

PLUS A Single Food Agency ■ New Efforts Against *Listeria* ■ How to Use Environmental Monitoring Data

Volume 25 Number 4
AUGUST/SEPTEMBER 2018

Food Quality & Safety

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From The Editors

The food industry has one specific mandate from government: to produce safe food. This is further emphasized with FSMA and the regulations passed to enforce it. To help ensure the safety of food and that occasional slips are properly contained, the FDA implemented programs to (hopefully) prevent outbreaks from expanding and affecting more people. For example, the Reportable Food Registry mandates that processors of foods/ingredients notify customers within 24 hours if they have issues. The FDA guidance states, "...to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals."



FDA also created a group called CORE, or the Coordinated Outbreak Response and Evaluation Network. This operation is made up of a Signals and Surveillance Team, three Response Teams, and a Post Response Team. It's the responsibility of the Response Teams to stop the outbreak.



But what about quality? Quality is what sells products. It is why people continue to purchase one brand or one item. Not only do processors have to ensure safety, their quality programs must also continue to maintain the quality parameters that make consumers happy. Years ago, one of my professors told the story of "Creeping Meatballism." The allegorical story describes how someone brought meatballs to a company potluck. They were so good that the company decided to produce the product. Sales went through the roof, but then R&D and marketing said even though the product was successful, it was a bit expensive to make. So, they embarked on a cost reduction program. Over the years, the product was cost reduced by comparing the new version to the previous iteration of the product. Within a few years, the new version had no relationship to the original gold standard, but there was no statistical difference between the evolving versions. Bottom line is, the product died.

As an industry we must produce safe foods. Failure to do so can damage a company (Chipotle and Peter Pan Peanut Butter) or shut down a business (Peanut Corp. of America, Sunland, and Bon Vivant). But we must ensure food quality remains high and meets consumer expectation. The food industry relies on repeat sales so it must retain customers by meeting their needs.

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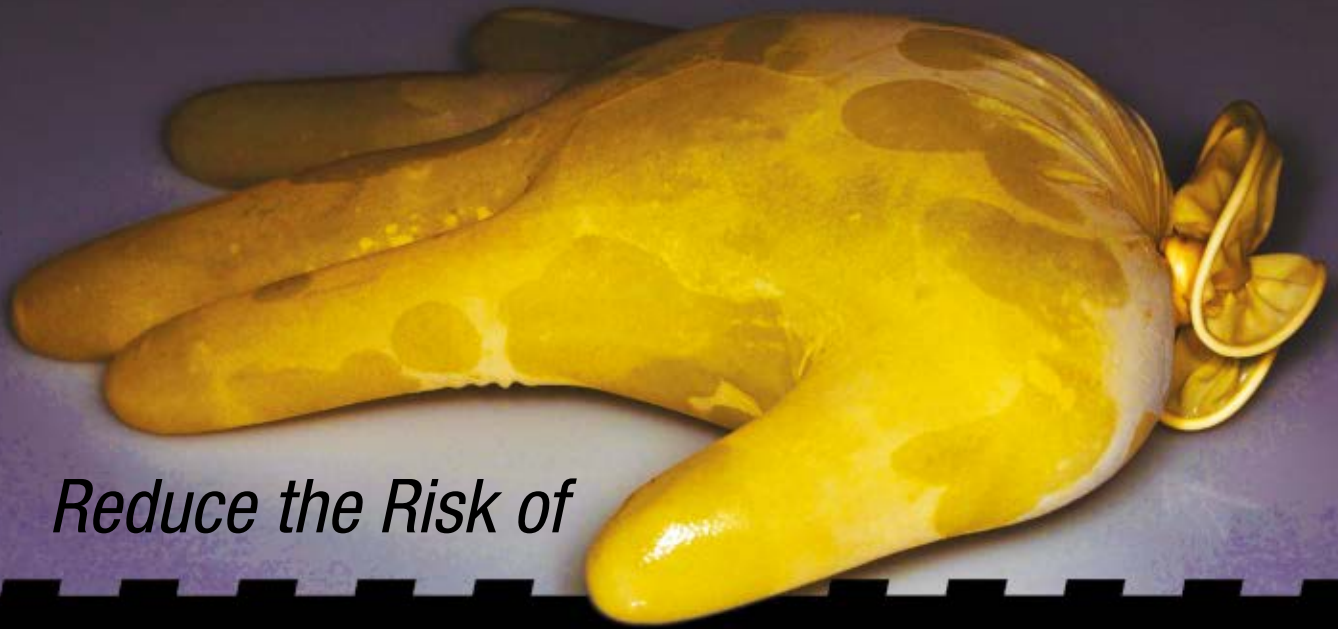
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NEWS & NOTES

