN FOOD QUALITY & SAFETY

Women's Role in Reforming Food Safety

BY **LORI VALIGRA**

Before U.S. women earned the right to vote in 1920, three female pioneers in food safety endured discrimination to make major contributions to the field. In the 19th century, Amanda Theodosia Jones (1835-1914) came up with the standard for vacuum canning. Effie Alberta Read, PhD, (1871 est.-1930) quietly spent two decades developing micro-chemical procedures to detect adulterated products, work that became crucial for enforcing the first comprehensive U.S. consumer protection law—the 1906 Food and Drugs Act. And later on, Mary Engle Pennington, PhD, (1872-1952) became the first female lab chief at the U.S. FDA, conducting research to make the food supply safer and fresher.

Effie Alberta Read, PhD, assistant chief of the micro-analytical lab at FDA's Bureau of Chemistry.

FDA HISTORY OFFICE

Jones had a penchant for science, but let spiritualism guide her decisions. In 1872, she reportedly received a message from the spirits to write to Professor LeRoy Cooley of Albany, N.Y., who she knew through her sister. The spirits further told her canning could be done in a better way by removing the air in the container. Though she had no prior experience with canning, she and Prof. Cooley were able to collaborate to create the "Jones Method," also known as the "Pure Food Vacuum Preserving Process(es)." They created the first model in 1873 and were granted five patents to cover the process, two of which were issued to her alone. The method became the standard for canning in the U.S. Jones discovered their method added more flavor to the food, but didn't remove any nutritional value. It killed bacteria by lack of oxygen instead of just heat.

She also founded the Women's Canning and Preserving Co. in 1890, but was unable to make a commercial success of it. The company, based in Chicago, employed only women, reportedly the first company to do so. It later was taken over by men after it was apparently unable to sell enough products because it was women-owned and run. Jones continued to invent and in 1906 came up with a vacuum process for drying food. She also created the first automatic safety oil burner, for which she also received a patent.

Dr. Read and Dr. Pennington also experienced gender discrimination, even as they contributed to food safety. Dr. Read earned both a PhD from Cornell University and MD from George Washington University. In acknowledging her contributions during Women's History Month, the FDA noted that she was among the best trained analysts when she joined the agency's Bureau of Chemistry in 1907.

"Although Dr. Read did not publish widely, she dedicated herself over the next two decades to developing and executing crucial micro-chemical procedures to detect adulterated products; her work represented an unsung scientific cornerstone in the enforcement of the 1906 Food and Drugs Act, the first comprehensive consumer protection law in the U. S.," according to FDA's report.

Dr. Read developed a new way to identify artificially colored imported teas. They were illegal because artificial color was used to conceal inferior products. Her method offered rapid reliable detection. It could be run with equipment found in most laboratories. In one high-profile case in 1912, her method helped secure a judgment against 1,000 packages of artificially colored tea from a Tennessee importer who wanted to pass off an inferior product.

Dr. Pennington became the first female lab chief at the FDA. She studied chemistry and biology at the Towne Scientific School at the University of Pennsylvania, which at the time did not award BA degrees to women, so instead she received a "certificate of proficiency." In the 1890s, she went on to earn a PhD from the University of Pennsylvania, one of the only schools in the country to grant such degrees to women.

After the Pure Food and Drugs Act, also known as the Wiley Act, became law in 1906, FDA chief Harvey Wiley asked Dr. Pennington to head the Bureau of Chemistry's Food Research Lab. While Wiley knew she was the best person for the job, according to the FDA, he also knew not everyone would agree, so he disguised her gender by referring to her as M.E. Pennington.

The FDA stated her research "helped revolutionize the food supply, making more safe fresh foods available at affordable prices, particularly in newly industrialized areas of the country." Her cold storage research at the FDA led to the recognition that fresh foods could be kept longer when stored at a constant low temperature, which also kept bacterial counts low. That discovery proved important in establishing food quality benchmarks.

Dr. Pennington left the FDA in 1919, but kept working on food preservation and cold storage. The FDA noted that her research influenced Clarence Birdseye as he perfected his flash-freezing technique. According to the FDA, today's supermarket refrigerated and frozen food sections are the direct result of her pioneering work. ■

Valigra is a writer based in Harrison, Maine. Reach her at lvaligra@gmail.com.

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