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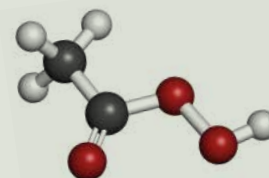


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Don't forget to keep up with trending topics by accessing our monthly blog at www.FoodQualityandSafety.com/category/food-quality-safety-blog. Here's a sample of popular posts:

- Why Farm Biodiversity Matters
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- Are Better Regulations Needed to Reduce Salmonella Outbreaks? BY STEVE SAYER
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From The Editors

Answers and inspiration can come from anywhere or from anyone. Legend has it that Sir Issac Newton's theories on gravity resulted from being hit on the head while sitting under an apple tree (actually, he saw it drop, but it's questionable whether it landed on his head), producing an "a-ha" moment in physics. Dr. Alexander Fleming's discovery of penicillin in 1926 came from a contaminated petri dish. He observed a zone of inhibition around a mold growing on the plate. Instead of pitching the plate, he asked himself why. The "why" ushered in an age of antibiotics.

Another inspiration comes from my UC Davis professor, Dr. Marty Miller. A food processor asked him to determine why intermittent spoilage was occurring in its canned- and glass-packed products. Dr. Miller spent days in the plant watching operations and reviewing records. He came up with nothing. He then decided to look at the night shift. Again, nothing.



He ended up chatting with the night shift janitor, a long-time employee. After Dr. Miller described the issue, the janitor said, "Well, a few years back we used to pay the boys on Friday. They could go out and whoop it up bit and sleep it off Saturday morning. Now, everyone gets paid on Wednesday and they still whoop it up."

With no other ideas, Dr. Miller looked back at the records, and lo and behold, each incident occurred on a Thursday after pay day. Company management was doubtful when his recommendation was simply, "Put pay day back on Friday." But they did, and the problem went away.

I had a similar moment 30 years ago when I went to China's Fujian Province to find out why there was *Staphylococcus* enterotoxin in canned mushrooms. The team and I got background material including slides from companies that purchased mushrooms in 1988 that were toxic. A few slides showed mushrooms stored in black PVC bags and tied shut. Mushrooms respire rapidly so these bags would soon become anaerobic. We saw many shaky practices in Fujian, but no product stored in bags as previously done. Those few slides inspired us to design experiments showing how enterotoxin could be produced in quantities that survived the thermal processes done on canned mushrooms.

The point: Be observant, listen, and consider the smallest or insignificant factors, which may be key to solving big problems.

Richard Stier
Co-Industry Editor



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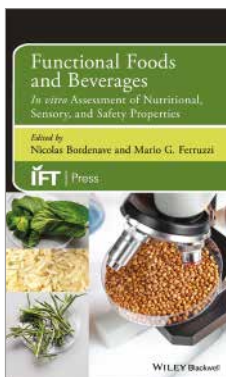
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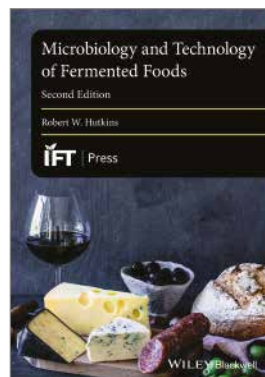
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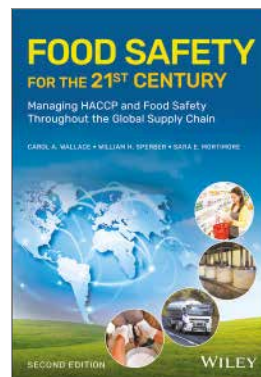
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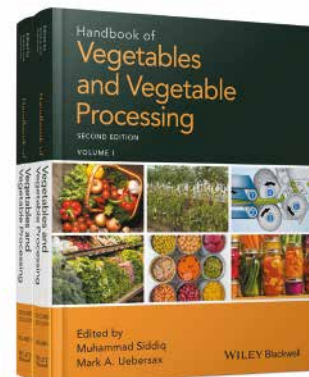
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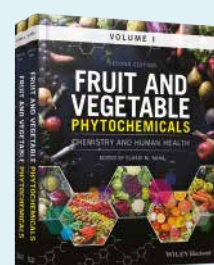
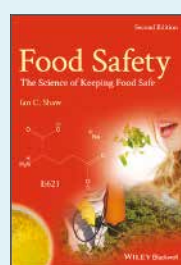
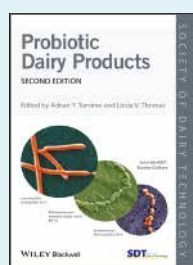
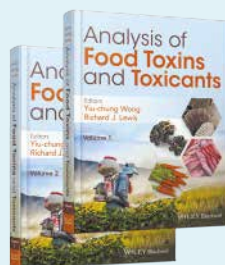
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NEWS & NOTES



Sampling Frozen Berries for Hepatitis A Virus and Norovirus

FDA is collecting samples of frozen berries from processors, distribution centers, warehouses, and retail locations throughout the year to test for hepatitis A virus and norovirus. Some consumers use frozen berries as ingredients in foods without first cooking them, increasing their risk of exposure to harmful viruses. The sampling assignment began in November and is estimated to last approximately 18 months. FDA is collecting domestic samples of frozen berries and is also collecting import samples from ports of entry, importer warehouses, or other storage facilities where foreign goods are cleared for entry into the country. The agency plans to collect and test 2,000 samples in all.

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New Organic Certification Mark

Quality Assurance International (QAI) is launching a new certification mark to help consumers understand that USDA organic certified products are required to be free of GMOs. In other words, “If it’s organic, it’s non GMO.” In a QAI study, 80% of participants said they were unaware that products with the organic seal were also non-GMO. Of survey participants who reported recently shopping at a well-known natural foods store, just one-quarter recognized organic products as non-GMO. The study suggests many consumers don’t understand organic products are non-GMO and may seek both labels to satisfy their needs. Makers of QAI certified products can choose to use the original QAI mark or the new “If it’s organic, it’s non GMO” mark.



We Want to Hear from You!

Food Quality & Safety magazine welcomes letters to the editor on any relevant industry topic.

Submit letters to:

Marian Zboraj, Professional Editor

Email: mzboraj@wiley.com

Letters should be approximately 350 words and may be edited for space or style.

Preparing Food Contact Notifications for Infant Formula

FDA recently issued [guidance](#) to provide additional information on how to prepare Food Contact Notifications for food contact substances that come into contact with infant formula and/or human (breast) milk. FDA evaluates the safety of all packaging materials before they enter the marketplace, including material that may be used in infant formula packaging, such as baby bottles, bottle inserts, nipples, and any other products used to collect and store human milk. The recommendations in this guidance are meant to help industry understand FDA’s process for evaluating the safety of food contact substances, which incorporates the latest scientific thinking about the effects chemical substances may have on infant health.

France to Ban Titanium Dioxide Whitener

[As reported by Reuters](#), France will ban the use of titanium dioxide as a food additive from 2020 after the country’s health and safety agency said there was not enough evidence to guarantee the safety of the substance for human consumption. Titanium dioxide is used in industry as a whitener, notably for paint, and in the food sector, where it is labeled E171 and goes into products from chocolate to chewing gum. France ordered a review of the substance in 2017 after a study found health effects in animals that consumed it. France’s National Institute for Agricultural Research and partners in a study of oral exposure to titanium dioxide had shown that E171 crosses the intestine wall in animals to reach other parts of the body.



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USDA Discontinues Toxoplasmosis Research with Cats

The USDA Agricultural Research Service is redirecting its toxoplasmosis research, stating that the use of cats as part of any research protocol in any ARS laboratory is being discontinued and will not be reinstated. *Toxoplasma gondii* (*T. gondii*) parasite causes toxoplasmosis, a disease considered to be a leading cause of death from foodborne illness in the U.S., especially for individuals with weak immune systems such as children and HIV patients. ARS research in this area has produced undeniable results—including helping to cut the prevalence of *T. gondii* by as much as 50% in the U.S. Over the course of this research, ARS worked to minimize reliance on cats—the only hosts in which *T. gondii* can complete its life cycle and produce oocysts (eggs)—as agency researchers worked to understand and combat toxoplasmosis.



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Business Briefs

Cloverleaf Cold Storage completes a transaction by which **Zero Mountain** merged into Cloverleaf, resulting in approximately 140 million cu. ft. of capacity in nine states.

Pure Bioscience partners with **Smart-Wash Solutions** for an antimicrobial pre-treatment on cut produce named SmartWash Boost.

Detectamet expands its metal detectable and X-ray visible products into Canada.

Tyson Ventures invests in **Clear Labs**; in addition, Clear Labs forms distribution agreement with **Oxford Nanopore** for rapid, intelligent food safety testing.

Hygiena acquires **Helica Biosystems** to expand its portfolio of precise food safety technology.

Testo North America partners with **Savour Food Safety International** and **Savor Safe Food** to advance food safety.

Codexis signs multi-year agreement with **Tate & Lyle** for the supply and licensing of Codexis performance enzymes used in manufacturing of Tate & Lyle's TASTEVA M Stevia Sweetener.

FlexXray acquires **Accu-ray**; the combined company will operate as FlexXray.

ANSI-ASQ accredits **LSQA S.A.** of Uruguay as a certification body under FDA's Accredited Third-Party Certification Program for Produce Safety and Preventive Controls for Human Food.

The National Institutes of Health awards **Zebra Analytix** a \$225,000 Phase I Small Business Innovation Research grant to investigate real-time measurement of volatile organic compounds in water samples.

NZMP, the global dairy ingredients brand of **Fonterra**, launches two probiotic ingredients, **BifidoB 019** and **LactoB 001**, into the sports and active lifestyle market in the U.S.

ProcessPro forms strategic partnership with **DocUnity**, a provider of document management and workflow software and services.

U.S. Beef Gains Full Access to Japan

U.S. Secretary of Agriculture Sonny Perdue announced on May 17 that the U.S. and Japan have agreed on new terms and conditions that eliminate Japan's longstanding restrictions on U.S. beef exports. Secretary Perdue met with Japanese government officials and affirmed the importance of science-based trade rules. The new terms, which take effect immediately, allow U.S. products from all cattle, regardless of age, to enter Japan for the first time since 2003. "We are hopeful that Japan's decision will help lead other markets around the world toward science-based policies," says Secretary Perdue. USDA estimates that this expanded access could increase U.S. beef and beef product exports to Japan by up to \$200 million annually. The agreement is also an important step in normalizing trade with Japan, as Japan further aligns its import requirements with international standards for bovine spongiform encephalopathy.



Edible Insects Market is Gaining Ground

The edible insects market is set to grow from its current market value of more than US \$55 million to over US \$710 million by 2024, according to a [new research report](#) by Global Market Insights. The global human population is anticipated to increase by more than 2 billion by the end of 2050, giving rise to food problems. An increase in food production will lead to more pressure on the environment, so consumption of edible insects is one of the food alternatives through which one can get high-quality protein, amino acids, and vitamins at affordable costs. Edible insects possess a high food conversion rate and emit less greenhouse gases than traditional livestock. Furthermore, insect farming is cost effective compared to cattle farming.



Global Project to Fight Food Fraud

The International Atomic Energy Agency's five-year research project with experts from 16 countries is working to apply nuclear-derived techniques to test for accuracy in food labels. The outcome of the project, carried out in cooperation with the FAO, will assist countries in combating fraud in high value food products, such as premium honey, coffee, and specialty rice varieties. It will help countries apply stable isotope techniques to protect and promote foods with added-value, such as organic food or products with specific geographical origins like Jamaican Blue Mountain coffee. The method works by looking at the ratio of stable isotopes in elements—such as hydrogen, oxygen, and carbon—and the concentration of elements in a sample of the product. These can provide a unique fingerprint that links a crop to the place where it is cultivated.

FDA-ACS Training on Emerging Chemical Science for Food Safety

FDA is partnering with the American Chemical Society (ACS) to provide a series of biannual training sessions focusing on chemical science related to food safety. These half-day training sessions are a continuing education opportunity for the FDA's Center for Food Safety and Applied Nutrition employees. The colloquia are open to the public and offer participants a venue to interact with leading technical experts in chemistry. The colloquia are not intended as a forum to discuss regulatory issues or to make recommendations to the agency. The series will be focused on high-quality, cutting-edge chemistry related to food, food additives, food packaging, and food safety topics. They will include the areas of flavor modifiers, manufacturing processes, specifications, and analytical methods. There is no cost to attend in person or through webcast, but space is limited. Visit the ACS website at www.acs.org for more information.

Washington Report



Outsmarting Food Pathogens

FDA to employ digital technologies to usher in 'New Era of Smarter Food Safety' | BY TED AGRES

The incidence of foodborne infections in the U.S. from *Campylobacter*, *Salmonella*, and other virulent pathogens increased sharply last year, creating a major public health problem, according to CDC. Among its many consequences is a growing strain on the ability of federal, state, and local government agencies to identify and mitigate potential food safety concerns.

Partly in response, FDA in April announced a "Blueprint for a New Era of Smarter Food Safety," in which government and industry would cooperate to leverage advances in digital technologies such as blockchain to enhance product traceability; artificial intelligence and machine learning to facilitate food import inspections; and new packaging and transportation approaches to help modernize the food industry and meet the growing demands of e-commerce.

While the Food Safety Modernization Act (FSMA) has enhanced oversight of the nation's food supply, "we recognize that it's time to look to the future of food safety once again with a view that builds on the

progress we're making with our regulatory framework, but also leverages the use of new and emerging technologies to create a more digital, traceable, and safer system," said acting FDA Commissioner Norman "Ned" Sharpless, MD, and Deputy Commissioner Frank Yiannas in a recent joint statement.

Toward this end, FDA this year will hold a public meeting and gather stakeholder input on "smarter food safety." The agency will also launch a pilot project using artificial intelligence to enhance its ability to review imports at ports of entry to ensure they meet U.S. food safety requirements. In addition, FDA will tap into its existing programs related to tracking the drug supply chain to see whether similar approaches might be adapted to tracking the nation's food supply.

"When you look at how other industries digitally track the movement of planes, ride sharing, and delivery of packaged goods, it becomes clear that we must explore how these types of technologies could improve tracking when it comes to food," Dr. Sharpless and Yiannas explained.

Pathogens on the Rise

The incidence of foodborne infections increased in 2018 compared to 2015-17, according to CDC's latest Foodborne Diseases Active Surveillance Network ([Food-Net](#)) report, released in April. Surveillance from labs in 10 states confirmed more than 25,600 infections, nearly 5,900 hospitalizations, and 120 deaths that were caused by eight enteric pathogens commonly transmitted through food.

As in previous years, *Campylobacter* was the most prevalent, being responsible for 9,723 illnesses, 1,811 hospitalizations, and 30 deaths. This was followed by *Salmonella* with 9,084 illnesses, 2,416 hospitalizations, and 36 deaths. *Campylobacter* is commonly associated with consumption of raw or undercooked poultry and meat, while *Salmonella* is an issue in many types of food, including eggs, meat, poultry, fruits, vegetables, spices, and nuts.

Both bacteria can cause mild to serious illness, from uncomplicated diarrhea to severe systemic infections, such as Guillain-Barré syndrome (*Campylobacter*), an autoimmune disease that can cause paralysis, and reactive arthritis (*Salmonella*), which can cause acute, debilitating joint pain.

Other bacterial pathogens included Shiga toxin-producing *E. coli* (with 2,925 illnesses), *Shigella* (2,414 illnesses), *Vibrio* (537), *Yersinia* (465), and *Listeria* (126). While *Listeria* caused the fewest number of cases, it was also the most virulent, hospitalizing 96 percent of its victims and killing 21 percent of them.

Compared to 2015-17, incidences per 100,000 population increased by 12 percent for *Campylobacter* and 9 percent for *Salmonella*. Incidences skyrocketed for the parasite *Cyclospora* (399 percent), followed by the bacteria *Vibrio* (109 percent), *Yersinia* (58 percent), and Shiga-producing *E. coli* (26 percent).

Nationwide, the actual number of cases are much greater. This is because FoodNet collects data from public health departments in only 10 states, covering

just 15 percent of the U.S. population. Additionally, the true number of foodborne illnesses always exceeds the reported number because many people who get sick do not seek, or necessarily require, medical treatment.

Some of last year's increase may be due to greater use by the reporting laboratories of culture-independent diagnostic tests (CIDTs), CDC says. But produce itself was a major culprit, with romaine lettuce linked to two multistate outbreaks of *E. coli* O157 infections. CDC specifically tied the jump in *Cyclospora* infections to outbreaks associated with produce.

"More targeted prevention measures are needed on produce farms, food animal farms, and in meat and poultry processing establishments to make food safer and decrease human illness," the CDC report said.

FDA this year began routine inspections of large farms for compliance with FSMA's produce safety rule. While this will hopefully mitigate some of the contamination problems, more needs to be done. For example, in December 2018, USDA reported that 22 percent of establishments that produce chicken parts failed to meet the *Salmonella* performance standard.

Despite all the increased attention and effort on improving food safety, there seems to be no reduction in problems. During the first few months of this year alone CDC has been tracking *Salmonella* in turkey and in pre-cut melons, and *E. coli* in ground beef, among many others.

Limits of Diagnostics Tests

The public health labs that contribute data to FoodNet are increasingly using CIDTs, such as immunoassays and nucleic-acid amplified tests. CIDTs are faster and easier to perform than traditional culture-based methods, which require

use of trained personnel. CIDTs can identify a general bacteria type within hours without having to culture or grow the pure bacteria strain (or isolate) in a laboratory, a process that typically takes days. But without the isolate, public health scientists are unable to determine the DNA subtype ("fingerprint"), its resistance

Last year, WGS replaced PFGE in PulseNet as the primary method for detecting and investigating *Listeria* outbreaks and is increasingly being used for *Salmonella*, *E. coli*, and *Campylobacter*.

pattern, or other characteristics necessary to detect outbreaks, track antibiotic resistance, monitor disease trends, and ultimately prevent outbreaks.

For example, PulseNet, the CDC-run network that connects public health and food regulatory agency laboratories, relies on the collection of DNA fingerprints of bacteria taken from sick patients to identify local and multistate outbreaks. The growing use of CIDTs is endangering PulseNet's effectiveness.

"Without a DNA fingerprint of the bacteria, CDC and public health labs will not be able to find, monitor, and prevent foodborne disease outbreaks, track antibiotic resistance, or follow trends to know if prevention policies are working," CDC says. Even in FoodNet, CIDTs "complicate data interpretation," CDC says.

This is where advances in technology, such as whole genome sequencing (WGS) for pathogen detection and blockchain for product traceability are expected to yield big dividends for food safety.

WGS can map the genetic sequence of pathogens and other organisms with such precision that researchers can distinguish between different strains of a bacterium or even slight variations by geography within the same strain. Prior to WGS, scientists used such tools as polymerase chain reaction and pulsed-field electrophoresis

(PFGE) to genotype microorganisms for diagnostic subtyping.