FDA Updates

The U.S. FDA releases its Small Entity Compliance Guide (SECG) to help smaller food facilities meet their registration requirements under the FD&C Act. The FD&C Act requires food facilities engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the U.S. to register with the FDA. The SECG explains what kinds of facilities must register, when, and how while also explaining the consequences to those who fail to register, when FDA can suspend a facility's registration, and the impact of a suspension order on a facility. The SECG is in accordance with the Small Business Regulatory Enforcement Fairness Act.

FDA also launches the new Substances Added to Food inventory, an upgraded version of the original Everything Added to Food in the U. S. inventory. The new inventory includes 4,000 substances while providing information on food and color additives and prior-sanctioned substances. Other new features include a search function tool that allows users to find out food ingredients and packaging inventories, direct links to applicable regulations for specific substances, and additional information such as other known names, common uses, and information by other entities when available. It's important to note that this inventory is only a partial list of food ingredients and the inventory of information from non-FDA entities does not include an FDA approval or evaluation of the usage.

In addition, FDA's new Export Listing Module (ELM) is an electronic portal for getting and processing requests from establishments that seek to be included on all export lists for FDA-regulated food products. For certain exported food products, some foreign food safety authorities require FDA to provide publicly available lists of exporters eligible to ship products to that country. This expanded module improves FDA's ability to efficiently process establishments' requests to be added to the lists, monitor listed companies, and generate updates for foreign regulatory agencies.



Forbes Chocolate Named Winner of 2018 Food Quality & Safety Award

Food Quality & Safety magazine honors Ohio-based Forbes Chocolate, a provider of cocoa and flavor powders, with the 17th annual Award. This prestigious honor recognizes the dedication and achievement of an organization that has made significant improvements in its safety and quality assurance programs. The company places great emphasis on using new technologies, updating equipment, and instilling ongoing employee training to stay at the forefront of manufacturing. Its SQF certification also underscores the company's development and implementation of strong food safety and quality management systems. For the complete story behind the success of Forbes Chocolate, read the in-depth profile scheduled to appear in the October/November 2018 issue.

Fighting Antimicrobial Resistance

Based off a new report from the FAO, OIE, and WHO, countries are stepping up to help tackle antimicrobial resistance (AMR). The report charts progress in 154 countries, but reveals some discrepancies. While some European nations have been working on AMR policies for humans and animal sectors for over 40 years, others have only recently taken action to contain this growing threat. Progress in developing and implementing plans is greater in high-income than low-income countries but all countries have scope for improvement. No place has sustained capacity in all areas. The report looks at surveillance, education, monitoring, and regulating consumption and use of antimicrobials. The most promising findings are in 105 countries that have surveillance systems to report drug-resistant infections, and 68 countries with systems to detect consumption of antimicrobials. The report also highlights the animal and food sectors, where there is an urgent need for more investment and action. For example, only 64 countries follow FAO-OIE-WHO recommendations to limit the use of critically important antimicrobials for growth promotion in animal production.

Business Briefs

Agri-Neo and Red River Commodities announce their partnership to use Agri-Neo's food safety solution, Neo-Pure, to treat seeds and grains.

USDA FSIS awards 3M Food Safety a contract for pathogen detection instruments and kits to detect *Salmonella*, *Listeria*, and *E. coli*.

Halter secures financing from **Airbnb**, **Facebook**, **Planet**, **SpaceX**, **Spotify**, and **Rocket Lab** to commercialize the company's AI-powered "point and click" application in combination with proprietary "Cowgorithm," letting farmers manage livestock globally.

Bio-Rad Laboratories signs a co-marketing agreement with Bruker to bring foodborne pathogen detection and con-

firmation workflow solutions to the food safety industry.

Bosch plans to look for a buyer for its pharmaceuticals and food units of the Packaging Technology division.

Hypred, **Anti-Germ**, **Medentech**, **LCB Food Safety**, and **G3** adopt a custom name, **Kersia**, and a common banner for a shared mission: inventing a food safe world.

Sealed Air enters into an agreement with **Kuraray America** to offer food packaging materials derived from its Plantic bio-based resins.

Q Laboratories opens a new 30,000-sq.-ft. laboratory facility in Cincinnati, Ohio.



FPSA Creates New Pet Food Council

The Food Processing Suppliers Association (FPSA) creates a new Pet Food Council, joining the Association's existing five industry Councils including Bakery, Beverage, Dairy, Meat, and Prepared Foods. FPSA Councils form the backbone of the Association with each group having representation on the Board of Directors and helping to guide all programs so that they are relevant for all major industry segments. The Pet Food Council, the first new Council in the last 12 years, will meet over the coming months with the objective of electing their leadership and deciding what they want to achieve.

A New AFDO and Industry Vision

The AFDO 122nd Annual Education Conference recently wrapped up in South Burlington, Vt., serving as a springboard for a new initiative, creating change through a shared vision with food industry representatives. The "Partners with a Common Purpose" initiative recognizes a common purpose embraced and supported by both government regulators and industry alike in improving public health and consumer services. The concept of "Partners with a Common Purpose" extends beyond individual stakeholder interests; rather, it aims to drive successful collaboration and innovation by establishing equal partnership at meetings and forums to allow greater input toward continuously improving the safety of the food supply and public health. To become involved or learn more, provide contact information via the registration link: <https://www.surveymonkey.com/r/J7P63LN>.



France Needs 'Food Safety Police' to Avoid New Lactalis Crisis

As reported by Reuters, lawmakers in France say the country should appoint a "food safety police" and increase fines on those who sell contaminated products to avoid a repeat of the *Salmonella* outbreak at a Lactalis milk factory last year that led to dozens of babies falling ill. Lactalis, the world's largest dairy group, had to recall more than 12 million tins of baby milk in France and around the world due to the outbreak. France's National Assembly launched a special inquiry into the scandal. In their findings, lawmakers recommended tougher judicial and financial sanctions against food makers. "Those who do not play by the rules must suffer the consequences: criminal and financial sanctions that will be much more important than the current ones," said Gregory Besson-Moreau, head of the committee. He also suggested imposing a fee on food producers to finance state-run inspections, something that has been allowed by the EU. This could raise 270 million euros per year, and lead to the creation of 800 jobs in a new "food safety police" reporting to the farm minister.

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Washington Report



Revisiting the Single Food Agency

Trump's turn to consolidate federal food safety activities to keep agencies from cracking under pressure

BY TED AGRES

Following in a long and thus far futile tradition of attempting to consolidate the federal government's disparate food safety activities, the Trump administration in late June proposed merging the functions of FDA with USDA's Food Safety and Inspection Service (FSIS). The resulting new Federal Food Safety Agency would be housed within USDA and, unlike the present bifurcated system, would have oversight over virtually all the foods that Americans eat.

Calling the present system "illogical and fragmented," the Trump administration argues that consolidating FSIS and the food safety functions of FDA "would allow for a better allocation of resources based on risk, better communication during illness outbreaks, and improved policy and program planning through development of a single strategic plan."

The new Federal Food Safety Agency would serve as the central point for coordinating with state and local food safety stakeholders, thereby "rationalizing the simplifying the federal food safety regulatory regime," according to the reorganization plan, one of more than 30 different government reform proposals

included in the "Delivering Government Solutions in the 21st Century" report, issued June 22, 2018.