Last year, WGS replaced PFGE in PulseNet as the primary method for detecting and investigating *Listeria* outbreaks and is increasingly being used for *Salmonella*, *E. coli*, and *Campylobacter*.

"The more widespread use of WGS has also increased the number of detected outbreaks and subsequent investigations," said then-FDA Commissioner Scott Gottlieb, MD, and Yiannas in a recent joint statement. But, they added, this has also increased FDA's workload to identify and mitigate potential food safety concerns. "As part of the president's 2020 budget, we're also requesting additional resources to support the use of WGS and expand our ability to respond when we identify food contamination," they explained.

Updating Technology Use

When it comes to food traceability, most companies keep records of one step back to identify the source and one step forward to where the food has gone, as required by federal law. And many companies keep these records on paper, not electronically. Investigators found this especially frustrating last year as they sought to determine the source of *E. coli*-tainted romaine lettuce. Had growers and shippers used electronic records and blockchain technology, tracing the origin might have taken minutes or even seconds, instead of weeks.

Blockchain uses a decentralized, secure ledger that's shared by all parties in the supply chain to provide transparency on a product's origins. It can greatly assist in warning consumers about risks with specific foods and in implementing more targeted and efficient recalls.

"Today's technology can provide us with insights that were not possible even a handful of years ago," says David Acheson, MD, former associate FDA commissioner for foods and founder and CEO of The Acheson Group. "But going even deeper than the DNA insights of an outbreak is the ability of today's technology to trace a food forward, backward, and sideways. The technological ability is there, but with the regulatory requirement being only one forward/one back, the incentive is, unfortunately, a bit lacking," Dr. Acheson says.

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Market Initiatives



Juicy Details

From robotic dispensers to tanker wash guidelines, the juice industry is striving to squeeze quality and safety into every product | BY LINDA L. LEAKE, MS

When was the last time you had cold pressed juice or a fresh smoothie served by a robot?

Given the fast-paced developments in technology, it should be no surprise that robots that serve such treats are already available, currently at approximately 16 sites in the Los Angeles area, all at middle schools, retail shops, and corporate cafes.

Meet JuiceBot, a Los Angeles firm that designs and manufactures the JuiceBot, which the company claims is the world's first robotic juice dispenser.

Class Project

The JuiceBot dispenser concept is the brainchild of Kamal Mohamed, JuiceBot's CEO, and his company co-founders, Loring "L. J." Stead and Eric Ploeger. Mohamed came up with the idea as a project for their business class at the University of St. Thomas in

Minneapolis. The trio started developing the vending machine in 2012. It was introduced commercially in 2015.

"Our mission is to make getting 100 percent raw, organic smoothies and cold pressed juices as convenient as getting soda from a vending machine," Mohamed relates. "Our goal is to work with cities, universities, hospitals, airports, middle schools, and so on to reach our mission."

Following Hazard Analysis and Critical Control Points (HACCP) guidelines for retail establishments, JuiceBot prepares fresh juice daily at a commercial kitchen in Los Angeles. All kitchen managers are ServSafe certified. The facility is subject to food safety inspections by the Los Angeles County Department of Public Health.

"Currently four employees work in the kitchen," Mohamed says. "We have two to three delivery personnel to ensure the machines are restocked, cleaned, and running efficiently. We also employ technicians and engineers to troubleshoot issues that may come up with the technology."

The juices are cold pressed and immediately chilled in 5-gallon stainless-steel tanks, which Mohamed says protects the products from oxidation caused by light. All the juices and smoothies are placed in the JuiceBot dispensers within 24 to 48 hours after preparation. The JuiceBots maintain the products at approximately 38 degrees Fahrenheit, with a range of 35 degrees to 41 degrees Fahrenheit.

Dispensing Process

After a customer selects a juice or smoothie by pressing a button, the JuiceBot does the rest. A biodegradable cup is automatically placed into the dispensing compartment with a robotic arm that sets it under a nozzle for dispensing.

"After the Bot is done dispensing, it will instruct the customer to take their beverage," Mohamed relates. "Each JuiceBot holds four different chilled juices or smoothies, which vary with the seasons, all made with certified organic ingredients."

The JuiceBot's robotic capabilities include automatic shut off for temperature control. And JuiceBot has the ability to be monitored remotely.

"There is even a button that customers can click on for live help," Mohamed adds. "We maintain a customer service call center at our office in downtown Los Angeles."

Cold pressed juice has a typical shelf life of three to five days when it's fresh and unpasteurized, Mohamed says. "We replace our product every 48 hours for optimum nutrients and freshness," he relates.

According to Mohamed, the JuiceBot is the only device approved for unpasteurized beverages to be dispensed through an unattended retail format under California legislation and the National Automatic Merchandising Association, an organization that certifies vending machines under FDA code standards.

CANARY Pathogen Detection

To help ensure the safety of its products, JuiceBot utilizes a technology called CANARY, which stands for Cellular Analysis and Notification of Antigen Risks and Yields. CANARY is available through PathSensors, Inc., Baltimore, Md., a biotech company that creates pathogen detection instruments.

“CANARY is a cell-based biosensor technology that delivers rapid detection of pathogens at high levels of sensitivity and specificity,” says Ted Olsen, PathSensors president. “CANARY incorporates pathogen-specific antibodies expressed on the biosensor surface, which, in the presence of a pathogen, trigger an intracellular calcium release that, in turn, activates bioluminescent proteins whose light output can be measured and analyzed. CANARY technology detects down to 1 colony forming unit of target pathogens in less than five minutes.”

The technology is capable of detecting foodborne pathogens, including *Listeria*, *Salmonella*, and *Campylobacter*.

For JuiceBot, CANARY is delivered through PathSensors’s Zephyr Pathogen Identifier. The Zephyr kit includes a touch-screen laptop complete with the CANARY detection technology, bench mount box, luminometer, centrifuge, and barcode scanner.

“The Zephyr platform is best suited for users who test lower volumes of samples, fewer than 40 tests per day,” Olsen relates. “Results offer PCR (polymerase chain reaction) levels of sensitivity and specificity.”

“The PathSensors system helps verify that our current food safety inspections, logs, and process of critical control points are working together,” Mohamed says. “It’s our last line of defense and a great verification tool for specific pathogens that we deal with in the fresh raw food beverage industry.”

A Hot Cold Juice Trend

Functional beverages, those marketed with natural health benefits from their ingredients, along with minimum fortification, are arguably one of the hottest trends in the industry, according to food scientist Alvin Lee, PhD, director of the Center for Processing Innovation at the Illinois Institute of Technology’s Institute for Food Safety and Health, Chicago, Ill.

“In recent years, the functional beverage category has shown an average annual growth rate of 20 percent in the U.S. and Europe,” Dr. Lee points out. “One of the top five trends for the functional juice sector is cold pressed juice.”

Cold pressed juice is typically made using a hydraulic press, compared with juices extracted using centrifugal presses.

High pressure processing (HPP), which employs pressure without heat, is a technique often used for juice, Dr. Lee says, noting that the primary advantages of HPP over thermal processing are the minimal chemical and physical effects exerted on most foods while imparting a microbial kill step.

“With fruit juices, HPP significantly reduces the number of spoilage microorganisms such as yeasts and molds, and pathogens like *Escherichia coli* O157:H7, *Salmonella* spp. and *Listeria monocytogenes*,” Dr. Lee relates.

“The finished juices give consumers the sensory perception of ‘fresh’ and ‘natural’ products, while they meet consumer demands for fresh, healthy, and great-tasting safe foods,” he notes. “The refrigerated shelf life of such products can be up to 30 days

or longer, and they have superior sensory quality compared with those prepared in a conventional manner.”

HPP-Treated Juices Research Project

Dr. Lee is the director of a landmark research project that is addressing the impact of juice characteristics on pathogen inactivation by HPP. The work is well underway, courtesy of a \$258,253 grant from USDA’s National Institute of Food and Agriculture.

In explaining the project, Dr. Lee says HPP treated juices are required by the FDA Juice HACCP regulations to demonstrate a 5-log reduction of colony forming units per milliliter of the pertinent organism in the juice. “Even though HPP-treated juices are now available at retail, there is currently no consensus amongst industry, academia, and government on a ‘standardized’ validation protocol for juices to be treated by HPP,” he relates.

According to Dr. Lee, it appears there is no common approach to preparing bacterial strains for validation and challenge studies, no consensus on the HPP parameters required for treatment of the juices, and no common approach on how shelf life studies are conducted.

“Our project seeks to develop coordinated industry and regulatory science-based consensus from the generated data and develop guidance on how validation should be conducted for HPP-treated juices,” he says.

Due to FDA’s requirement to validate the 5-log reduction, microbial challenge testing is often conducted with strains of *E. coli* O157:H7, *Salmonella* spp., and *L. monocytogenes*, Dr. Lee notes. “However, bacterial strain sensitivity to pressure, microbiological recovery methods post-HPP, and HPP conditions can impact validation outcomes,” he relates. “While most pathogens are inactivated by HPP, defining the specifics can provide consistency in helping regulators evaluate validation reports, set precedence on how the juice industry conducts HPP validation, and allow manufacturers to produce safe juices for consumers.”

Tanker Wash Guidelines

The Juice Products Association (JPA), Washington, D.C., and other key juice industry stakeholders, including the Florida Citrus Processors Association (FCPA), are quick to boast about the JPA Model Tanker Wash Guidelines for the Fruit Juice Industry they developed collaboratively for tankers hauling juice and juice beverages.

“Our JPA manufacturers represent more than 80 percent of the U.S. volume of juice and fruit beverage production,” says Patricia Faison, JPA’s technical director.

“The guidelines, also known as the Tanker Wash Code of Practice, first published in 2002 and updated in February 2019, define terms, describe wash protocols in terms of the most recently hauled product type, and include a list of acceptable food materials that may be transported by food-grade tankers,” Faison relates, noting that HACCP principles are the basis for the guidelines.

Faison points out that in April 2016, FDA published the final rule, “Sanitary Transportation of Human and Animal Food,” as mandated by the Food Safety Modernization Act (FSMA). FSMA regulations “establish requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary

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Legal Update



Strict Criminal Liability

Why corporate food safety is no walk in the “Park”

BY SHAWN K. STEVENS, ESQ. AND JOEL S. CHAPPELLE, ESQ.

As a general rule, criminal liability requires criminal intent. The legal term of art, “*Mens Rea*,” (Latin for “guilty mind”), stands for the concept that deliberate wrongdoing is a condition precedent to criminality. It is based on the principle that society should not punish people for unintended violations of law. There are, however, exceptions to this rule—so-called strict-liability offenses.

With strict-liability, the perpetrator’s intent and awareness of wrongdoing are irrelevant. Speeding, for example is a strict-liability offense. It does not matter whether the driver intended to speed or was aware they were speeding. Absent extraordinary circumstances, the driver is guilty of speeding purely by virtue of having exceeded the speed limit. Like speeding, violating the Food Drug and Cosmetic Act (FD&C Act) is a strict-liability offense.

Park Doctrine

The Responsible Corporate Officer Doctrine (RCOD), colloquially known as the “Park Doctrine,” is a controversial pros-

ecutorial tool that allows for the criminal prosecution of companies and officers, regardless of whether they had unlawful intent or awareness of the violation. In *U.S. v. Dotterweich*, the Supreme Court explained that FD&C Act prosecutions dispense “with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.”

In the decades since *Dotterweich*, federal prosecutors have routinely used the RCOD to successfully prosecute corporations and officers for FD&C Act violations. To obtain a conviction for an FD&C Act violation, prosecutors must prove each of the following beyond a reasonable doubt:

- The corporate officer was in a position of responsibility relevant to the violation;
- The corporate officer was able or authorized to prevent or correct the violation; and
- The corporate officer failed to prevent the violation.

RCOD jurisprudence, or case law, is both interesting and instructive. The written opinions of judges and justices are more than a mere conveyance of a rule’s meaning. They tell a story, putting the rule in meaningful context. Often, the story is far more instructive than the analysis of the rule. The story teaches us how to avoid unwittingly coming into conflict with the rule.

For example, we all understand that delivering adulterated food into interstate commerce is a violation of federal law. But until we understand what befell John Park, who, absent any intentional wrongdoing, was tried, convicted, and now has a criminal legal doctrine named after him, we cannot begin to understand how the law works.

United States v. Dotterweich, 320 U.S. 277 (1943)

The *Dotterweich* case, decided by the U.S. Supreme Court in 1943, established that corporate officers could be prosecuted for violating the FD&C Act, regardless of any knowledge or awareness of the violation.

Joseph Dotterweich was the president of Buffalo Pharmacal Company, Inc. Buffalo’s business involved purchasing bulk drugs, repackaging them, and selling them under its own label. Unbeknownst to Dotterweich, the company received a batch of adulterated drugs, which it subsequently repackaged and shipped into commerce. Dotterweich had no idea the products—which were guaranteed by the manufacturer—were adulterated. Nonetheless, Dotterweich and Buffalo were criminally charged for violating the FD&C Act.

Determined to prove his innocence, and apparently that of his company, Dotterweich took the case all the way to trial. Despite the supplier guarantee and Dotterweich’s lack of knowledge regarding the adulteration, the jury found him guilty.

Dotterweich appealed his conviction, and the case eventually reached the U.S. Supreme Court. Unfortunately for Dotterweich, the Court upheld his conviction, reasoning that “the only way in which a

corporation can act is through the individuals who act on its behalf.”

Perplexingly, the jury found the company *not guilty*. To find Dotterweich guilty and Buffalo not guilty is illogical, and Dotterweich’s attorneys argued the verdict should be invalidated. The Supreme Court disagreed, holding “Whether the jury’s verdict was the result of carelessness or compromise or a belief that the responsible individual should suffer the penalty...is immaterial. Juries may indulge in precisely such motives or vagaries.” There is an important lesson here: Letting a jury decide your case is very risky. Juries are manifestly unpredictable, and even when a verdict is seemingly unjust, courts will rarely overturn it.

United States v. Park, 421 U.S. 658 (1975)

Three decades later in the early 1970s, Acme Markets, Inc. operated a large national retail food chain with 874 stores, 16 warehouses, and approximately 36,000 employees. As Acme’s CEO, John Park had broad operational oversight responsibility, but little involvement in the day-to-day operational duties. As CEOs often do, Park delegated operational responsibilities, including sanitation, to qualified division heads who, in turn, had their own staffs and departments under them.

Beginning in November 1971, FDA inspectors carried out a 12-day inspection at an Acme warehouse in Baltimore. During the inspection, inspectors discovered evidence of rodent activity in the warehouse. During a follow-up inspection three months later, the inspectors noted improvement, but nonetheless found evidence of continuing rodent activity.

Park first became aware of the violation a month after the fact, at which point he immediately contacted Acme’s vice president for legal affairs, who assured Park the head of the respective division “was investigating the situation immediately and would be taking corrective action and would be preparing a summary of the corrective action to reply to the letter.”

Soon thereafter, Park and Acme were charged with multiple misdemeanor violations of the FD&C Act. Acme, in its capacity as a corporate entity, pleaded guilty. Park, who had no personal involvement or knowledge, pleaded not guilty.

During his trial testimony, Park acknowledged that, as Acme’s CEO, he was ultimately responsible for “any result which occurs in our company.” That testimony was enough to ensure his conviction.

[Park](#), widely regarded as the seminal case on the RCOD (hence the “Park Doctrine”), reaffirmed the holding of *Dotterweich* from 30 years earlier. Park stands for the proposition that FD&C Act violations

While knowledge and intent may be immaterial in terms of the law, they are very material to the investigators responsible for making charging decisions.

are chargeable against anyone and everyone with a share of the responsibility for preventing such violations. In other words, criminal liability for a violation of the FD&C Act attaches “not only to those corporate agents who themselves committed the criminal act, but also to those who by virtue of their managerial positions or other similar relation to the actor could be deemed responsible for its commission.”

For the last 40 years, *Park* has withstood all challengers, and remains the law of the land. Upon conviction, defendants face the potential for significant fines and even jail time. Fortunately, there are some safeguards in place to prevent overzealous prosecutors from overstepping. For instance, before the U.S. Department of Justice (DOJ) can begin pursuing an investigation into criminal violations of the FD&C Act under the RCOD, the U.S. Attorney’s office must first notify and consult with the Consumer Protection Branch of the Civil Division. This additional layer of scrutiny is intended to foster uniformity in prosecutorial decision-making and is perhaps why criminal prosecutions have been the exception rather than the rule.

Nevertheless, even the possibility of prosecution is cause for alarm for food industry executives. Every executive should at least be cognizant of the potential for criminal liability. This is especially

true given the increasingly aggressive approach taken by FDA and DOJ in recent years.

United States v. DeCoster, 828 F.3d 626 (8th Cir. 2016)

Austin “Jack” DeCoster owned Quality Egg, an Iowa company that operated a processing facility, six farms, and 97 barns housing chickens and hens. His son, Peter DeCoster, was Quality Egg’s COO. The DeCoster family also owned and operated several egg production companies in Maine.

The DeCoster family employed an environmental testing program for *Salmonella*. In 2006, the number of environmental positives began to gradually increase year over year. In 2009, seeking to reverse the increase in *Salmonella* positives, the DeCoster family retained Dr. Charles Hofacre, a poultry disease specialist, and Dr. Maxcy Nolan, a rodent control expert. The DeCoster family purportedly adopted all the consultants’ recommendations. They also provided a second round of *Salmonella* vaccinations to their chickens.

In August 2010, the company was responsible for an outbreak of *Salmonella enteritidis*. During the subsequent investigation, FDA identified a litany of sanitation problems at the chicken farms, eventually compelling the company to euthanize its animals, clean and repair its facilities, and disinfect its barns.

Following a criminal investigation, Quality Egg and the DeCoster family were charged criminally. Quality Egg was charged with and pleaded guilty to: 1) felony bribery of a USDA inspector, 2) felony violation of the FD&C Act, and 3) misdemeanor violation of the FD&C Act. The DeCoster family were not implicated in the felonies but were charged with misdemeanor violations of the FD&C Act under the RCOD. After pleading guilty, Jack and his son were each fined \$100,000 and sentenced to three months in prison.

The DeCoster family appealed, arguing that, because they did not know the eggs were adulterated, imprisonment was unconstitutional. The Eighth Circuit disagreed, succinctly and eloquently summarizing the [law](#) as follows:

The FD&C Act punishes neglect where the law requires care, or inaction where it imposes a duty because according to

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Food Defense



Audits vs. Assessments

What's the difference between FSMA food defense/EMA audits and assessments? | BY DAVID K. PARK

The Food Safety Modernization Act (FSMA) “Mitigation Strategies to Protect Food Against Intentional Adulteration” or IA Rule, as it is commonly known, specifies that covered food facilities are required to perform a vulnerability assessment prior to developing a Food Defense Plan as part of the published regulation final rule.

There is a reason why FSMA calls for an assessment rather than the more typically performed audit. Frankly, I have struggled with food industry approaches to audits used to best “measure” preparedness of food safety and food defense responsibilities, policies, and procedures, along with identification and assignment of risk/threat mitigations, as prescribed by FDA regulations.