The report represents findings of the Office of Management and Budget (OMB), which was tasked by President Trump in March 2017 to produce a comprehensive plan to reform and reorganize the government "to better meet the needs of the American people."

"This reorganization plan is intended to balance the mission, service, and stewardship responsibilities of the executive branch, while reducing inefficiency, risk, and duplication," Margaret Weichert, OMB deputy director, told the House Oversight and Government Reform Committee in June. The proposals, she explained, came from the agencies themselves, from federal employees, academics, and interest groups, and included more than 106,000 comments from members of the public.

"A transformation of this size will take time and teamwork to implement," Weichert noted. While some changes can be made directly by the federal agencies involved, other "more complex proposals" will require action by the president or Congress, she said. The proposals span a

wide range, from "reorganizing statistical agencies" and "restructuring the postal service," to "reforming the federal role in mortgage refinancing."

Fragmented Food Safety

The OMB report notes the Government Accountability Office (GAO), the investigative arm of Congress, has been urging reform of the nation's fragmented food safety oversight system for more than 40 years. According to GAO, food safety efforts are currently performed by an inefficient patchwork of 16 separate federal government agencies, led by FDA and FSIS, which together administer at least 30 different laws relating to food safety and specific food commodities.

Adding to the overall complexity, the federal system is supplemented by more than 3,000 states, localities, tribes and territories, many of which have their own laws and agencies to inspect facilities and investigate and contain illness outbreaks.

GAO, in its most recent report on the subject (January 2017), highlighted some confounding examples: FSIS inspects manufacturers of packaged open-face meat or poultry sandwiches (those made with one slice of bread) while FDA inspects manufacturers of packaged closed-face meat or poultry sandwiches (those made with two slices of bread).

And consider pizza, the poster child for *what's wrong with this system*: FDA has primary responsibility for regulating manufactured frozen pizzas made with cheese, but FSIS has primary responsibility for those made with meat or pepperoni. Multiple other federal agencies play roles in regulating other components of both types of pizza.

Creating a new, separate food safety agency "would reduce duplication of inspection at some food processing facilities, improve outreach to consumers and industry, and achieve savings over time while ensuring robust and coordinated food safety oversight," the OMB report says. FDA, which would be stripped of

most of its food responsibilities, would be renamed the Federal Drug Administration, and focus on drugs, devices, biologics, tobacco, dietary supplements, and cosmetics.

(Only days after release of the OMB's proposed reorganization, FDA Commissioner Scott Gottlieb, MD, posted an update about *E. coli* in romaine lettuce, which concluded: "Our food safety program at the FDA has never been stronger, and we seek to strengthen it further still... Our agency has a long history of focusing on public health protection through our food safety efforts. Food safety is part of a culture of public health that's integral to our agency.")

The OMB report says USDA is "well-poised" to house the new Federal Food Safety Agency. The agency is a "strong leader in food safety, having a thorough understanding of food safety risks and issues all along the farm to fork continuum." The Agricultural Research Service (ARS) spends about \$112 million annually on in-house food safety research, and ARS scientists work with both FSIS and FDA to help develop research priorities and food safety practices.

USDA also has established relationships between state departments of agriculture, local farms, and processing facilities, "and is thus keenly aware of food safety issues at all levels," the report adds.

The proposed consolidation would merge approximately 5,000 full-time equivalent (FTE) employees and \$1.3 billion from FDA with about 9,200 FTEs and \$1 billion in resources in USDA. "In the long term, the administration expects this proposal would result in improvements in food safety outcomes, policy and program consistency, and more efficient use of taxpayer resources," the report says.

History of Reform Proposals

In 2007, GAO added federal oversight of food safety to its list of government areas "at high risk for fraud, waste, abuse, and mismanagement, or most in need of transformation." In addition to GAO's recommendations, consolidation proposals have been raised over the years through reports by the National Academy of Sciences and other organizations.