How can the industry best determine if a food facility obtains an accurate picture of its real exposure to adverse internal and external risks and threats? How can a food business, religiously following its food protection plans and operational implementation of these plans, have full confidence it has accomplished, in operational practice,

what it is supposed to do to best protect valued assets? How committed is management in understanding its business risk? Does it insist that assessments performed within its own site use the best means accurately determine the probability, severity, and criticality of hazards and risks and its mitigation strategies that expose its people, product, or the food facility to situations that could cause serious injury or death in humans or animals?

In my 47 years of wrestling with the merits of various risk/threat management approaches, I find fault in our overreliance upon internal and external audits to measure our confidence level as the fundamentally accepted way to verify that our food protection risk and threat detection systems are “always on” and working effectively.

Audits and Assessments

We need to first understand the difference between an audit and an assessment from a proven historical event perspective. We now rely upon industry food safety and food defense (and economically motivated

adulteration, or EMA) standards organization audit formats. Those used are based upon requirements found in the Global Food Safety Initiative (GFSI) or often specified in supplier requirements. These formats are not designed, nor do they probe, long-standing gaps and system flaws that are deeply-rooted, often unnoticeable but often critical, in the identification of risk and threats in any given operational environment. Generally, even well-performed audits are more likely to miss what a true assessment for system weaknesses can uncover.

An audit, according to Merriam-Webster, is “a careful check or review of something.” I believe an audit consists of an evaluation of an organization’s systems, processes, and controls, performed against the set standard or documented process, often a generic, one-size-fits-all approach. A food defense and EMA audit is designed to verify whatever standard is in place and is often set up using a checklist approach to ensure product, personnel, and facility security. An audit may also provide a gap analysis of the operating effectiveness of the internal controls in meeting a system or control requirement.

Audits are designed to provide an independent evaluation of system processes and controls using personnel with expert knowledge about the system or process. But they are addressed with prescribed audit tools that limit the ability to identify other hidden system hazards/risk/threats. By design, audits may identify system and control gaps, but only provide limited feedback from the auditor as to how to best mitigate such gaps. Worse, full reliance on audit results may allow unintentional and nondetectable food safety breakdowns to occur.

An assessment, as defined by Merriam-Webster, is an “action or an instance of making a judgment about something.” For example, a food defense vulnerability assessment is a fundamental, risk-based review and gap analysis of a site or a system control strengths that could cause failure in achieving the underlying criteria used to set a system standard or process control. This process involves the identification and classification of both the known and unknown product security vulnerabilities that may impact the site or its system functions.

It is important to recognize these differences between the purpose and performance of an audit and that of an assessment. In my opinion, the purpose, importance, and structure of an audit has been over-emphasized in the determination and control over given risk/threat identification in food production and food manufacturing environments. More emphasis needs to be placed on performing a comprehensive assessment that is not taken from a “checklist” of generally well-known issues and concerns.

We have become overly reliant on the conclusions of auditors and their audit results. Peanut Corp. of America (i.e. *Salmonella*) and Jensen Farms (i.e. *Listeria monocytogenes*) are two memorable industry public health events with root-cause failures that were not identified through audits performed by highly regarded auditing firms. Audits professionally performed by third parties preceded these unfortunate events, and generally high audit result scores were issued to these firms.

In these unfortunate industry system failures, the auditors missed the use of substituted contaminated product washing and cooling equipment, poor technical assumptions, and erroneous validation and verification data. It is difficult to always identify where these unidentified and unrecognizable hazard/risk/threat gaps may latently linger, unaddressed, in a food safety or food defense (and EMA) plan unless a well-structured hazard/risk/threat assessment is performed.

The way in which FSMA rules are written has strengthened the expectations and requirement that the hazard/vulnerability/threat and control/mitigation identification will be more comprehensive than in the past. These assignments must now be thoroughly deliberated by the facility Food Safety and Food Defense Teams. Decisions to include (or not to include) a hazard/risk/threat/mitigation must now be formally justified and a part of the written facility all-hazard food protection plans. This will go far to help ensure that expert food defense-qualified individuals have enough education, experience, recognition, and training for any facility vulnerability assessments that will be performed to support the specific activities within a Food Defense Plan.

An Outside Eye

If your facility is relying solely on a food defense or GFSI-style certification program owners approach to perform this assessment activity, I again caution management not to rely upon an audit list alone. Instead, invite other outside competent individuals, not familiar with your operational activities, to assist in an assessment activity.

When I performed food defense and food fraud facility vulnerability assessments, I heard facility employees who were shadowing me during my visit say numerous times, “I never noticed that” or “We don’t have a procedure for that.” During one food defense and food fraud vulnerability assessment walk-through, a manager said that “it never occurred to me that our raw packaging and packaging waste materials could be used to counterfeit our products.”

Several years ago, I was challenged by a large food manufacturer to penetrate one of their facility’s food defense systems, which were, according to their corporate

physical security manager, considered to be “the best product protected security site within our manufacturing group.” Unfortunately, it was surprisingly easy to defeat the facility perimeter defenses, enter the facility from the outside, and then move unseen into the production area with exposed product through unused and unlocked dark office space. This was accomplished during normal business hours.

The point from these observations is there is no perfect site-specific audit tool that will accomplish what a true assessment can deliver to help safeguard product security. Prior to performing a more thorough assessment, these mentioned facilities used industry and/or government food defense audit templates to measure their own product security readiness. But, in doing so, these facilities failed to identify several of their later-proven site-specific and potentially catastrophic product security vulnerabilities. Assessing food defense system vulnerabilities after hours is another way to observe potential system failures. At

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these times, there is less supervision, more unrestricted access to product, packaging materials, and rework. Materials are often unsecured, warehouses are lightly manned or un-manned, and generally, fewer employees are onsite in sensitive production areas, often when contract night or weekend work occurs.

If your business intention is to meet best-practice food defense and food fraud business protection for you, your customers, and consumers, focus on a deeper-dive effort and commitment to performing a comprehensive vulnerability assessment. Don't be tempted to default to a traditional short-version food defense audit format to merely comply with the IA Rule vulnerability assessment requirement. In doing so, in my opinion, it doesn't comply with the intent of the rule.

An answer to an audit question regarding an issue, without offering an opportunity to ask an additional relevant question, can suggest compliance, but may still hide a significant underlying gap that could breach a facility, personnel, or product security system. A true vulnerability assessment is more likely to uncover such gaps since a competent assessor can move to any line of additional security questioning based on previous responses given.

Conducting an Assessment

There is no more important component to a Food Defense Plan than conducting a credible and comprehensive vulnerability assessment. There are several FDA-approved training courses offered for anyone, including facility food defense-qualified individuals, to improve upon their vulnerability assessment skills and applied methodologies. The courses also showcase available tools that can be used in this type of critical intentional adulteration activity, including the following.

FDA's **Food Defense Plan Builder** has a built-in vulnerability assessment tool and helps the user to numerically rank a given vulnerability and perpetrator accessibility. It can accommodate unique vulnerability and accessibility concerns at an individual site. In fact, this food-based risk assessment tool has been used with other non-food industry applications to

help identify and mitigate product security gaps.

The Food Safety and Preventive Controls Alliance (FSPCA) at the Institute of Food Safety and Health offers **online, self-paced courses** including "Food Defense Awareness for the IA Rule," "FSPCA Overview of the IA," "FSPCA IA Conducting Vulnerability Assessments using Key Activity Types," and "FSPCA IA Identification and Explanation of Mitigation Strategies." In addition, an onsite "FSPCA IA Conducting Vulnerability Assessments" certificate course is offered using vulnerability assessment lead instructors. These lead instructor candidates completed FSPCA prerequisite certificate courses. There are plans for extended training requirements to a food defense-qualified individual who meets strict criteria based upon education, experience, and training. Their lead instructor certification comes after successful completion of a three-day "Vulnerability Assessment Lead Instructor Training" at various domestic locations starting May 2019. More Vulnerability Assessments Lead Instructor Training will be scheduled for later this year.

The Food Defense and Protection Institute (FPDI) recently introduced a one-day **FDA-standardized FSPCA course** on "IA Conducting Vulnerability Assessments" as included as day one of a two-day "FDPI Food Defense Industry Training" course. The first such course was held May 1-2, 2019.

IA Rule Compliance

With the first FSMA IA Rule compliance date of May 27, 2019, for large food facilities that manufacture, process, pack, or hold (store) food, it is imperative to conduct a comprehensive vulnerability assessment for your facility. Ideally, this effort should be supported by outside food defense experts, identify vulnerabilities and actionable process steps, and determine optional mitigation strategies and priorities proposed by those experts and Food Defense Team. Also, facility financials will no doubt be affected by a number of these vulnerability mitigation decisions, particularly those requiring more significant capital budget approvals prior to implementation. After a food defense vulnerability assessment has been performed and mitigation strategies are in place according to your es-

tablished Food Defense Plan, don't be satisfied with this outcome. More can be done in challenging your plan. Consider the use of food defense experts in conducting a red team exercise with the intention of identifying any remaining significant vulnerabilities, viewing alternate methods for attack and revealing other outstanding product security risks for your specific facility.

Partnering with outside food defense experts provides a deeper dive into your food defense and food fraud assessment. Such experts have established their broad product security perspectives from spending many hours at different food and non-food facility environments performing vulnerability assessments.

Is every effort made to best address the purpose of the IA Rule requirement? Is your facility approaching its assessment responsibility by "checking a box" that appears to meet a regulatory requirement?

Conducting well-constructed and comprehensive food defense and EMA vulnerability assessments is in the best interest of all stakeholders. It is obvious that, under FSMA, the FDA, academic institutions, and standards organizations will be providing stepped-up IA Rule training efforts that include how to conduct vulnerability assessments to ensure industry will be better prepared to identify and mitigate all-hazards that, if not effectively managed, have the potential to affect public health and jeopardize your business viability. ■

IA Inspections to Begin March 2020

In April, FDA announced during a public meeting that routine inspections to verify compliance with the IA Rule will begin in March 2020. FDA heard from stakeholders that due to the novel nature of the IA Rule and its requirements, they believe more time is needed to develop a fully compliant food defense plan. To allow industry time with resources, tools, and trainings, FDA will be starting routine IA Rule inspections next year.—*FQ&S*

Park is the principal for Food-Defense, LLC. He has practiced food protection technical and management consulting for 46 years, is an FDA-recognized international processing authority, and an FSPCA PCQI Lead instructor. Reach him at dkpark72@aol.com.

Allergen Control

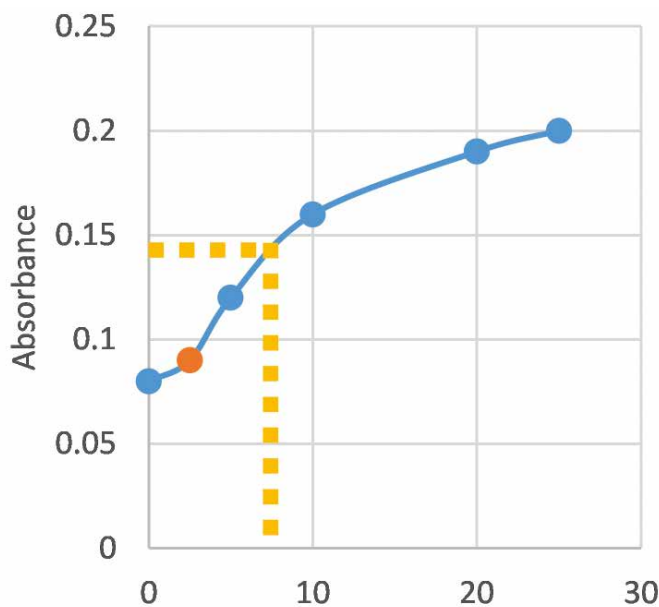


Figure 1. Quantification using a standard curve.

gen control plans or navigating potential allergen recalls.

How Methods Work

Currently, the detection and quantification of food allergens in finished food products is primarily conducted using enzyme-linked immunosorbent assays (ELISAs). ELISAs detect proteins from allergenic foods by using antibodies that specifically recognize the food proteins of interest. Method developers produce these allergen-specific antibodies in laboratory animals by exposing them to the food or protein target of interest. After an immune response has been developed, antibodies can be collected, screened for specificity and affinity, and subsequently used in an ELISA.

Most ELISAs utilized for food allergen detection use a sandwich ELISA format. In a sandwich ELISA, one source of allergen-specific antibody is coated onto the surface of microwells, generally in a 96-well plate format. After coating with the antibodies (also referred to as capture antibodies), the wells are coated with a blocking agent to prevent any non-specific binding of components from the sample. In commercial allergen ELISA kits, pre-coated and blocked wells are provided as one of the kit reagents.

When conducting a sandwich ELISA method, an extract from the sample of interest or method controls is then added to individual microwells. During an incubation period, any proteins present in the sample from the target allergenic food will bind to the antibodies present on the surface of the microwell. The region on the protein that is recognized by the antibody is known as an epitope.

Following incubation, the wells will be washed thoroughly to remove any unbound sample components. A second allergen-specific antibody will then be added to the wells and will bind to target proteins already captured in the microwells, forming an antibody sandwich with

(Continued on p. 22)

Understanding Food Allergen ELISAs

These allergen-specific tests can protect your business—if you choose the right one

BY MELANIE L. DOWNS, PHD, AND JOSEPH L. BAUMERT, PHD

Undeclared food allergens are a significant food safety hazard, and manufacturers need to have practices, processes, and controls in place to prevent the presence of undeclared major food allergens in their products. The detection and quantification of food allergen residues is an important capability for robust food allergen control, and methods capable of detecting and quantifying proteins from allergenic foods can be used in a number of ways. Food manufacturers can use allergen detection methods to assess various aspects of allergen control plans, including cleaning procedures, supply chain controls, and overall allergen management. In addition,

manufacturers may need to rely on food allergen detection methods to confirm an alleged instance of undeclared food allergens in a product and conduct root-cause analyses. Food allergen detection methods are also used by regulatory authorities to investigate the presence of undeclared major food allergens in products on the marketplace, either as part of research studies or as enforcement actions.

Understanding how food allergen methods work, how to select the appropriate method for a particular application, how results from these methods are interpreted, and what potential issues may arise with the methods is critical for food manufacturers when implementing aller-

(Continued from p. 21)

the target protein in the middle. In commercial assays, this second antibody will have an enzyme attached (or conjugated) to it, and the second antibody is therefore commonly referred to as the conjugate antibody. Following another washing step to remove unbound conjugate antibody, the substrate for the conjugated enzyme will be added to the wells. The enzyme present in the microwell will convert the substrate to a specific color product, indicating the presence of an intact antibody sandwich and therefore the presence of the food allergen target.

The amount of color generated in the microwell will depend on the amount of enzyme present, which in turn depends on the amount of target allergen protein present. This relationship between color intensity and amount of target allergen protein can be used to quantify the amount of target allergen in a sample.

In order to produce quantitative results, a series of standards containing known amounts of the allergenic food protein is analyzed alongside the samples. The absorbance values for both the standards and samples are measured using a plate reader. When the absorbance values from the standards are plotted against the known concentrations, a standard curve can be developed (see Figure 1 on p. 21). The absorbances from the unknown samples can then be used to interpolate the amount of allergen present.

Interpreting Results

Understanding how to interpret the results from a food allergen ELISA method can be challenging, as a number of different factors can impact the method's outputs.

Units and calibrators. Most commercial food allergen ELISAs report results in the concentration range of parts per million (ppm). The units of ppm indicate a concentration value for the analyte, which can also be expressed as mg analyte per kg product (mg/kg). Just using units of ppm or mg/kg does not, however, provide enough information for food allergen ELISAs. It is also important to know specifically what form of analyte the units are being expressed in. The most common analyte units for food allergen ELISAs are either whole commodity (e.g., ppm pea-

nut, walnut, egg, etc.) or total protein (e.g., ppm peanut protein, walnut protein, egg protein, etc.). For some foods, however, there are commercial ELISA kits that express results on the basis of soluble protein from the allergenic food or a single protein analyte (e.g., ppm beta-lactoglobulin). In order to both understand the implications of a result from an ELISA and to compare results from different ELISA methods, it is

In order to both understand the implications of a result from an ELISA and to compare results from different ELISA methods, it is crucial to have complete units expressed.

crucial to have complete units expressed. The same sample analyzed by methods that use different units will have very different quantitative results, even if all other method conditions are similar.

Limit of detection, limit of quantification, and lower limit of applicability.

As with many types of detection and quantification methods, food allergen ELISAs work only within a certain range of target analyte concentrations. The concentration below which a method is not able to distinguish a true positive from a true negative is known as the limit of detection (LOD). The LOD of a method, therefore, controls against false-positives arising from the food matrix and is generally estimated using a statistical evaluation of blank matrices. Because the LOD of a food allergen ELISA is highly dependent on the specific background food matrix being analyzed, it may not be as applicable across a diverse range of food products and ingredients as other method metrics.

The limit of quantification (LOQ) for a method is the lowest level at which a method can quantify an analyte with a specific level of precision (i.e., with a specific coefficient of variation, frequently 10 percent CV). The LOQ of a method as determined by statistical calculations is

also dependent on the background matrix and may not represent an indication of the method performance across different food matrices. Method developers may therefore set a lower limit of applicability that better represents the performance of the method as the LOQ and establish that level by including it as the lowest positive value on the standard curve.

Selecting an Appropriate Method

One of the main considerations that needs to be accounted for when selecting a food allergen ELISA is whether the method detects the allergen-derived ingredient of concern. The ability to detect allergen-derived ingredients can depend on a number of factors. The first method characteristic that should be understood is what protein or groups of proteins the method is targeting—particularly important for allergenic foods from which the food industry produces ingredients containing different protein fractions.

The classic example of this issue is for the detection of milk residues. The food industry produces and utilizes ingredients that are composed of different milk protein fractions, specifically whey protein and casein protein fractions, both of which pose risks to allergic consumers. Milk allergen ELISAs, however, are frequently produced to recognize specific proteins (e.g., beta-lactoglobulin from the whey fraction or α_{s1} -casein from the casein fraction) or protein fractions (e.g., caseins). If the milk allergen cross-contact of concern is due to a whey protein isolate ingredient, it would be ineffective to use a method targeting caseins for assessment or validation as the casein proteins would be present at extremely low levels, if at all, in the whey protein isolate ingredient. The opposite would be true when the source of cross-contact was a sodium caseinate ingredient, in which case it would not work to use a beta-lactoglobulin ELISA for detection. In addition to understanding the target of the ELISA, it is also important to have information about whether the allergen-derived ingredient has undergone substantial processing, which could affect detection.