These groups "have recommended that the core federal food safety respon-

sibilities should reside in a single entity or agency, with a unified administrative structure, clear mandate, a dedicated budget, and full responsibility for the oversight of the entire U.S. food supply," the OMB report says.

Not mentioned in the OMB report is the Obama administration's proposal in 2015 to remove food safety-related components from both FDA and FSIS and consolidate them into a single new agency that would remain within the Department of Health and Human Services (HHS), which also houses FDA, CDC, and other public health agencies. (USDA is an independent agency and not part of HHS.) At that time, the proposed agency would have had primary responsibility for food safety inspections, enforcement, applied research, and outbreak response and mitigation.

Nor does the OMB report mention congressional legislation that would have created a single food safety agency. These, like other similar proposals, have gone nowhere. While the single agency concept makes theoretical sense, there has been a notable reluctance on the part of federal officials and others to do much about it.

There are at least three reasons for this, says Timothy D. Lytton, PhD, a law professor at Georgia State University. First, he says, there are many Congressional committees that currently oversee federal agencies that regulate food safety, and they are unlikely to support any reorganization that would reduce their power. Second, industry associations are unlikely to support reorganization because "consolidation threatens to reduce their access and influence over agency decisions." Third, meaningful consolidation "would require a complete overhaul of federal food safety laws and regulations, a task of extraordinary legal and political complexity," Dr. Lytton said in a recent analysis.

Perhaps recognizing such challenges, the most recent GAO recommendations focus on developing a national strategy for food safety oversight, which in turn, could lead to a consensus on how to proceed.

Indeed, such a change would require considerable time and effort, explains Jonathan Havens, vice chair of the food and beverage practice at Saul Ewing Arnstein & Lehr and former regulatory counsel at FDA. "Merging the food safety functions of FDA and USDA would require Congressional

action and reconciliation of regulatory approaches, which the administration acknowledged in its proposal," Havens says.

"To be sure, several previous single food safety agency legislative proposals have been unsuccessful. However, given the uptick in foodborne illnesses and recalls in recent years, perhaps Congress will view President Trump's proposal more favorably than it did President Obama's plan," Havens told Food Quality & Safety magazine. But he emphasized that he was not forecasting any particular outcome.

Bolstering Collaboration

But interagency cooperation is not at a standstill. FDA and USDA in January issued a formal agreement, in which the agencies pledged to "bolster coordination and collaboration" to streamline regulations and reduce inspection inefficiencies, particularly when both agencies have jurisdiction over a food producer, such as a canned soup facility or pizza manufacturer.

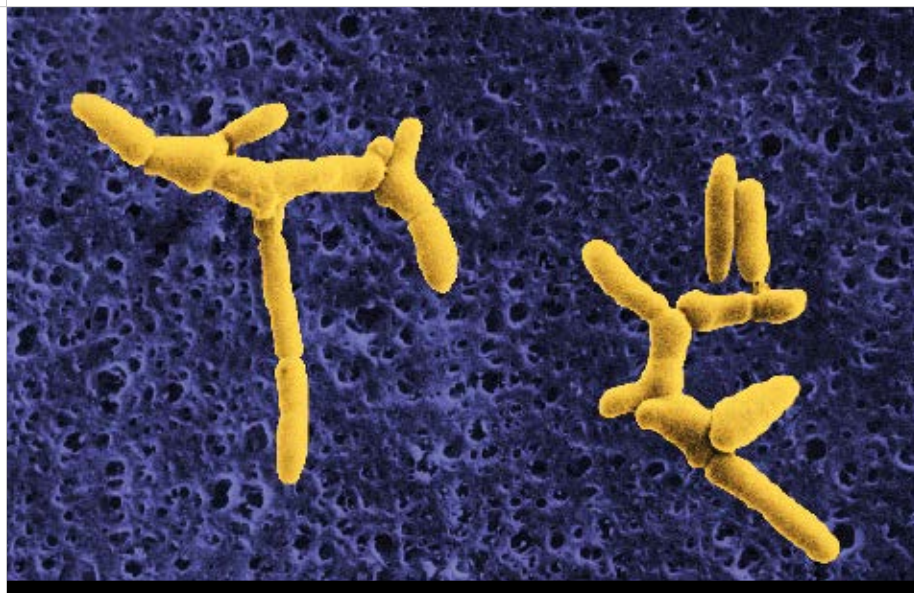
More substantively, in June the agencies announced a collaborative effort to streamline produce safety requirements for farmers by aligning USDA's Harmonized Good Agricultural Practices Audit Program with the requirements of FDA's FSMA Produce Safety Rule. The goal is to ensure a better understanding of and compliance with safety standards by produce farmers, and avoid duplication of inspection efforts.

"I have been an advocate for a single food safety agency for years," says David Acheson, MD, former FDA associate commissioner for foods and founder of The Acheson Group. "The challenges and inefficiencies of having two separate departments overseeing food in the U.S. and the need to streamline the regulations of FDA and USDA are topics that tend to come up in discussion every time a major rule or standard is introduced," he says.

"And with the recent announcement from the agencies, it's likely to arise again," Dr. Acheson continues, "but this time it is the regulatory bodies themselves which have taken positive action to streamline requirements," he says, referring to the interagency produce safety agreement. ■

Agres is an award-winning writer based in Laurel, Md. Reach him at tedagres@yahoo.com.

Pathogen Patrol



Leaning on *Listeria*

New efforts are striving to minimize the impacts of this relentless lurker

BY LINDA L. LEAKE, MS

“It’s the worst documented listeriosis outbreak in global history.” So says microbiologist Lucia Anelich, PhD, principal of Anelich Consulting, Pretoria, South Africa, of the devastating public health crisis that has tallied a mindboggling 1,056 cases and 214 deaths as of July 4, 2018.

According to the South Africa Department of Health, the source of the outbreak that began in January 2017 has been identified as a bologna-like sausage known as polony. The implicated product containing the outbreak strain was traced to Enterprise Foods in Polokwane. Enterprise demonstrated the presence of the ST6 strain in its facilities, according to the South African National Institute for Communicable Diseases.

Not surprisingly, massive recalls have been conducted across the country and in neighboring countries that imported those products from South Africa. “An

estimated 4,000 tons of food has been recalled,” Dr. Anelich relates. “The recall has included not just polony, but also many other products produced by Enterprise, as a precaution.”

Unbelievably, babies are the population group most dramatically impacted by the polony listeriosis tragedy. Some 92 babies have died in South Africa as a result of the outbreak.

“Obviously, babies are not eating polony,” Dr. Anelich relates. “The transmission of *Listeria monocytogenes* occurs when a pregnant woman eats the contaminated food and transmits the organism via her placenta to the unborn baby. This may result in miscarriage, stillbirth, or preterm delivery. Another potential outcome may be delivery on time, but then the baby could be born with meningitis, pneumonia, or septicemia, from which they may succumb.”

The pregnant mother is often not seriously affected, Dr. Anelich notes. “The

mother may only show flu-like symptoms and may never even know that she was infected with the pathogen if she did not seek medical attention,” she points out.

The World Health Organization (WHO) is calling the incident in South Africa the largest *Listeria* outbreak that has ever been detected and is offering assistance in diagnosing and monitoring the organism to any impacted governments as needs arise.

“This *Listeria* outbreak has been the crisis that made South Africa, and possibly the whole of Africa, realize the importance of food safety and foodborne diseases and the need to invest in improving the control of them,” says Peter Ben Embarek, PhD, WHO’s global food safety specialist. “South Africa has embarked on a deep reform of its food safety system including strengthening of its regulations, standards, and food inspection activities.”

U.S. Stats

An estimated 1,600 people get listeriosis in the U.S. each year from *L. monocytogenes*, resulting in some 1,500 hospitalizations and about 260 deaths, according to the CDC.

In 2017, 158 cases associated with *Listeria* were reported to CDC.

Along with pregnant women and their newborns, listeriosis is most likely to impact adults aged 65 or older and people with weakened immune systems.