The specificity of ELISA method should also be considered as a factor in some cases. Most food allergen ELISAs are incredibly specific for the target allergenic

food of interest. But in some cases, very closely related foods may cross-react with the antibodies used in the ELISA method. This type of cross-reactivity issue has been observed among closely related allergenic foods such as walnut and pecan. Cross-reactivity can also be observed between foods designated as major allergens (e.g., peanuts) and related foods that are not designated as major allergens (e.g., peas). In most cases, commercial ELISA developers have screened for cross-reactivity with closely related species during development and should be able to provide users with information on the specificity of the assays. If novel food ingredients that are closely related to major allergenic foods are used in a product, it may be advisable to evaluate potential cross-reactivity to those ingredients before evaluating finished product.

Potential Food Allergen ELISA Issues

While food allergen ELISAs provide high-quality quantitative data with sufficient sensitivity and specificity in many cases, there are certain situations where ELISA methods face specific challenges.

Thermal processing. Extensive thermal processing (e.g., retorting, deep frying, UHT) has been shown to affect the ability of ELISA methods to detect and quantify some allergenic foods. The effects of thermal processing are two-fold. First, thermal processing can denature food proteins in a way that decreases the ability of the ELISA antibodies to recognize the proteins. However, these denatured food proteins are still considered to be allergenic.

The second effect of thermal processing is that it may result in target proteins that are aggregated in a way such that they are not extracted by the typical ELISA extraction procedure. If the target proteins are not extracted, they will not be included in the assay and will not be detected. Similar to denaturation, aggregated and insoluble proteins should still be considered as allergenic.

Fermentation and hydrolytic processing. Processes such as fermentation that can result in partial hydrolysis of proteins can also have a detrimental effect on quantification by ELISA. In these cases, the partial hydrolysis may result in cleavage of the part of the protein rec-

ognized by the assay antibodies. While there are circumstances where extensive hydrolysis can reduce allergenicity (e.g., extensively hydrolyzed infant formula or acid hydrolyzed vegetable proteins), it is not possible to determine allergenicity using ELISA methods. This is particularly true with sandwich ELISA methods that generally target intact proteins or large peptides, where the hydrolysis of just one

part of the protein can prevent detection, as the two separate recognition areas required to form the antibody sandwich may not remain connected, even though other large pieces of the protein remain intact. ■

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THE RISKS BEHIND LEAFY GREENS

**Challenges and possible
solutions to prevent contamination
throughout the supply chain**

BY KAREN APPOLD

Unlike many foods, fresh produce such as leafy greens doesn't have a kill step. "No heat or chemical treatment can eliminate microorganisms that might cross-contaminate fruits or vegetables," says Bob Whitaker, PhD, chief science officer, Produce Marketing Association of Newark, Del., which provides connections and industry solutions to members of the fresh produce and floral industries. This means that rigorous food safety measures must be in place at every point in their supply chain.

Despite best efforts, however, human pathogens can get into the nooks and crannies of fresh produce where wash water can't reach. Assuring the safety of fresh produce depends on preventing contamination throughout the produce supply chain, from farm to fork. "This can be a challenging task given that most fresh produce is grown outdoors, where it may be exposed to environmental contaminants in the soil, air, water, and wind," says Jim Gorny, PhD, senior science advisor for produce safety, FDA Center for Food Safety & Applied Nutrition, College Park, Md. "Therefore, it's essential to ensure that agricultural inputs such as agricultural water and soil amendments are as free of human pathogens as possible and that food contact surfaces that touch fresh produce, such as hands and conveyor belts, don't become a means of produce contamination."

Challenges in Investigating Outbreaks

Considering that about a billion servings of fresh produce are consumed daily, the number of foodborne illness outbreaks (correlated with the rate of contamination) is remarkably low, says Jennifer McEntire, PhD, vice president of food safety and technology, United Fresh Produce Association, a Washington, D.C.-based national trade association representing the fresh produce supply chain. [According to CDC](#), fresh produce accounted for 17 percent of outbreaks from 2008 to 2015, causing about 1,200 illnesses per year.

But the year 2018 challenged the U.S. food industry to reconsider whether produce safety practices are indeed reasonably effective at preventing a single contamination event from occurring when two *E. coli* outbreaks and a *Cyclospora* outbreak in the U.S. were traced to romaine lettuce and were reported in April, July, and November, respectively.

Outbreaks often perplex federal health officials as to how and why they originated because during an outbreak investigation, they respond to a failure in food safety measures somewhere within a large number of potential points between the farm and consumer. "At many points in the supply chain, the food from several sources could mix, which makes the traceback investigation far more complex," Dr. Gorny says.

"Even if the traceback investigation leads to a common food source or several potential sources, it's possible that harvesting or processing may have ceased. In the case of perishable commodities, such as leafy greens, there may not be any product left in the marketplace or in consumers' homes to test," Dr. Gorny continues. "Therefore, by the time an epidemiologist identifies a potential food source, many of these products have passed their expiration dates and are no longer available, making it much more difficult for investigators to collect the necessary information to help identify a source."



"Significant progress has been made by the lettuce and leafy greens industry to assure moving forward that the growing region is clearly and uniformly labeled on romaine lettuce products,"

**SAYS JIM GORNY, PHD,
SENIOR SCIENCE ADVISOR FOR
PRODUCE SAFETY, FDA CFSAN.**



To further complicate matters, investigators might have to cover hundreds of acres of farmland or thousands of square feet in a processing facility. When multiple farms are potentially involved, the investigation area could be spread over many miles. "Essentially, investigators are looking for invisible bacteria, much like looking for a needle in a haystack," Dr. Gorny says.

Focusing on Traceability

Following the large leafy green multistate outbreaks of the mid and late 2000s in the U.S., the produce industry voluntarily worked to develop the Produce Traceability Initiative to develop a standardized industry approach to enhance the speed and efficiency of traceability systems for the future. "This voluntary approach is a great start because it allows the industry to align the way it collects and uses data based on Global Standards One (GS1) US, which sets standards for global commerce; it works toward case-level traceability," says Ben Miller, PhD, MPH, senior director of food safety, The Acheson Group, a global food safety consulting group in Northfield, Minn.

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(Continued from p. 25)

FDA strongly encourages the leafy greens industry to adopt traceability best practices and state-of-the-art technology. This would ensure quick and easy access to key data elements from farm to fork when leafy greens are involved in a potential recall or outbreak. “Leafy greens are a highly perishable commodity; traceability information should facilitate the rapid tracking of involved product throughout the entire supply chain to expedite its removal from commerce, prevent additional consumer exposures, and properly focus any recall actions,” Dr. Gorny says.

A key element that would assist tracing efforts during an outbreak is the ability to identify specific farms or ranches that contribute to production lots, especially when the product has been comingled. While it’s important to identify where a product was grown and not simply the location of the business entity that shipped or processed it, it is equally important to be able to determine which specific farm(s) and growing region(s) are responsible for supplying the contaminated product. “This information is crucial to developing accurate public health messaging to protect the public from exposure and empower consumers to take appropriate actions,” Dr. Gorny adds.

United Fresh Produce Association and Produce Marketing Association, with input from the Romaine Task Force, are leading an initiative to include voluntary labeling on all romaine lettuce packaging that identifies its origin and a means to determine its harvest date. “Having this information will improve our ability to provide more targeted information to consumers during an outbreak,” Dr. Gorny says. “Significant progress has been made by the lettuce and leafy greens industry to assure moving forward that the growing region is clearly and uniformly labeled on romaine lettuce products.”

Without the ability to identify the growing region or specific suppliers of suspected shipments, public messaging by FDA and other public health partners during recalls or outbreaks is broad out of necessity, possibly implicating farms and growing regions that aren’t responsible for the contamination. “If supplier data are maintained when a product is comingled, it is easier to narrow the number of suspected shipments and suppliers of the contaminated product once it has been processed,” Dr. Gorny says.

But Dr. Miller doesn’t foresee improvements in supply chain traceability unless there’s a regulatory requirement. “Distributors and retailers don’t have an immediate financial reason to maintain case-level traceability, so it’s likely that the FDA will need to address this through authority granted under its Food Safety

Modernization Act [FSMA] of 2011 before we see full supply chain traceability,” he says. “Essentially, supply chain traceability is no longer a technology problem; rather it’s a political and policy problem.”

To improve the traceability process, Dr. Miller believes that blockchain technology holds promise but will require operational changes in the supply before

it’s fully effective. “Blockchain technology creates the ability to accurately associate transactional data across the supply chain. Companies such as distributors would have to make operational changes that would capture case-level data as shipments are received, pallets are broken down, and orders are filled for outgoing shipments,” he says. “But without operational changes like these, more integrated data systems will continue to capture data that lack the detail and granularity that public health investigators need to rapidly trace an outbreak and possibly prevent ongoing illnesses.”

Eyeing Water Safety

In addition to efforts to make it easier to identify sources of foodborne illness outbreaks, research is being conducted on how to prevent contamination from occurring in the first place. One aspect that is currently being studied is ensuring that water sources that come into contact with leafy greens are safe.

Lettuce producer and manufacturer Fresh Express formed a panel of independent scientific, production, and policy experts in November 2018 to make recommendations for new or improved ways to prevent *Cyclospora* outbreaks. Michael T. Osterholm, PhD, MPH, chair of the Fresh Express Blue-Ribbon Panel on Prevention of *Cyclospora* Outbreaks, who is also a regents professor, University of Minnesota, Minneapolis, says leafy greens outbreaks differ from other types of foodborne illness outbreaks because humans must play an essential role given that *Cyclospora* requires a human host to complete its lifecycle. The panel was formed as a result of 2018 *Cyclospora* outbreaks involving fresh produce grown and harvested in the U.S.

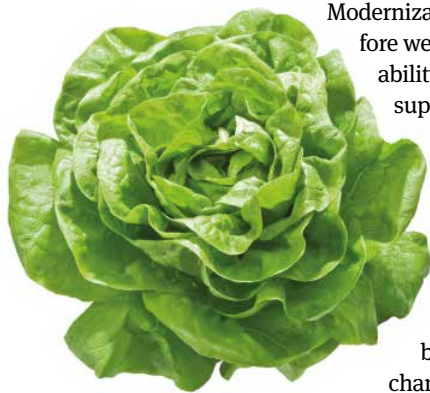
Cyclospora outbreaks since the 1990s have had high attack rates. “This suggests that contamination doesn’t occur sporadically, and that there’s a much more widely disseminated source for the parasite,” Dr. Osterholm says.

The parasite must live seven to 14 days outside of the human body to mature and be capable of infecting other humans. “If a parasite is excreted in a human stool, for example, it requires that time period to pass before it becomes infectious,” he says. “This is much longer than *E. coli* and *Salmonella*.” They can take three to four days and six to 72 hours, respectively.

Given this information, the panel is looking to determine potential sources and preventive controls, including if water can spread *Cyclospora*. Dr. Osterholm surmises that water used for irrigation or spraying could be the culprit. Perhaps water could become contaminated from septic systems leaking into water sources.

“We need to make sure that there’s no intentional or unintentional release of human fecal material into waterways,” Dr. Osterholm says. “A number of actions could be implemented to reduce the potential for *Cyclospora* to enter water and to prevent water that contains the parasite from being used on plants. Because the parasite is highly resistant to chlorination, the chemical can’t be used to help solve the problem.”

On April 19, the California Leafy Greens Marketing Agreement (LGMA) Board adopted more stringent requirements designed to reduce risks related to water used in growing leafy greens. The updates include specific directives such as no longer allowing the use of untreated surface water for overhead irrigation of leafy



greens prior to harvesting, says April Ward, MSc, communications director, California LGMA, Sacramento, Calif.

The new standards are in direct response to FDA investigations of last year's *E. coli* outbreak involving romaine lettuce. Clues pointed to irrigation water from sources such as canals and reservoirs as a possible cause.

California LGMA devised the new water metrics by working closely with Western Growers, who coordinated a working group, and Arizona LGMA. The organizations looked at water sources and how they're being used in production. "It's unlikely that water from deep wells could be contaminated with human pathogens because the Earth provides an effective filtration process to eliminate bacteria," says Dr. Whitaker. "Well water can therefore be used without fear of cross-contamination, provided the delivery system is well maintained and inspected.

"But surface waters such as ponds or canals are more likely to be impacted by runoff from pasture lands or animal operations, wild animals, wind-blown dust, or even septic systems—making it necessary that they're evaluated and perhaps treated with disinfectants to manage potential pathogen contamination," Dr. Whitaker continues.

"LGMA's program has always required growers to test their water because it can carry pathogens," Ward says. "But the new requirements include additional safeguards that ensure farmers categorize the water source and consider how and when water is applied to a crop; conduct testing to ensure water is safe for the intended use; and sanitize water if necessary."

The new metrics will become part of mandatory government audits that comprise the LGMA's food safety system. The LGMA will also begin an education and outreach effort to ensure that all members of the leafy greens community understand how to comply with the new standards, Ward says.

Other Efforts to Ensure Safety

Many other groups and organizations are also committed to improving leafy green safety. The CEOs of the United Fresh Produce Association and the Produce Marketing Association are co-leading a Romaine Task Force that includes a diverse group of industry thought leaders, FDA, CDC, trade groups, public interest groups, and academic scientists throughout the supply chain.

Following the 2018 outbreaks involving romaine, the task force is tackling key issues around produce labeling to allow consumers to know where their romaine was grown, permit supply chain-wide traceability, explore science-related issues around agricultural water and root cause analysis, and identify and prioritize improvements in the investigative process, Dr. Miller says.

"We expect to conclude our work this year and then reach across the entire supply chain to provide educational opportunities to ease the implementation of changes that will be recommended or create awareness around any new tools in development," Dr. Whitaker says.

The Center for Produce Safety (CPS), which provides the produce industry with information on enhancing the safety of fresh fruits and vegetables, has prioritized produce safety research (including but not limited to leafy greens) for more than a decade. Nearly 150 research programs have been funded thus far, with an investment of nearly \$26 million. Among the research priorities,



“Essentially, supply chain traceability is no longer a technology problem; rather it’s a political and policy problem,”

SAYS BEN MILLER, PHD, MPH, SENIOR DIRECTOR OF FOOD SAFETY, THE ACHESON GROUP.



CPS is currently focused on industry issues involving animal feeding operations and agricultural water, Dr. Whitaker says.

The Acheson Group works closely with food producers at every level of the supply chain and determines how risk that isn't adequately controlled upstream in the supply chain can carry through to the consumer. "When working with companies that grow, harvest, and process leafy greens, we look at the areas of greatest risk relative to food safety using FSMA's regulations as a guide," says Peyman Fatemi, PhD, vice president, Scientific Affairs, The Acheson Group, Big Fork, Mont. "FSMA regulations, when fully implemented, will go a significant distance in developing programs that will prevent microbial contamination in leafy greens."

The Acheson Group is also working to incorporate the most current science to guide its recommendations. "Prior to the romaine outbreaks of 2018, the industry had not been treating its overhead irrigation water, which was drawn directly from irrigation canals," Dr. Fatemi says. "There are still simple and logical steps, such as understanding the use and management of nearby land, that the industry can use to minimize the contamination of leafy greens."

"The key is to perform a hazard analysis and then develop preventive controls to manage those risks," Dr. Whitaker concludes. "And when contamination is discovered, it is equally important to perform a root cause analysis to identify why the contamination occurred and how it can be prevented in the future." ■

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Safety & Sanitation

SANITATION



Sanitation: Perfecting the Process

Three guidelines that can optimize sanitation in the facility to ensure equipment performs at maximum capacity | BY RIGO FRIAS

Foodborne illness is a common and costly—yet preventable—public health problem. CDC estimates that one in six Americans gets sick from contaminated foods or beverages each year, with 3,000 deaths. USDA estimates that foodborne pathogens impose over \$15 billion in economic burden annually. Food and beverage manufacturers have set effective sanitation practices as a top priority to prevent foodborne illnesses and protect public health, along with complying with FDA regulations. However, due to day-to-day customer demands,

equipment reliability issues, personnel issues, and quality concerns among many others, there is very little time to focus on ensuring each sanitation cycle is effective and efficient.

Ineffective sanitation practices are a result of inadequate cleaning methods, lack of standard cleaning tasks, lack of an understanding of how to execute the job, and personnel lacking the right materials or tools to perform the job. Inefficient sanitation often occurs when the sanitation cycle takes longer than planned, resulting in reduced productivity and low utilization

of an organization's assets due to rework (known in the industry as a re-clean) to swab and test equipment again because it didn't pass post-operation sampling. With repeated instances of ineffective sanitation practices, it is only a matter of time before a food safety risk detonates into a reality.

Myriad reasons contribute to ineffective and inefficient sanitation practices, including:

- Employees spending large amounts of time looking for tools and materials;
- A lack of a streamlined and well-defined process, resulting in poorly coordinated execution; and
- Employees having to wait for equipment to shut down or for other employees to finish their tasks before starting sanitation procedures.

The following three guidelines provide a basis for building the foundational elements to optimize a sanitation program that fully leverages time and resources and ensures that equipment is performing at maximum capacity.

I. Use SMED (Single Minute Exchange of Dies) Principles to Streamline and Optimize the Process

SMED is a lean technique where the premise is equal to the Formula-1 racing pit stop mentality. The objective is to get the car back to racing as safely and quickly as possible. This mentality should be the equivalent of the time it takes to perform sanitation and get a production line up and running in the safest, most effective, and most efficient manner.

Using SMED principles will make each sanitation cycle more structured, repeatable, and easier.

SMED consists of seven steps, which can be applied to any sanitation process.

1. Measure the process. First, you must have a clear understanding of all cleaning requirements, such as which assets must be cleaned and what exactly must be done to ensure each asset is thor-

oughly cleaned. When measuring, you must start by observing the process and documenting assets or areas to be sanitized, who performs each task, steps to perform each task, and the time it takes to complete each task. A Gantt chart should be used to perform this first step and should be used as a baseline to start implementing your improvement efforts.

2. Determine and separate the internal and external steps.

Internal steps are those that can be done only with the equipment stopped. External steps can be done while the equipment is working. In the Gantt chart, next to each task, indicate whether it is internal or external. Once you have identified all external and internal activities, the process will need to be refined with the objective of performing all external activities before shutdown. Some of these activities include staging cleaning carts, ensuring all cleaning supplies are readily available, ensuring water temperature is adequate, and preparing standard cleaning cards for personnel involved in the sanitation process.

3. Create parallel activities. Sometimes multiple employees perform sanitation activities in parallel. The goal is to perform simultaneous activities throughout the process to prevent employees needing to wait for another employee to complete a task before starting another job. For example, if two assets require a hot temperature washdown and each asset takes one hour to wash down, it takes a total of two hours to wash down both assets. By installing another high-pressure hose, you could reduce the cycle time to one hour to wash down both assets.

4. Reduce internal steps. This consists of improving the efficiency and execution of all internal tasks. Start by exploring the option of purchasing cleaning tools that will reduce labor efforts. Those may include handheld foamers and spray devices, foam tanks, foam carts, and cleaning carts to prevent employees from excessive walking to gather cleaning tools.

Centerlining is an excellent methodology for expediting setup time and achieving vertical start-ups. Parts color-coding and hard stops are another way to optimize setup times.

5. Reduce external steps. Similar to the reduction of internal steps, you'll need to reduce external steps by moving all necessary items as close as possible to their location of use, ensuring all materials needed are available in sufficient quantity and appropriately stored (e.g., the 5S method, see sidebar on p. 30 for more information), displaying setup kits on the machine or on tool boards or carts dedicated to the setup, and using a preparation checklist (to be included in the setup standard).

There is no limit to creativity when it comes to finding new ways to make internal and external steps more efficient.

6. Test and verify the new process. Once the new method is refined, it is now time to test, validate, and improve the new process. Start by observing the process once again. Make sure you have sequenced all tasks appropriately, adequately categorized internal and external activities, verified that all non-value activities have not been re-introduced, and most importantly, that you refine the process as you uncover additional opportunities for improvement.

7. Standardize the new process. Taiichi Ohno, the father of the Toyota Production System, famously said, "Without standards, there can be no kaizen (continuous improvement)."

(Continued on p. 30)

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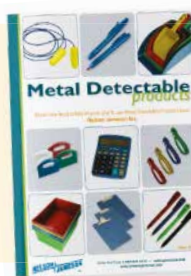


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After the new process is established, develop standard work for each one of the tasks required. Standard work routines will ensure that the work is done the same way every time and will not only drive efficiency in the sanitation process, but also effectiveness to make sure the job is done right the first time. Standard work routines must include lock-out tag-out procedures, safety considerations, tools to be used, chemicals and cleaning materials, and steps to perform each task. Standard work routines must be as visual as possible. Pictures are a great method for visually depicting critical points.

After sanitation standard routines are developed, it is critical to ensure the workforce is appropriately trained. It is quite common to hear that standard operating procedures are in a binder somewhere in a cabinet collecting dust. There's a lot of truth in the age-old saying, "Out of sight, out of mind." Standard work routines must be as visible and accessible as possible.

II. Implement a Sanitation Management System

Management consultant, educator, and author Peter Drucker, who contributed to the foundations of the modern business corporation, is credited with one of the most important quotes in business management: "If you can't measure it, you can't improve it." Once the new sanitation process is implemented, you must measure its effectiveness to determine if you have reaped the benefits of your efforts.

Sanitation procedures should be treated like the large-scale downtime

The 5S Method

As Industry Editor Richard Stier summarized in his February/March 2019 article on tips to enhance food quality and safety programs, the 5S method can be described simply as "Everything has a place and everything in its place." It was first developed in Japan with the five "S"s as seiri, seiton, seiso, seiketsu, and shitsuke. These translate to sort, set location, shine and sweep, standardize, and sustain.—*FQ&S*

events that they are and as a practice that if not done correctly, will put public health at risk. Thus, a Sanitation Management Operating System (SMOS) should be installed. The SMOS is a closed-loop process that allows the team to plan, prepare, align, monitor/control, report, and improve sanitation cycles.

The following meetings and tools can be utilized as part of an SMOS.

The goal is to perform simultaneous activities throughout the process to prevent employees needing to wait for another employee to complete a task before starting another job.

Pre-sanitation preparation meeting.

The objective of this meeting is to review and discuss improvements or changes that have been implemented since the previous sanitation cycle, production cutoff times to determine what and when sanitation preparation activities will take place, food safety considerations for the upcoming sanitation cycle, and workforce availability and assignments.

Sanitation visual board. This is used to monitor sanitation cycle time on a short interval control basis. Also, the sanitation visual board can be used for other items such as communication of assignments, pending corrective actions from previous sanitation cycles, and discussion of the performance of prior sanitation cycles. The sanitation visual board is a strong visual aid during sanitation shift pass-on meetings.

Sanitation shift pass-on meeting.

The objective of this meeting is for leads and supervisors to review and discuss the status of the sanitation efforts, watch-outs, or areas that require extra cleaning, as well as any challenges presented during the previous shift.

Sanitation post-mortem meeting.

Sanitation performance is reviewed through measures such as actual sanitation cycle time versus planned cycle time,

number of re-cleans, microbial loads, labor hours, and setup and start-up times.

III. Use Kaizen Events as a Platform to Continuously Improve

Who better to help make improvements than those who execute the work? The philosophy of kaizen is to involve all employees in making small, incremental improvements in their work areas every day while giving the process owners the tools to continually improve the process, resulting in the removal of time and resource waste.

Kaizen events is a proven technique that will accelerate improvements and change while gaining employee support and buy-in.

The first step is to develop a kaizen charter to define the problem and scope, determine the impact to business and target, identify team members, and set the schedule. This is followed by training to teach the team basic lean techniques and, most importantly, the principles of SMED, 5S, and standard work. After everyone is trained, sanitation must be observed to identify variances in the process and standard work routines or to identify improvements.

Once observation is completed, the team will brainstorm and prioritize ideas for improvement. The idea is to implement most of the ideas during the kaizen event, but action items will be captured for those ideas that require more time to implement. It will be critical to define and agree to a kaizen follow-up strategy to ensure completion of all action items.

Finally, we must measure the results and celebrate the victories!

Sanitation improvement efforts are not a one-and-done event. A process management operating system and kaizen execution require a structured, disciplined approach where sponsorship and follow-up from upper management are paramount. ■

Frias, a transformation director at Myrtle Consulting Group, has more than 18 years of experience in manufacturing and operations. Reach him at rigo.frias@myrtlegroup.com.

Note: The author would like to thank Ted Curry, manager at Myrtle Consulting Group, for his contributions to this article.



Power of Concentration

Verifying the concentration efficacy of food-grade chemical sanitizers helps keep sanitation systems under control

BY JOHN WILLIAMS JR.

Given what we now know about the opportunistic nature of food spoilage organisms, it is somewhat difficult to comprehend that processing plants and food service operations were once filled with food contact surfaces (e.g., wooden cutting boards, hard plastic sinks, and rubber conveyor belts) that greatly abetted their growth.

For even the most industrious sanitation crews of bygone times, cleaning and sanitizing a wide assortment of food contact surfaces were difficult, at best, to near impossible at worst.

Due to technological advances in hygienic food equipment design (clean in place), innovations in production equipment (i.e., the widespread implementation of stainless steel), and enhancements in preparation utensils, many contact surfaces are less prone to harbor potentially harmful food residues.

Nevertheless, the challenge of deterring the growth of bacteria, fungi, viruses, and other spoilage organisms on food contact surfaces is more pressing than ever in a heightened food safety-minded environment. Contaminated equipment and utensils have been [cited](#) as one of the leading risk factors most responsible for foodborne illness outbreaks in the U.S.

Local public health officials and federal regulators emphasize the importance of cleaning and sanitizing contact surfaces to prevent foodborne disease, and verification of the concentration of widely used chemical sanitizers through requisite testing. In addition to food plants, food service operations, and restaurants, contaminated food contact surfaces have been identified in a broad spectrum of institutions that prepare and serve meals, such as hospitals, military bases, long-term care facilities, supermarket delis, and schools.

The Food Safety and Inspection Service (FSIS), the meat and poultry oversight branch of USDA, states that the proper sanitization of contact surfaces is a fundamental and important task for food establishments. When performed correctly, according to FSIS, the sanitization of food contact surfaces: 1) decreases the chance of spreading foodborne illness from a food handler to a consumer; and 2) reduces the likelihood of contaminating previously safe food by destroying microorganisms found in food processing, preparation, and storage areas.

Gone in 30 Seconds

In accordance with sanitation standard operating procedures exercised across the food industry, food chemical sanitizers are used in tandem with detergents and water to kill potentially harmful microbes on food contact surfaces.

A food product contact surface is defined as a surface in direct contact with food residue, or where food residue can drip, drain, diffuse, or be drawn. Among the most frequently referenced contact surfaces in peer-reviewed scientific literature are cutting boards, knives, prep tables, sinks, scales, slicers, mixing bowls, food containers, and thermometers.

Food-grade chemical sanitizers from reputable suppliers, such as Ecolab, Inc., Birko Chemical Corp., ChemStation International, Diversey, and Zep Manufacturing, are approved by FDA for use in food facilities.

FDA-sanctioned sanitizers must destroy 99.999 percent of harmful bacteria within 30 seconds of a single application, be stable under a myriad of environmental conditions, and have low toxicity. Chemical sanitizers, which are registered through EPA, are reviewed for concentration efficacy, safety data, and product labeling information prior to being approved.

Noting it is difficult to overstate the importance of chemical sanitizers, Mark Carter, executive vice president of corporate development of Matrix Sciences, a full-service food testing and consulting laboratory that provides companies with analytical and business-based solutions, says the effective control of spoilage

(Continued on p. 32)

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organisms is a “hidden gem” in strong and sustainable sanitation programs.

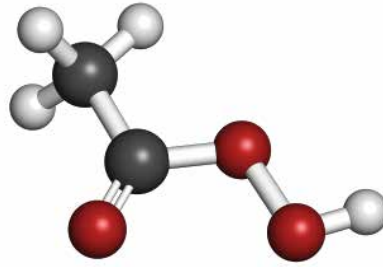
“The value of effective sanitizer use can sometimes get lost or overlooked in sanitation programs,” Carter proclaims. “It is inherently obvious, however, that chemical sanitizers—when applied at appropriate concentrations—are highly beneficial in helping industry stakeholders safeguard food products from disease-causing microorganisms.”

Sanitizer Scorecard

Scores of chemical sanitizers are utilized in food establishments. When choosing one for a particular food environment, users must weigh a host of considerations. Chief among them are the effectiveness at reducing microbial contamination in specific conditions, ease of application, need for rinsing, toxic/irritating properties, and compatibility with available water. The following section provides a brief synopsis of some of the most commonly used food-grade sanitizers.

Chlorine. Highly effective and relatively inexpensive, chlorine is the most commonly used chemical sanitizer agent. Typical chlorine compounds include liquid chlorine, hypochlorites, inorganic chloramines, and organic chloramines. These germicides attack microbial membranes, oxidize cellular protein, and inhibit cellular enzymes involved in glucose metabolism. Chlorine is effective against most bacteria, viruses, fungi, and bacterial spores. Chlorine solutions are highly corrosive and should not be used on surfaces that rust easily. The activity of chlorine is affected by such factors as pH, temperature, and soil load. In comparison with other sanitizers, chlorine is less affected by water hardness. Like most chemical sanitizers, the efficacy of chlorine can be diminished by the presence of food residues. Household chlorine should not be utilized in food facilities as it often contains substances and additives that are not approved for food use.

Quaternary ammonium compounds. Commonly known as quats or QACs, quaternary ammonium compounds are positively charged ions that are naturally attracted to negatively charged materials such as bacterial proteins. Effective against bacteria, yeasts, molds, and viruses,



Peroxyacetic acid (PAA) molecule.

quats are active and stable over a broad temperature range. Usually odorless, non-staining, and non-corrosive, quaternary ammonium compounds are relatively nontoxic to users.

Iodophors. These act against bacteria, viruses, yeasts, molds, fungi, and protozoans. They attach themselves to sulfurs in proteins, which basically renders those proteins inactive. Iodophors have a continuous effect on microbial death due to a sustained-release effect. From a cost consideration, they are pricey and can stain some surfaces, especially plastics.

Peroxyacetic acids. Effective against most microorganisms, peroxyacetic acids (PAAs) are also efficient in removing biofilms. Normal cleaning and sanitizing methods, including chlorine use, usually do not eliminate disease-producing microorganisms that live in protective biofilm. Deemed as environmentally friendly, PAAs break down into acetic acid, oxygen, and water.

The Human Element

Proper sanitization occurs when specific chemical concentrations, time/temperature requirements, and water conditions are met. A lengthy list of factors, however, can affect the efficacy of chemical sanitizers, including:

- **Concentration of the sanitizer (ppm)**—too much can be toxic, too little is ineffective;
- **Temperature of the sanitizing solutions**—each has an ideal temperature for best effectiveness;
- **Contact time with the surface or equipment to be sanitized**—time needed to have a sanitizing effect;
- **The pH and/or hardness of the water being used;**
- **Cleaning and rinsing**—poor cleaning and rinsing can inactivate or reduce the effects of the sanitizer;

- **Material being cleaned (plastic, metal, wood, glass)**—some sanitizers are better on certain surfaces;
- **Microbial load**—the number of microbes on the equipment or surface initially; and
- **Type of microorganism present**—some microorganisms are more tolerant to certain sanitizers than others.

The knowledge of employees is another crucial factor that can greatly affect the efficacy of chemical sanitizers. Throughout the U.S., large numbers of food workers are trained on safe food handling practices, including cleaning and sanitizing procedures. [Studies](#) have revealed that training improves the food safety knowledge of industry employees. Unfortunately, this knowledge does not always transfer to the application of prescribed sanitary practices.

Consequently, it is imperative for companies to measure the effectiveness of sanitation training through employee testing, observing worker competencies up close in actual work settings, and reinforcing learning as necessary to achieve desired training outcomes.

Workers, at a minimum, should know how to mix sanitizers properly and how to test sanitizer concentrations at assigned temperatures. Without question, food employees are a critical human element in the appropriate use and optimal performance of chemical sanitizers.

Effective Sanitization

Drawing upon 24 years of experience as a food microbiologist and researcher with Kraft Foods and the McKee Food Corp. among others, Carter states it is necessary to verify every aspect of sanitation programs, including sanitizer concentration.

“Verifying sanitizer efficacy is a key process in managing a rigorous cleaning and sanitizing program,” he says. “Verification can be accomplished through various means, but when done correctly, it can help companies keep their sanitation systems under control.”

Federal, state, and local health regulations require companies to verify the concentration of chemical solutions through sanitizer test kits.

Through the efforts of companies like Micro Essential Laboratory (Hydrion) and

other sanitizer kit suppliers, test strips have largely become the verification method of choice among chemical sanitizer manufacturers and users. Micro Essential supplies pH test papers, sanitizer test papers, and pH buffer standards to the global market.

Test strip kits, which are not interchangeable, contain detailed instructions (i.e., proper water temperature, contact time, correct level of sanitizer in solution) and color charts to determine accurate concentration measurements based on the type of chemical used. Generally, chemical manufacturers determine the concentration for effective sanitization.

When placed in the chemical solution, test strips produce a color change based on the amount of active chemical in the solution. Each color on the chart represents a different sanitizer concentration in ppm.

Pouring sanitizer solution into sinks and buckets can create foam. Usually, foam has a higher concentration of

sanitizer and must be allowed to dissipate prior to testing unless a clear area in the solution can be found. Once the foam is gone, the test strip should be dipped directly into the solution and held still—without swirling or moving—for the correct amount of time based on the type of sanitizer being used. The test strip should then be immediately compared to the color chart located on the test strip dispenser to determine the concentration of the sanitizer.

Throughout the day, results should be documented, analyzed, and tracked as part of sanitation standard operating procedures.

For all types of sanitizers used in the food environment, the frequency of testing should be performed as needed to keep the water clean, to ensure effective sanitizer concentration, and aid in the entry of safe food into the consumer marketplace. Test kits have a maximum shelf life and should be discarded in accordance with expiration dates.

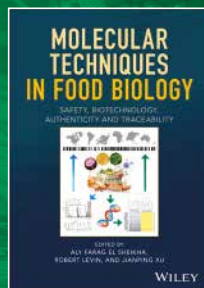
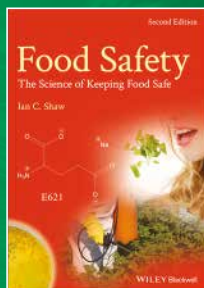
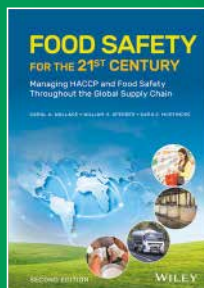
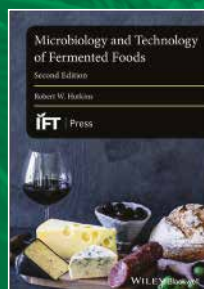
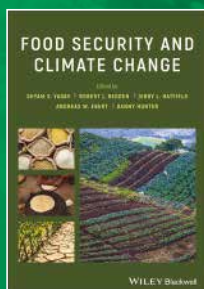
The strategic placement of technical information sheets and instructional posters in the workplace has been shown to be beneficial in reminding employees of the importance of following cleaning and sanitizing procedures. Some chemical suppliers also offer onsite training to assist operations with their sanitation efforts.

Definitive Step

Sanitation programs must operate on all cylinders to protect the integrity of food from a diverse gamut of spoilage microorganisms. It's been said proper sanitization is often the final—and definitive—step to ensure safe food reaches consumers. This daunting maxim significantly raises the ante on food safety stakeholders to confirm their chemical sanitizers are performing at peak efficiency. ■

Williams is a food writer, editor, and marketer whose articles have appeared in numerous food industry publications. He previously served as communications manager (North America) at Mérieux NutriSciences. Reach him at johnjr1145@gmail.com.

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Quality

SUPPLY PLANNING

All Aboard!

Simplifying supplier onboarding in order to fit each organization's needs and processes

BY RENATA MCGUIRE AND SCOTT ARNALD



Approving new suppliers is often atop the list of the most common nonconformances, and anecdotally, nearly every company we talk with says they struggle with managing their suppliers. So, what's the solution?

The bottom line is, managing supplier quality and safety is hard work. One thing our experience has shown us is that doing a considerable amount of work up front

through an effective onboarding program can prevent issues and headaches down the road.

Identifying a solid supplier onboarding process is critical and needs to be defined in a way that accommodates varying circumstances. (How quickly does a supplier need to be qualified? Is this a small supplier? Is this supplier critical to our business?) In all circumstances the outcome should be the same—you've evalu-

ated the supplier against a set of requirements and are confident you've assessed and managed the risk of introducing the product into your process or served directly to customers.

Culture Is Critical

Many programs are doomed to fail if the organization doesn't have a strong quality and safety culture. No QA department alone will be able to support an effective onboarding function if quality and safety aren't part of the fabric of the organization. Without it a "buy first check later" culture ensues, and we wear ourselves down fighting fires, managing complaints, recalls, upset customers, and, of course, panicked audit days.

Perfecting the Process

Creating a sound process that works for any organization will and should take more time than you think. The process needs to work for your business. The onboarding process should be integrated to meet the needs of all stakeholders in the organization including purchasing, legal, quality, food safety, operations, product development, and marketing. Having the right people engaged in developing and executing the process is key.

A clear strategy on sourcing goals needs to be defined with your brand, and the requirements of your supplies must align with this. For example, a brand that stands for local, small-scale sourcing yet requires Global Food Safety Initiative (GFSI) certification isn't likely to find anything compatible.

In defining the specific QA and food safety requirements of your suppliers, regulations and standards provide a lot of flexibility in how you structure a supplier approval program (within the confines of making a high-quality and safe food). Think about what it's going to take to trust your supplier. A risk assessment should help determine exactly what is required and the frequency at which those requirements need to be assessed. Will sharing some documentation be enough, or would a conference call or site visit give you the confidence you need? Do all the onboarding requirements/documents need to be refreshed each year for every supplier?

When considering requirement for onboarding suppliers, take into account:

- Inherent risk of the product/ingredient;
- Regulatory requirements (Food Safety Modernization Act, Foreign Supplier Verification Program, Safe Food for Canadian Act);
- GFSI certification;
- Brand standards (sustainability attributes, food fraud, and social compliance like Non-GMO, Organic, Free From, etc.); and
- Small suppliers (how will you deal with them?).

Once you understand what it will take to trust a supplier, how will you com-

No QA department alone will be able to support an effective onboarding function if quality and safety aren't part of the fabric of the organization.

municate these requirements to the suppliers? This piece is very often missed, and usually takes the shape of a demand rather than a step toward a working partnership. Personalizing the message and having an initial phone call with your supplier QA team can go a long way in building a reliable relationship. Often, the most time-intensive step is encouraging suppliers to provide the needed documents. The request requires a supplier's cooperation and having the right communication plan can speed this step immensely.

Expanding the Scope

The scope of responsibility of the food safety and QA function is also expanding to include assessment in areas such as social compliance, sustainability, brand standards, and food fraud considerations, along with regulatory compliance. The right people need to be in place to evaluate the supplier to determine the business risk. A produce supplier and a meat supplier are two different creatures; add in social compliance, and it's difficult to find all the skills needed in a single person. If it does all fall on the QA team, ensuring your

team receives the proper professional development to be knowledgeable in all the areas being evaluated is vital.

It's inevitable that one day we will look back and scratch our heads at how we used to onboard suppliers and manage the data. Plenty has been written on revolutionary technology on its way, but until then, we must evaluate the existing options in the marketplace that can work

for us now. There are many ways to ease the onboarding process and ongoing management of data. However, they all require the foundational elements described here and should be evaluated to fit your organizational needs and processes. ■

McGuire and **Arnald** work at NSF International Consulting Division providing supplier management services to food and beverage clients including outsourced services in supplier onboarding. Reach McGuire at rmcguire@nsf.org.



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In The Lab

AUTHENTICITY



Authenticating Spices

Determining the metal content of spices and identifying the country of origin

BY JENNY NELSON, MBA, PHD; COURTNEY K. TANABE; GREG GILLELAND; LINDSEY WHITCOTTON; ELAINE HASTY; AND LEANNE ANDERSON

International trade in spices has continued to thrive over thousands of years. Present-day producers and importers need to be aware of any legal requirements relating to food safety and quality standards. In addition to pathogens and impurities, the level of metal contaminants present in spices is a further product safety issue. Spices can be contaminated with metals during the growth cycle of the plant or during processing and packaging. Food fraud is another problem, as competitive gains can be made through intentional counterfeiting, substitution, adulteration, or mislabeling/misrepresentation of ingredients within products. Many of these tricks go unnoticed by consumers and regulating government agencies due in part to the lack of standardized methods for the identification of geographic origin.

High-value foods such as wine, rice, oils, honey, fruit juices, tea, coffee, and spices that are marketed according to their provenance are susceptible to food fraud. Additional profits can be made in several ways, for example by blending good quality, authentic products with inferior and cheaper ingredients or by deliberately misbranding a low-quality product as one with a higher value.

Elemental fingerprinting can help combat fraudulent activity. Foods can be authenticated based on the pattern of their trace element content, which is characteristic of the soil composition in the region of production—one study used multi-elemental profiling of 29 tea samples through inductively coupled plasma-mass spectrometry (ICP-MS) for authentication purposes. A similar elemental profiling approach was used in this study to identify

the origin of 55 spices from various countries and to differentiate between assorted spices produced in the same country.

Versatile Multi-Element Analysis

Many food testing laboratories already use ICP-MS for the quality control of their products. It is a well-established, fast, multi-element technique to determine a wide range of elements present in a sample at different concentrations. However, given the variety of food types, many foods contain a complex or variable matrix that can give rise to the formation of polyatomic interferences in the ICP-MS spectrum that can affect the accuracy of the data for some elements. A series of recent developments has enhanced the matrix tolerance of ICP-MS and control of polyatomic interferences, improving its suitability for the analysis of foods. ICP-MS equipped with an ultra-high matrix introduction system enables the plasma to tolerate samples containing up to 25 percent total dissolved solids (TDS). Octopole-based collision/reaction cell (CRC) technology removes polyatomic interferences arising from the plasma and sample matrix using kinetic energy discrimination (KED) with a single gas (helium mode), improving the data quality of foods with complex matrices.

Over 50 spices from around the world of known origin were received from a business-to-business spice supply company based in the U.S. Knowing the origin of samples is critical to the development of a reliable model that can be used to authenticate unknown samples. All spice samples were microwave digested in acid (MARS 6, CEM).

Since our lab is equipped with both ICP-optical emission spectroscopy (ICP-OES) and ICP-MS, we first used ICP-OES as a screening technique to establish the concentration levels of elements present in the spice sample digests. The same samples were then analyzed using ICP-MS. Rather than dilute the samples to bring the high-level elements (aluminum, calcium, germanium, potassium, magnesium, sodium, phosphorus, sulfur) into range, we used the ICP-OES results for these elements in the statistical analysis.

A 7900 ICP-MS and 5110 ICP-OES (Agilent Technologies) fitted with an SPS 4 autosampler (Agilent Technologies) were used to analyze various spice samples.

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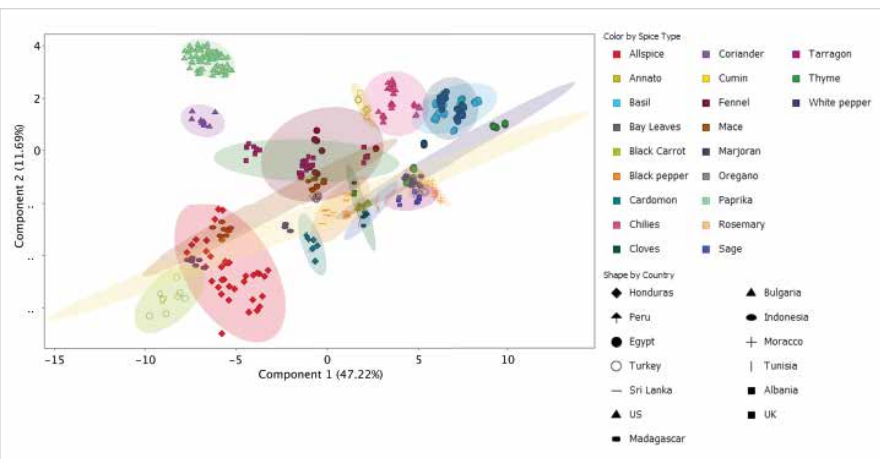


Figure 1. PCA of spice samples based on country of origin and spice type.

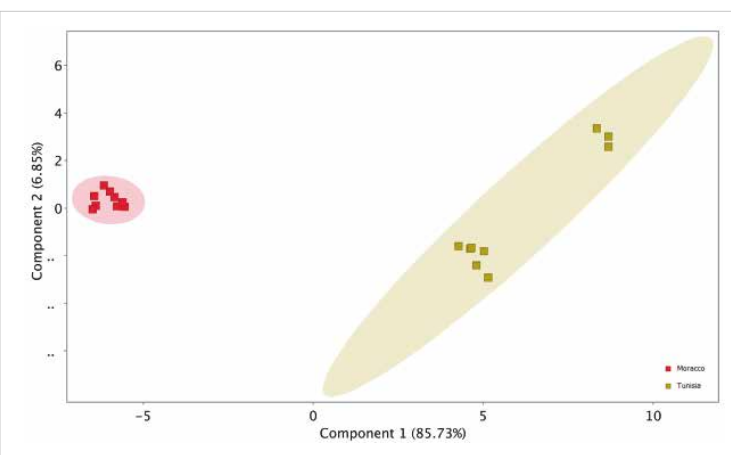


Figure 2. PCA of rosemary from two different countries (Morocco and Tunisia).

Mass Profiler Professional (Agilent Technologies) chemometric software was used for statistical analysis of the data set.

Validating the Analytical Method

To verify the spice sample digestion process, three National Institute of

Standards and Technology (NIST) standard reference materials (SRMs) were analyzed by ICP-MS and ICP-OES. The mean concentrations (ppm) of three repeat measurements of three SRM digests were in good agreement (80–120 percent) with the certified concentra-

tions, where certified concentrations were provided.

A spike recovery test was then carried out to check the accuracy of the elemental method for spice sample analysis. Four random spice samples were spiked with all elements at 20 and 60 ppb and measured using ICP-MS and ICP-OES. The quantitative results for the spice samples showed that the concentrations of aluminum, potassium, calcium, magnesium, sodium, iron, phosphorus, sulfur, silicon, zinc, and manganese were relatively high in all four spice samples. The spike results for these elements were therefore invalid as the spike levels were too low (20 times lower) relative to the levels present in the unspiked samples. The recoveries for all remaining elements were within ± 20 percent.

Elemental Fingerprinting

All spices were analyzed, and the multi-element data batch file (55 spice samples, nine replicates) was imported into MPP chemometric software for statistical analysis. Principal component analysis (PCA), an unsupervised technique, was used to find the direction of the greatest variance in the elemental data and display the samples based on these differences and similarities. As shown in Figure 1, the spice samples were separated fairly well based on country of origin and by spice.

Overall differences between the elemental composition of spices from the 13 different countries were found. As seen in the PCA (see Figure 1), spice elemental profiles were found to discriminate coun-

(Continued on p. 38)

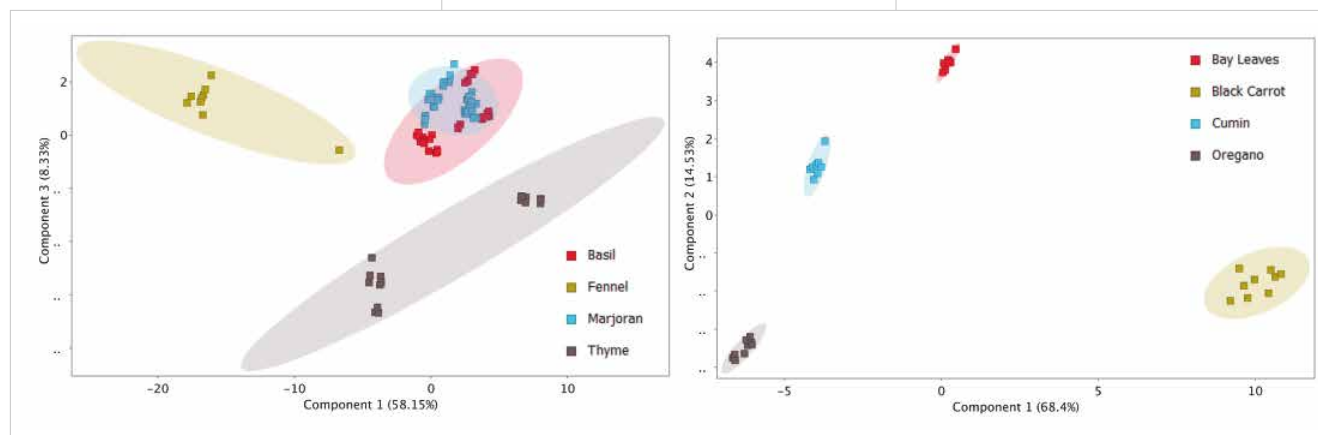


Figure 3. Left: PCA of different spice samples (basil, fennel, marjoram, and thyme) from Egypt. Right: PCA of four different spices from Turkey (bay leaves, black carrot, cumin, and oregano).

(Continued from p. 37)

try of origin and explain 47.22 percent and 11.69 percent of the variance in PCA components 1 and 2, respectively; however, the countries were not completely separated.

We were interested to see if origin could be distinguished when examining one spice. This can be demonstrated in the PCA of rosemary, where clear separation between samples from Morocco and Tunisia is shown (see Figure 2). In addition to discriminating between countries, we saw in Figure 1 that elemental profiles could also distinguish some spices. We further investigated whether spices originating from one country could be separated. The PCA in Figure 3 shows the elemental composition of multiple spices within Egypt and Turkey. Clear separation was seen between four spices from Turkey, and possible spice discrimination was seen in samples from Egypt.

Initial Findings and Future Aspirations

ICP-MS can be used for the quantitative analysis of the widest range of elements in spice samples, producing large data sets for statistical analysis. ICP-OES can also be applied for elemental fingerprinting studies using data for all but the lowest concentration elements.

Exploratory data analysis using PCA showed that the elemental composition of spices is influenced by the country of origin, allowing discrimination between 13 countries. Four different spices from the same country were also separated using the methodology, as was the same spice from two different countries.

More samples are needed to strengthen and test the fingerprinting model to authenticate spices. However, because of current tracking issues, obtaining spices of known origin is challenging. Once established, the method could form a valuable part of a food manufacturing and distribution facilities' food fraud program—potentially with economic- and health-related benefits for the consumer. ■

Dr. Nelson, an assistant adjunct professor for viticulture and enology at University of California Davis, is a market development spectroscopy scientist at Agilent Technologies. Reach her at jenny_nelson@agilent.com. **Tanabe** is a graduate student of agricultural and environmental chemistry in the Department of Viticulture and Enology at UC. **Gilleland** and **Whitecotton** are application engineers at Agilent Technologies. And **Hasty** and **Anderson** work for CEM Corp.

Table 1. Quantitative results (n=3) for four random spice samples. ICP-MS results are reported for all elements apart from aluminum, boron, barium, calcium, germanium, potassium, magnesium, sodium, osmium, phosphorus, and sulfur, which were acquired by ICP-OES using the wavelengths (nm) given in the table.

Element (mass and wavelength)	White Pepper Sample 58	White Pepper Sample 45	Paprika Sample 24	Basil Sample 50
	Measured conc, ppb			
¹⁰⁹ Ag (328.068 nm)	2.5	6.0	5.3	11.5
Al (396.152 nm)	12863	35209	1022222	1290444
⁷⁵ As (188.980 nm)	62.5	7.3	114.7	298.8
B (249.772 nm)	21289	4264	38800	18339
Ba (614.171 nm)	9707	5563	32433	31658
⁹ Be (313.042 nm)	1.1	2.5	34.0	19.7
Ca (317.933 nm)	4074444	2095333	25833333	7244444
¹¹¹ Cd (214.439 nm)	451.5	43.1	31.5	37.6
¹⁴⁰ Ce	14.6	52.6	1105	722.7
⁵⁹ Co (238.892 nm)	586.7	41.8	786.6	44.5
⁵² Cr (267.716 nm)	207.5	449.4	1640	3825
¹³³ Cs	6.0	199.3	36.5	209.0
⁶³ Cu (327.395 nm)	9461	9315	28900	14090
¹⁶³ Dy	1.0	4.0	90.9	42.4
¹⁶⁶ Er	0.5	1.7	48.4	21.8
¹⁵³ Eu	0.3	1.9	27.3	8.6
⁵⁶ Fe (238.204 nm)	178889	42313	1104444	650133
⁷¹ Ga (294.363 nm)	4.6	13.6	277.5	324.9
¹⁵⁷ Gd	1.2	5.1	107.4	47.6
Ge (209.426 nm)	332.4	4335	<DL	4486
¹⁷⁸ Hf	0.5	1.2	42.9	16.9
²⁰² Hg	<DL	5.8	<DL	21.2
¹⁶⁵ Ho	0.2	0.7	18.1	8.0
¹⁹¹ Ir (224.268 nm)	1084	299.4	382.0	213.8
K (766.491 nm)	36576667	412522	35601111	4483111
¹³⁹ La	9.2	45.8	511.4	468.8
⁷ Li (670.783 nm)	3658	1028	902.3	1206
¹⁷⁵ Lu	<DL	0.6	7.2	1.9
Mg (280.270 nm)	2694889	841078	7852000	1583556
⁵⁵ Mn	13724	46072	89087	98118
⁹⁵ Mo (202.032 nm)	309.8	396.3	1072	927.6
Na (589.592 nm)	1044667	15157	694644	149900
⁹³ Nb	2.6	6.3	106.4	58.3
¹⁴⁶ Nd	7.2	27.9	578.4	299.9
⁶⁰ Ni	843.7	374.6	1646	1259
P (213.618 nm)	4000000	1757778	4879222	1117333
²⁰⁸ Pb (220.353 nm)	16.2	74.5	506.8	751.0
¹⁰⁵ Pd	0.7	0.8	6.3	0.9
¹⁴¹ Pr	1.9	7.6	132.7	85.4
⁸⁵ Rb	6738	34776	15829	20362
¹⁸⁵ Re	0.7	<DL	5.0	0.2
¹⁰³ Rh	4.9	<DL	0.5	1.7
S (180.669 nm)	2346778	842411	3976222	1065889
¹²¹ Sb (206.834 nm)	2.9	2.6	17.4	55.7
⁷⁸ Se	303.1	14.9	47.2	83.1
²⁸ Si	54902	162328	348062	324616
¹⁴⁷ Sm	1.5	5.0	120.5	55.9
¹¹⁸ Sn (189.925 nm)	18.3	2099	57.6	189.0
⁸⁸ Sr	36350	14511	214044	60908
²³² Th	1.8	19.1	93.8	509.7
⁴⁷ Ti	393.7	1604	59520	12882
²⁰⁵ Tl	<DL	5.2	10.9	11.2
¹⁶⁹ Tm	0.1	0.2	6.6	2.9
²³⁸ U	22.1	3807	37.4	<DL
⁵¹ V	104.0	21.6	2724	852.8
¹⁸² W	9.5	1.7	5.9	31.1
¹⁷² Yb	0.5	1.1	39.2	18.6
⁶⁶ Zn	21503.0	22931.7	39538.3	18788.4
⁹⁰ Zr	16.2	29.9	1375.1	455.7

Manufacturing & Distribution

FOREIGN OBJECT CONTROL

X-Rays Mark the Spot

X-ray detection solutions, like inline and third-party inspection services, are helping to address the growing problem of foreign material contamination

BY CHRIS KEITH

Preventing food contamination by foreign materials begins with understanding where the danger lies. There are a number of different ways for contami-

Third-party X-ray inspection services are a supplement to existing screening and detection methods, not an alternative.

nants to enter the food supply, and as the food chain becomes increasingly global, those entry points continue to grow. Any time a new ingredient is introduced, from the field to the final stage of packaging, it also introduces a new opportunity for physical contamination.

Among the many sources of foreign contaminants in food products are pieces of manufacturing equipment, such as a blade, a wire, or a cracked gasket, that fall into the food. They can come from employees losing objects like an earring or a pen; a broken glass during packaging can also contaminate product. Or, it might come in the form of a rock or pieces of wood from where the food product or ingredient originated.

Further adding to contamination is the growing use of plastic materials. Today, plastic and rubber are two of the most common materials used in a food manufacturing plant—and while that makes the process easier for manufacturing in many ways, it has also created new headaches for food producers. Recently, two of the largest meat and poultry producers had to [conduct recalls](#) on their products, which totaled almost 100,000 pounds, due to rubber contamination.

Regardless of what type of physical contaminant it is or where the contam-

(Continued on p. 40)

Food contamination caused by bacteria or chemicals gets most of the attention when it comes to news stories. In 2018, the main headline-grabbing contaminants were *Listeria*, *Salmonella*, and *E. coli*—all three of which prompted recalls that included cheese products, salads, meats, and pet foods.

While recalls due to such bacterial contamination get a lot of attention, the fact is that the presence of foreign material in food continues to be a larger growing problem. It's a significant enough problem that, on March 8 of this year, the USDA Food Safety and Inspection Service (FSIS) announced a [new guideline](#) for the meat and poultry industry dealing with customer complaints in direct response to contamination from plastic, metal, and other foreign materials.

Those new guidelines require contamination incidents to be reported to the FSIS within 24 hours.

The government agency says it renewed its emphasis on responding to

complaints of foreign materials following dozens of complaints and recalls last year due to foreign contamination in chicken, sausage, and other meat products.

Are Contaminants More Common, or Are We Better at Catching Them?

As the number of reported incidents continues growing, many consumers question what's going on with the food supply. Are there more instances of contamination, or does our 24/7 news cycle just make sure we're hearing about them?

The truth is, it's probably a little bit of both. The industry has become more sophisticated in its ability to detect contaminants, whether they are biological, chemical, or physical. A September 2018 story on [National Public Radio's Morning Edition](#) noted that then-FDA Commissioner Scott Gottlieb believed today's food supply is safer than ever; what has changed is our ability to identify threats to our food and stop them from reaching consumers.

(Continued from p. 39)



Because third-party X-ray inspection services are dedicated entirely to inspection, they operate at a much slower speed to allow technicians to monitor each item individually.

ination occurred, the time to correct it is before that product hits the shelves and reaches consumers. Today's increasingly sophisticated detection systems are designed to do just that.

Finding Foreign Materials in Food

Today's food manufacturers have many choices when it comes to the type of equipment they use to safeguard their food. One of those options is X-ray inspection.

X-ray inspection machines have the ability to find all types of foreign material, including metal, bone, plastic, glass, rubber, wood, and more. The machines use a detector and programming algorithm to reject potential foreign contaminants based on a difference in their density. Since they are able to detect all types of foreign objects, they're particularly effective in food manufacturing environments.

Even within the category of X-ray inspection machines, there are certain differences to consider. Inline X-ray inspection

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machines typically use flat-panel technology and are small enough to fit into the body of the inspection machine. They're similar to the equipment used by the TSA for baggage screening at airports and will flag the presence of foreign materials, but they have certain limitations due to the speed of the production line and the power of the X-ray.

Since a food manufacturer may be running thousands of pounds of product per hour, inline machines aren't able to typically keep up with the speed of production and likely can only alarm that there is a problem. That, in turn, means the indication of foreign material can cause the quarantine of thousands of pounds of product. At the same time, the higher rate of speed combined with operational desensitization to limit a higher rate of defaults can also keep the machine from detecting smaller contaminants, such as those less than 3 to 5 mm.

These machines let manufacturers become aware of the presence of foreign materials, allowing food producers to decide what their next steps will be to prevent the contaminated product from reaching consumers.

Third-party X-ray inspection services are a supplement to existing screening and detection methods, not an alternative. When an inline machine flags a problem, a third-party X-ray inspection service can then work through the quarantined product to find the contaminated product faster and more affordably than any other option. Dollar for dollar, it's less expensive to have the product examined by a third-party service than it is to try reworking the product in the existing facility, to dispose of the full production run, or to risk a lawsuit or recall.

Because third-party X-ray inspection services are dedicated entirely to inspection, they operate at a much slower speed, which allows technicians to monitor each item individually as it passes through the machine. In a food production environment, it's not feasible to have a designated worker visually watching a screen to look for contaminants. The speed of the line makes this an impossibility, but for a third-party inspection service, such monitoring is critical and is more effective.

For example, FlexXray's custom X-ray inspection machines can detect multiple contaminants as small as 0.8 mm (or even

smaller in most cases), and line technicians are trained to notice issues and changes in density that signal the presence of foreign material contamination. When such a change is noted, the technician can stop the line and zoom in on the area in question for a magnified image. If identified as a foreign contaminant, the product in question can be immediately removed from the line and segregated from the saleable product for safe and proper disposal.

Foreign material contamination issues aren't an isolated problem—they're something that every food manufacturer faces. Knowing your options and having a plan in place to resolve an issue when it occurs is the best insurance to avoid a costly recall or lawsuit and to keep business operations running smoothly. ■

Keith is the vice president of sales, marketing, and customer service at FlexXray. Reach him at k Keith@flexxray.com.

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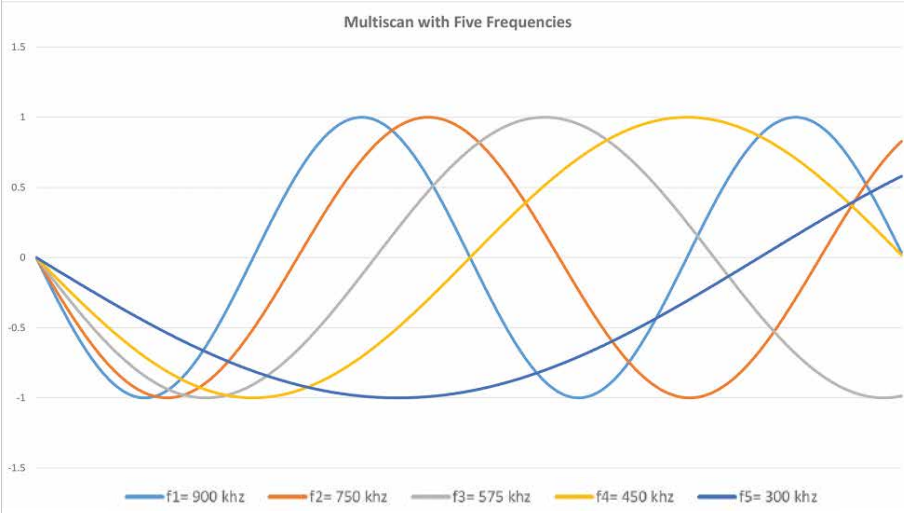
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METTLER TOLEDO

Multifrequency Metal Detection

Multiscan technology can scan up to five adjustable frequencies, raising the probability of detection | BY BOB RIES



Imagine watching the news and a story entitled “Check your fridge and pantry for food products recalled this week” brings up a picture of your brand’s packaging. It’s not that uncommon. For example, in late 2018 [one manufacturer](#) recalled 29,028 pounds of frozen, ready-to-eat poultry and pork sausage links after five people called USDA’s Food Safety and Inspection Service to let agency know they found metal pieces in their sausage.

While regulatory pressure and the risk of financial loss have pushed many manufacturers to invest in detection technologies, mitigating risk entirely remains a challenge. Thankfully, today’s metal detectors and X-ray detection systems offer higher levels of sensitivity, but that wasn’t always the case, and not every manufacturing facility has the latest technology.

This article explores the evolution of metal detection technology for food safety. Metal detection systems provide reliable, cost-effective protection from even the smallest metal contaminants found anywhere in a food production process.

They can also help improve operational efficiency and eliminate expensive downtime, service costs, and repair bills. And metal detectors are suited for a wide range of demanding food processing applications and packing environments.

Metal Detector Technology

Metal detectors are common across food processing facilities to meet HACCP (Hazard Analysis and Critical Control Point) requirements. Most often they are placed at the end of the line as the last defense against escape before a packaged product is sent on its way to the consumer. The core technology, though, has always had limitations, such as the so-called “product effect,” where a detector cannot differentiate between a conductive product or one with high mineral content and the metal contaminant and susceptibility to “noise” coming from many possible sources in the typical harsh, industrial food production environment.

Basic metal detector technology relies on coils that are wound on a non-metallic frame and connected to a radio frequency

transmitter and receiver. The transmitter “excites” any unexpected metal objects and generates very small changes in return signals to detect foreign contaminants. Digital signal processing algorithms are used to differentiate between the expected product signal and that of an unexpected foreign object. The technology works, but historically performance can be inconsistent and sometimes even unpredictable. Recently, with the introduction of multi-scan metal detection technology, this is starting to change.

The Evolution of Frequencies

Early metal detection technologies for the food industry were limited to single, fixed frequencies. A manufacturer could best detect a piece of stainless steel using a high frequency, but when a wet, warm, or salty product was introduced it would be forced to reduce the frequency and thus the sensitivity due to the product effect. This simple frequency change required setup by skilled technicians who might spend hours selecting the “best” frequency for detection of all metal types. A user could not make this change themselves.

Single, fixed-frequency metal detectors had limitations for the typical food manufacturing environment given the range of products to be tested and the variability of metal contaminants that could enter the process. That’s why manufacturers started adding second and third frequency choices (always running just one frequency at a time), giving users more flexibility. Manual frequency switching became more common but was only marginally less onerous: Expertise was still needed to optimize detection. Nonetheless, this was an advancement since it introduced more frequency flexibility to metal detection.

The next advancement in metal detection was the development of frequency selection via software. The “best” single frequency for a given application could then be selected prior to production by scanning a product many times and testing detection. This was known as variable frequency metal detection, and it enabled setup without the need for a specialist. Manufacturers still were forced to

live with the “best” single frequency compromise, however, and accept its lower overall performance.

A recent advancement in metal detection enabled detection at two frequencies simultaneously, essentially performing like a low and high frequency detector in one. Although the dual-frequency metal detection approach improved overall sensitivity, the combination of frequencies that could run simultaneously was still limited. The opportunity to miss metals with frequencies between or on either side of the dual setting still led to compromise that left quality managers wanting more.

The Advent of Multiscanning

Multiscan technology is said to be the long-awaited innovation in metal detection. Metal detectors with this capability can identify contaminants that are up to 50 percent smaller in volume than previous technologies, including food items with high product effect. With multiscan technology, the CCP can scan up to five adjustable frequencies, raising the probability of detection exponentially. Essentially, it's the equivalent of having up to five completely adjustable metal detectors back to back in a production line.

Multiscan detectors don't continuously broadcast the five frequencies simultaneously. If they did, the power requirement would be too high and expensive. Instead, the frequencies are scanned thousands of times per second, equivalent to broadcasting simultaneously without requiring as much energy.

Another benefit of multiscan technology is complete flexibility to set frequencies and the associated detection parameters. This is important given that the interaction of the product and metal in all applications is different, depending on factors such as the ingredients in the product, the type of packaging, the product temperature, and variation in all of the above. Most times these interactions are impossible to predict too. With multiscan technology users can make changes in software, selecting the appropriate five frequencies in the 50 to 1,000 kHz range. If a quick test shows detection for an application is best in the 400 to 600 kHz range, the user can easily select five frequencies in that range to maximize performance. To counteract product

effect, the user can simply select a lower frequency range, such as 100 to 250 kHz. Different combinations can be selected for different products and they can be changed at will at any time. Multiscan detectors are based on the idea that there is no perfect frequency, and that the best range of frequencies changes depending on the application.

A not-so-obvious benefit of multiscan technology is that it can be used to address an all-too-common metal detection problem—electromagnetic interference (EMI), which can happen in almost any factory at any time. EMI is an invisible field typically generated by a motor or variable frequency drive that moves through the air into the metal detector aperture, causing interference with the detection signals. EMI can come from a variety of other sources in a harsh industrial setting and the aperture can't be shielded because it's where the products pass through. Users can simply look at the screen on an advanced multiscan detector to see which frequency or frequencies are affected by EMI and adjust accordingly. This can be done in a matter of minutes and doesn't require a specialized skill set.

Finding the Best Metal Detection Solution for You

There is no “one size fits all” approach to metal detection. The best protection against metal escapes is ensuring that the solution you implement is the right one for your products. Even with advanced multiscan technology, it's critical that manufacturers consider their unique systems, processes, equipment, and product types before making a final decision about which technology to deploy and how.

To ensure future detection performance, a best practice is to have the metal detector manufacturer conduct controlled tests on the detection equipment of interest. The test must simulate, as closely as possible, how product will ultimately be inspected on an actual processing line. Product-specific factors such as temperature and package configuration must be replicated.

While no product test can replicate actual conditions, the more rigorous the test, the better. A testing process should specify performance requirements to provide confidence that the inspection solution will be

suited to a specific application. Even for an advanced metal detector, such as one with multiscan capability, it's important to follow a strict process to ensure each requirement is addressed. At a minimum, the testing should consider the following.

Product presentation and orientation. Results could be invalid if the product passes through the metal detector in the wrong way.

Production conditions. Temperature, pitch, and speed should match the actual production environment. Because temperature affects the electromagnetic signal given off by products, failing to factor in the unique signal of a hot versus cold product on a production line would lead to false rejects. Pitch should also be tested to understand the total amount of signal in the detector at any time and how many products might be detected at a time.

Placement of metal. Testing should be performed by placing metal in multiple locations on a package, including the center of the aperture, the weakest detection point because it is the farthest away from the metal detector coils. A thorough assessment should include tests on leading, trailing, absolute center, and sides to ensure metal is detected anywhere in the package.

Analysis of results. After testing is complete, a formal report should provide recommendations for each tested product, including recommended conveyor speed, frequencies, and setup parameters.

Finding the best metal detection solution is certainly easier than it once was. The most advanced instruments are now more reliable and versatile, bringing greater efficiency to manufacturers while requiring fewer trade-offs. It's possible to have confidence, high throughput, and flexibility at the same time. Today, the high bar is multiscan technology, yet future advancements are inevitable. It may never be possible to make escapes 100 percent preventable, but today's technology—supported by best practices—is already saving millions for manufacturers by avoiding costly recalls and, most importantly, ensuring food is safer for consumers. ■

Ries, the lead product manager for metal detection and X-ray inspection at Thermo Fisher Scientific, advises customers on specifying, installing, and using metal detection and X-ray systems to improve food safety and quality. Reach him at Bob.ries@thermofisher.com.

Food Service & Retail

DISINFECTING & SANITIZING



Properly Disinfecting and Sanitizing in Food Service

What operators and staff need to know to help prevent the spread of foodborne illnesses

BY MIKE WATT

Depending on the size and type of food service location or commercial kitchen, the number of cleaning solutions used to maintain the facility can be considerable. For instance, degreasers are invariably used to clean floors, walls, metalwork if there is a heavy buildup, and other areas. All-purpose cleaners are used just about anywhere and everywhere. Solutions to

clean and polish stainless steel are always needed.

Further, many food service locations have very specific needs. For instance, selecting cleaning-related products in order to keep the drains running smoothly, spot removers to clean carpets, and if they fully clean their own carpet, cleaning solutions made just for this purpose.

But there are two more cleaning solutions that are used in virtually every food service location. They are not designed to make surfaces look cleaner or shinier. They are designed to help make surfaces healthier, more hygienically clean, by eliminating or minimizing the number of pathogens—germs, bacteria, viruses, and other contaminants—on a surface that could possibly cause illness.

These two ubiquitous products are sanitizers and disinfectants. In many ways, we can view them as we did penicillin and other antibiotics when they were first introduced. Discovered in 1928, penicillin was labeled as one of the first “miracle drugs” ever created. And in some ways, sanitizers and disinfectants are “miracle” cleaning solutions because of their ability to attack pathogens. How-

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ever, just like penicillin, it was learned over time that if these cleaning products are not used properly and safely, their benefits can be cut short—something we cannot allow to happen in any facility, and certainly not in a food service location.

Defining Terms

Although some countries may define sanitizers and disinfectants differently, the following are the two most commonly accepted views of sanitizers and disinfectants in Canada and the U.S.

Sanitizer. When we sanitize a surface, we are taking steps to *reduce* the number of pathogens on that surface to what is considered a safe level for public health. In most types of cleaning situations, including in food service locations, a sanitizer may be all that is needed. This is good to know, since sanitizers may be less costly and easier to use than disinfectants. In addition, some are certified Green—meaning the product is independently evaluated to ensure it meets specific standards and that, when used properly, the product has a reduced impact on the health of the user and the environment.

Disinfectant. When disinfectants are used, hygienic cleaning is taken to a much higher level. While sanitizers are designed to *reduce* the number of pathogens on a surface to safe levels, disinfectants are designed to *kill* pathogens on a surface based on the product’s “kill claims” and how it is used as directed per the manufacturer’s instructions. When selected and used properly, disinfectants are able to kill most germs, bacteria, and other pathogens on a surface that could cause or spread disease.

Disinfectant Categories and Types

In the U.S., disinfectants are not certified Green. EPA, which regulates disinfectants, categorizes them as pesticides. What EPA is most concerned about is if the product works effectively and safely per the manufacturer’s instructions, with ingredients designed to kill pathogens.

For food service purposes, there are three categories or classifications of disinfectants.

1. General disinfectant. This type of disinfectant is effective against a variety of different types of bacteria, germs, and other pathogens. In most cases for the food service industry, the goal is to clean

and disinfect, not attack a specific pathogen. Because of this, a general disinfectant should usually suffice.

2. Limited disinfectant. A limited disinfectant is effective against only a specific group of microorganisms. If, for instance, there are concerns about norovirus pathogens in a commercial kitchen, food service administrators should select a disinfectant specifically designed to kill norovirus microorganisms.

To help prove disinfectants are still effective, food service operators can test surfaces using ATP monitoring systems or swab surfaces...

3. Hospital-grade disinfectant. These disinfectants have proven effective at eliminating many types of nosocomial (healthcare-acquired) bacterial pathogens. As the name implies, they are generally for use in hospitals, clinics, dental offices, or other healthcare-related facilities.

When selecting a disinfectant, the product’s label and marketing material should indicate what type of disinfectant it is and how or where it should be used. It will also indicate the product’s kill claims, which identify the specific types of pathogens—*Salmonella*, *Staphylococcus aureus*, etc.—that the disinfectant is designed to kill.

How to Properly Use Sanitizers and Disinfectants

For a sanitizer or disinfectant to be effective in a commercial kitchen, the surface must be clean. This means it’s a two-step process: clean first, then sanitize or disinfect.

Sanitizers are typically very easy to use. As always, read the label first and follow manufacturer instructions. What is key when selecting a sanitizer is to ensure it is NSF (National Sanitation Foundation) certified. This means the product has been proven effective and rinsing is not required after use, which can speed up cleaning considerably.

On the other hand, using disinfectants can be more complicated. Food service professionals should:

- Make sure the product will not prove corrosive to metalwork;
- Never mix two different types of disinfectants (or sanitizers for that matter) as they have different ingredients that may not work well when mixed, and sometimes mixing can produce noxious fumes, especially if mixed manually;
- Keep in mind pathogens can develop an immunity to disinfectants, so use only when and where necessary and change disinfectants occasionally;
- Never use too much or too little disinfectant—follow manufacturer dilution instructions;
- Be aware if the product is marketed in Canada to see if it has a DIN (drug identification number), which simply verifies the product is effective when used correctly;
- Be aware of quaternary ammonium compounds (quat) binding, when the “quats”—the key pathogen killing ingredients in disinfectants—become absorbed into cleaning cloths or mops because when this happens, the disinfectant loses its efficacy; and
- Read the label to determine if rinsing is needed for disinfectants, as some may leave a chemical residue on surfaces that can, ironically, attract pathogens.

To help prove disinfectants are still effective, food service operators can test surfaces using ATP (adenosine triphosphate) monitoring systems or swab surfaces and place the findings in a petri dish. A laboratory should be called in to verify the results.

In many ways, especially in today’s fast-paced world, sanitizers and disinfectants are indeed miracle cleaning products. We no longer have the time or resources to manually or even machine scrub surfaces with the goal of ensuring they are hygienically clean.

With the proper use of these products, we can rest assured our kitchens and food service locations are preventing the spread of foodborne illnesses—protecting the health of all who enjoy our food products. ■

Watt is head of training and new product development at Avmor. Reach him at mwatt@avmor.com.

Outsmarting Food Pathogens *(Continued from p. 13)*

“We can blame it on all sorts of things, but there’s no denying that the industry could, and can, do better.”

Tracing is only one area where technology can enhance food safety. “We’ll also be looking at how to leverage emerging technologies and other approaches that are being used in society and business sectors all around us, such as distributed ledgers, sensors, the Internet of Things, and artificial intelligence,” explained Dr. Sharpless

and Yiannas—who before joining FDA last December had overseen the implementation of blockchain technology at Walmart.

“There’s a lot industry and government—whether it’s the states or the federal government—can do to advance food safety,” they added. “Tackling food safety is a shared responsibility, and there’s much more we can do together and in a manner that benefits people, food companies, and the planet.”

Dr. Acheson agrees. “We have to find a way to move faster in these types of outbreaks,” he says, “and that will require a commitment and resources from the government at the state and federal levels, likely new regulations, and, of course, industry at all levels—including retail and food service—using the technology that is already available.” ■

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Juicy Details *(Continued from p. 15)*

transportation practices to ensure the safety of the food they transport.”

“The JPA Tanker Wash Guidelines assist with this mandate by detailing cleaning procedures, training practices, documentation, and security measures for the bulk transport of juice products,” Faison says.

In an effort to provide a standard method for auditing tanker wash facilities, members of the FCPA developed a program for implementation using the JPA Tanker Wash Guidelines, Faison says. “The audit program subsequently transitioned to the JPA, which administers the program and maintains the JPA Tanker Wash website, a resource for the juice transportation industry,” she points out.

Key elements of this voluntary audit program are the standardized audit form, standardized audit protocols, a list of participating audit firms, and a list of successfully audited washing facilities.

“Currently there are 45 tanker wash facilities that participate in the audit program, located in the U.S., Canada, and Mexico,” Faison says, adding that tanker wash facilities that participate in the audit program are not required to be members of JPA.

“The use of the audit firms and standardized audits minimizes audit redundancy by multiple juice and beverage companies,” Faison relates. “Moreover, we believe standardized protocols for washing tankers and wash facility auditing,

coupled with voluntary industry compliance with these programs, are keys for our members to meet regulatory requirements for safe juice and beverage transportation. These programs are identified by both state and federal regulatory agencies as effective mechanisms that provide the necessary oversight for monitoring safe liquid foods transportation.” ■

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For bonus content on the juice industry, go to the June/July 2019 issue at www.FoodQualityandSafety.com/issue/june-july-2019/.

Strict Criminal Liability *(Continued from p. 17)*

Congress, the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors.

The Supreme Court denied the DeCosters’ petition for review, thus closing any possibility of the RCOD being declared unconstitutional.

Where Do We Go from Here?

Over the last 20 years, food science, microbiology, forensic epidemiology, and information technology have vastly improved

our understanding of food safety. As food-borne illness surveillance and traceability continue to improve, the food industry will likely face ever-increasing regulatory scrutiny. With it, there may come a corresponding increase in the number of RCOD prosecutions.

Unfortunately, no amount of effort or diligence can guarantee perfection every time; some things are simply beyond control. When it comes to the RCOD, the best defense is a good offense, as the adage goes. While knowledge and intent may

be immaterial in terms of the law, they are very material to the investigators responsible for making charging decisions. In turn, the companies and executives who exercise the highest standard of care are not only less likely to violate the FD&C Act, they are also less likely to be targeted for prosecution. ■

Stevens, a food industry attorney, is a founding member of Food Industry Counsel, LLC. Reach him at stevens@foodindustrycounsel.com. **Chappelle** is also a food industry lawyer and consultant at the same organization. Reach him at chappelle@foodindustrycounsel.com.

NEW PRODUCTS



Quality Testing in Craft Brewing

The Thermo Scientific BeerCraft software package for the GENESYS 50 and GENESYS 150 UV-Vis Spectrophotometers is designed to streamline quality assurance testing and to achieve batch-to-batch consistency. Together, Thermo Scientific BeerCraft software and GENESYS UV-Vis Spectrophotometers reduce the dependency on sensory testing and can provide American Society of Brewing chemist-quality testing methods for more than 20 beer attributes, including color, bitterness, protein, sugar, carbohydrate, polyphenol levels, and more. BeerCraft software is configurable for use with reagents and chemistries from many vendors. **Thermo Fisher Scientific Inc.**, 866-356-0354, www.thermofisher.com.

Hand Towels and Bathroom Tissue

The Latte Collection, available within the Cascades PRO Select and Cascades PRO Perform collections of paper towels, toilet paper, and facial tissue, is manufactured from a combination of white recycled fiber and cardboard. According to the company, the white recycled fibers and cardboard deliver an end result that is equivalent to white products in terms of quality and is also eco-friendly. The company's paper towel and toilet paper offerings undergo the stringent requirements needed to ensure a Green-e, Green Seal, and UL/Ecologo-certified end product. **Cascades Inc.**, 800-246-0711, www.pro.cascades.com.



Truck Refrigeration Unit

The Supra S6 new-generation truck refrigeration unit is designed for small- to medium-size trucks. APX control technology incorporated into the Supra platform provides intelligent performance optimization, automatic trip data recording, and enhanced system diagnostics. Drivers can conveniently tap into the APX system's functionality through the dash-mounted Cab Command control interface with a backlit LCD display that provides at-a-glance operating information. The Supra S6 unit integrates with Carrier Transcold's eSolutions telematics offering, enabling remote monitoring and control of the refrigeration system as well as GPS location data and geofencing. A streamlined internal architecture for key components, including the diesel engine and compressor, results in a more logical configuration that uses less re-



frigerant and fewer parts. **Carrier Transcold**, 800-227-7437, www.transcold.carrier.com.

In Other News

Originally released in 2017, **Best Sanitizers'** Alpet D2 Quat-Free Surface Sanitizer is now approved under the Washington State Department of Agriculture Organic Food Program for hard, non-porous surfaces.

Hygiena's (a Warburg Pincus portfolio company) GlutenTox Pro test for detecting gluten receives a renewal and transfer of its AOAC Research Institute certification, certifying that it performs according to Hygiena's specifications.

MilliporeSigma's Milli-Q CLX 7000 clinical water purification systems now offer a cloud-based, remote lab water service and monitoring capability.

3M Food Safety's Molecular Detection Assay 2—*Salmonella* earns matrix extensions from AFNOR Certification for its NF VALIDATION and is now certified for samples taken from primary production as well as from animal feed and pet food.

InfinityQS updates its native-cloud Quality Intelligence platform Enact with new features, including Workflows, which notify plant personnel of process/quality events and provide guidance on how to resolve them.

Ashton Potter enhances its ProLinc traceability technology with targeted product recall management functionality that mitigates recalls before they occur by identifying anomalous practices in harvesting, processing, manufacturing, and distribution.

Kadant Solutions obtains HACCP International certification so certain blades and blade holders for use in food manufacturing processes now carry the HACCP International certification mark.

Bacharach adds 22 halogen refrigerants for its MGS-400 gas detectors in commercial and industrial gas leak monitoring applications.

(Continued on p. 48)

(Continued from p. 47)



Real-Time Reporting and Notification Platform

PSSI's real-time performance metrics platform enables its sanitation teams to proactively track and respond to critical data that can impact the overall effectiveness of a sanitization process. Data that was previously recorded with a pen and paper on a clipboard as part of a nightly sanitation log post-cleaning is now logged digitally into an application on a tablet or mobile device in real time during the sanitation process. Data is monitored closely by PSSI site managers and can easily be shared or accessed by other key stakeholders to perform analytics and make real-time adjustments to the sanitation process. The system can also send alerts and notifications regarding changes or updates that need to be made. The PSSI team focuses on documenting several key factors, including time, water temperature, titration (concentration of cleaning agents), and mechanical force (i.e., water pressure). PSSI, 888-871-6335, contact@pssi.com, www.pssi.com.

No Rinse Disinfecting Wipes

Dreumex Food Contact Surface Disinfecting Wipes help destroy norovirus, *E. coli* O157: H7, and *Shigella dysenteriae*, along with other foodborne pathogens and viruses (10 pathogens, three viruses total). The no rinse formula allows surfaces to be wiped and left to air dry, unlike other surface disinfectants that require a potable rinse before use. No pre-cleaning and rinsing is necessary prior to use as required with food contact surface sanitizing wipes. Food establishments, convenience stores, schools, grocery stores, and other facilities can easily implement wipes into workers' daily routines to provide a safer environment. Dreumex USA, Inc., 800-233-9382, dreumex@dreumex.com, www.dreumex.com.

Meat and Olive NIR Analyzer

The DA 6200 NIR analyzer is based on next generation Diode Array Near-Infrared Transmission Spectroscopy technology, which in 30 seconds can provide accurate test results of fat, moisture, and protein levels in a sample—as well as collagen, salt, and ash. This accuracy and speed also translate to very large, inhomogeneous samples. According to the company, producers of sausage, ground meat, or poultry products are able to get the highest yield from the incoming unprocessed meat. And olive oil producers can verify olive quality, predict the potential yield of oil, and optimize the oil extraction process. The compact analyzer features a battery power option and has an intuitive touchpad screen to help technicians and scientists generate clear, easy-to-read results. It is also equipped with customized meat and olive product calibrations designed to work across a range of product types, eliminating the need for onsite collaboration development. PerkinElmer, Inc., 877-754-6973, www.perkinelmer.com.

UV Disinfection Unit for Food Packaging

The BlueLight Hygienic System is a modular, UVC ultraviolet disinfection unit that offers processors surface disinfection of food packaging and up to 90% energy savings compared to traditional UV disinfection systems, according to the company. This easy-to-clean system can ensure food processing safety (DIN ISO14159/EN 1672-2 and IP66). Processors can obtain reliably longer shelf life and reduced product recall risks. The system delivers 3-log reduction of most reference germs in the food industry (*Aspergillus brasiliensis*, bacteria, yeast, and mold spores). Integration into existing and new FFS packaging machines and lines for the treatment of packaging surfaces such as caps, preform necks, closures, cups and lids, trays, sealing foil, and flexible films is convenient due to the system's modular and compact design. It is Industry 4.0 ready with a touch display that enables automated control and monitoring. The system does not use chemicals or water. Heraeus Noblelight, 301-527-2660, www.heraeus-noblelight.com.

Forward Osmosis-Based for Heatless Product Concentration

TIDAL Forward Osmosis (FO) technology utilizes osmosis—a natural process that allows concentration of food, dairy, and beverage products without exposure to heat, thereby preserving their intrinsic properties. According to the company, while heat exposure during traditional thermal evaporation can compromise the essential properties of high-value products, TIDAL FO systems can preserve product quality. These automatically controlled systems process food and beverage streams from 3-50 gpm (1-10 m³/hr.) and are easily scalable to larger flow rates. Additionally, the company offers potential users lab and pilot scale units for feasibility tests and demonstrations. Koch Membrane Systems, 888-677-5624, www.kochmembrane.com.



All-in-One Cleaning Spray for Food Service

The all-in-one spray replaces the use of different cleaning, sanitizing, and disinfecting products. It is specially formulated to clean multiple hard non-porous surfaces, sanitize food contact surfaces, and disinfect commonly touched surfaces. The spray is a non-bleach formula that is effective against norovirus, making it ideal for use in food service environments—no rinsing required. It is effective against most common foodborne pathogens, including *Listeria monocytogenes*, *Staphylococcus aureus*, *Escherichia coli*, and *Shigella boydii*. With no mixing or measuring necessary, the company says the spray allows users to complete cleaning procedures in an efficient manner, saving time while increasing effectiveness in preventing cross-contamination. Sani Professional, 866-673-4376, www.saniprofessional.com.

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Events



JULY

21-24

IAFP

Louisville, KY.

Visit <http://www.foodprotection.org/annualmeeting/>, email info@foodprotection.org, or call 800-369-6337.

23

Microbiology and Food Safety Course

Fresno, Calif.

Visit <http://fsns.com/services/educationmicrobiology-and-food-safety-course>.

AUGUST

19-23

Introduction to Food Science Course

New Brunswick, N.J.

Visit <http://www.cpe.rutgers.edu/courses/current/lf0201ca.html>, email ocpe@njaes.rutgers.edu, or call 848-932-9271.

21-22

FSAI Science Conference 2019: The Science of Food Safety - What's our Future?

Dublin, Ireland

Visit <http://foodsafety2019.com/>.

27-29

Preventive Controls for Human Foods Certification

University Park, Penn.

Visit <https://extension.psu.edu/preventive-controls-for-human-foods-certification>.

SEPTEMBER

8-11

AOAC Annual Meeting & Expo

Denver, Colo.

Visit www.aoac.org, email AOAC@aoac.org, or call 800-379-2622.

23-25

Pack Expo

Las Vegas

Visit <https://www.packexpolasvegas.com/>.

OCTOBER

8-11

PROCESS EXPO

Chicago, Ill.

Visit www.myprocessexpo.com or call 703-663-1212.

15-16

Dairy Plant Food Safety Workshop

Minneapolis, Minn.

Visit <https://www.idfa.org/events/dpfs#Minneapolis>, email registrar@idfa.org, or call 202-737-4332.

15-17

Food Safety and Sanitation for Food Manufacturers Short Course

University Park, Pa.

Visit <http://agsci.psu.edu/sanitation> or call 877-778-2937.

17-18

2nd International Conference on Food Safety and Health

Abu Dhabi, UAE

Visit <https://foodsafety.nutritionalconference.com/>

30-31

China International Food Safety & Quality Conference

Beijing City, China

Visit www.chinafoodsafety.com.

NOVEMBER

6-8

Dairy Practices Council Annual Conference

Portland, Maine

Visit www.dairypc.org/dpc-conferences or email dairypc@dairypc.org.

13-14

Sensory Evaluation

New Brunswick, N.J.

Visit <http://www.cpe.rutgers.edu/courses/current/lf0606ca.html> or call 848-932-9271.

15

Statistics for Food Scientists

New Brunswick, N.J.

Visit <http://www.cpe.rutgers.edu/courses/current/lf0607ca.html> or call 848-932-9271.

JANUARY

28-30

International Production & Processing Expo

Atlanta, Ga.

Visit <http://ippexpo.com/>, email info@ippexpo.org, or call 770-493-9401.

FEBRUARY

25-28

GFSI Conference

Seattle, Wash.

Visit <https://www.theconsumergoodsforum.com/events/gfsi-conference>.

MARCH

1-5

Pittcon

Chicago

Visit <https://pittcon.org/pittcon-2020> or email expo@pittcon.org.

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SCIENTIFIC FINDINGS

For access to complete journal articles mentioned below, go to “Food Science Research” in the June/July 2019 issue at www.foodqualityandsafety.com/issue/june-july-2019, or type the headline of requested article in the website’s search box.



ARTICLE: [Extracellular Protease AprX from *Pseudomonas* and its Spoilage Potential for UHT Milk](#)

The negative effects of proteases produced by psychrotrophic bacteria on dairy products, especially ultra-high-temperature (UHT) milk, are gaining attention worldwide. These proteases are especially problematic because it is difficult to control psychrotrophic bacteria during cold storage and to inactivate their heat-resistant proteases during dairy processing. The predominant psychrotrophic species with spoilage potential in raw milk, *Pseudomonas*, can produce a thermostable extracellular protease, AprX. A comprehensive understanding of AprX on the aspects of its biological properties, regulation, proteolytic potential, and its impact on UHT milk can contribute to finding approaches to minimize, detect, and inactivate AprX. The progress of current research on AprX is summarized in this review. Reducing the production and activity of AprX has potential for alleviating the problems from the instability of UHT milk during shelf life. **Comprehensive Reviews in Food Science and Food Safety, Early View, First published May, 10 2019.**

ARTICLE: [Impact of Postharvest Operations on Rice Grain Quality](#)

Postharvest operations, such as drying, storage, and milling, have been used to ameliorate the aging of rice grains and to maintain desirable rice grain quality, and thus play a key role in determining rice commercial value. Rice drying mainly affects milling quality as kernel fissuring that may occur during drying leads to head rice yield reduction. Rice grain aging occurring during storage is inevitable and responsible for the changes in appearance, milling, eating, cooking, and nutritional quality. As milling significantly changes the chemical composition of rice by removing protein- and lipid-rich bran layers, milling can alter the aging process of rice and also affect appearance, eating, and sensory quality, but mainly affects the nutritional quality. Therefore, drying methods, storage conditions, and milling methods warrant further research to achieve desired rice grain quality. This review contributes to better understanding of the impacts of postharvest processes on rice grain quality, and provides insights into potential improvements in these practices for rice production and utilization in the whole rice industry. **Comprehensive Reviews in Food Science and Food Safety, Volume 18, Issue 3, May 2019, Pages 626-640.**

ARTICLE: [Efficacy of Food Safety Training in Commercial Food Service](#)

Proper food safety training is essential to decrease incidences and overall rates of foodborne illnesses and outbreaks. Though many commercial restaurants should provide proper food safety training to food handler employees, this training is not always offered or effective. This article summarizes the results of a primary literature study concerning the effectiveness of food safety training in commercial settings. The literature chosen for review contained only studies with experimental food safety training, with before and after training data. Through evaluation of these studies, the best practice for ensuring effective training and follow-through were the use of food safety training programs, which incorporated both knowledge and behavior-based training. **Journal of Food Science, Early View, First published May 8, 2019.**



ARTICLE: [Thermal Resistance of *Listeria monocytogenes* and Background Microbiota in Liquid Egg Yolk](#)

Listeria monocytogenes is a major foodborne pathogen that may contaminate liquid egg yolk (LEY). A background microbiota, purified and identified as *Enterococcus faecium* with a 99.0% probability, was found in pasteurized unsalted LEY. This study was conducted to investigate the thermal resistance of *L. monocytogenes* and the background microbiota in unsalted and 10% salted LEY at temperatures between 55 and 67.5°C. Both Weibull model and linear survival model were used to analyze the survival curves. The results of this study may be used to design adequate heating conditions to inactivate *L. monocytogenes* and *E. faecium* in LEY. **Journal of Food Safety, Early View, First published May 22, 2019.**

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