According to FoodSafety.gov, foods particularly susceptible to *Listeria* contamination include ready-to-eat deli meats and hot dogs; refrigerated pâtés and meat spreads; unpasteurized (raw) milk and dairy products; soft cheese made with unpasteurized milk, such as queso fresco, feta, brie, and camembert; refrigerated smoked seafood; and raw sprouts.

Minimizing Virulence

Researchers at North Carolina State University (NCSU), Raleigh, have completed a proof-of-concept study in which they identified several compounds that may be effective in minimizing *Listeria*’s virulence.

In this case, the process started with the key understanding that inhibiting a particular enzyme of *Listeria*, glucose-1-phosphate uridylyltransferase (GalU), leads to rather dramatic modifications of the bacterial cell surface, according to Paul Orndorff, PhD, professor emeritus of microbiology.

“From this point we determined that these chemical modifications in turn rendered *Listeria* much less virulent than it normally is, and thus less able to cause illness,” Dr. Orndorff says. The work was published in *Molecular Informatics* in March 2018.

Dr. Orndorff and his collaborators in the NCSU Department of Chemistry, post-doctoral researcher Melaine Kuenemann, PhD, and Denis Fourches, PhD, an assistant professor of computational chemistry, embraced the task of identifying potential compounds that could inhibit the function of GalU. Using computers and cheminformatics methods, Dr. Fourches and Dr. Kuenemann characterized, analyzed, and virtually screened more than 88,000 drug-like compounds using a technique called 3D molecular docking.

All those computations, which were based on the three-dimensional structure of the GalU protein and virtual representations of each compound, took several weeks to accomplish, Dr. Fourches mentions.

“Through computer modeling, we prioritized 37 compounds predicted to bind the GalU active site and thus looked promising enough to be tested *in vitro*,” he relates. “Of the 37, three compounds showed good experimental activity and were deemed effective enough to warrant further study. This is a great result, considering we had no idea what type of chemical could actually bind the GalU pocket.”

Moreover, all those compounds, including the less active ones, yielded important information about how their chemical structures relate to their activity in inhibiting GalU’s function, Dr. Fourches notes. “We were able to derive several predictive structure-activity relationships based on those 37 compounds, and these relationships will help us design even more effective GalU inhibiting compounds,” he elaborates. “This study shows that one can develop small molecules to shut down the activity of one specific bacterial enzyme,

leading to the suppression of virulence. This is a completely new avenue, especially for fighting antibiotic-resistant bacteria.”

More Robust Risk Assessment

To benefit the dairy processing industry, researchers in the South Dakota State University (SDSU), Brookings, Dairy and Food Science Department, in a cooperative effort with a commercial ice cream and frozen desserts manufacturer, are developing

models to more accurately predict the risk from *Listeria*.

To that end, SDSU food microbiology professor Sanjeev Anand, PhD, and doctoral student Neha Neha, MS, are focusing specifically on the recovery potential of any *Listeria* cells injured in a variety of ways.

“Our risk assessment models use both product matrix parameters and environmental considerations, such as storage

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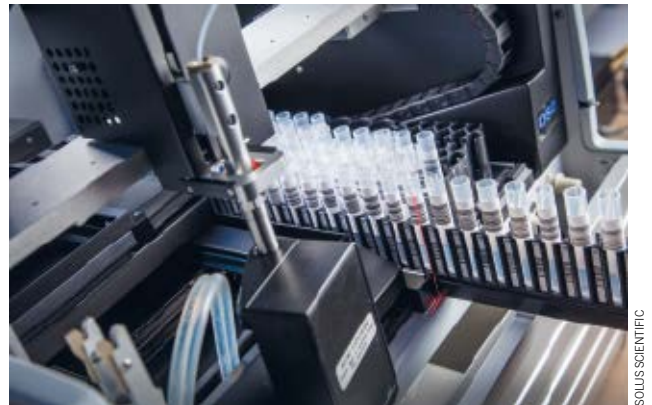
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(Continued from p. 15)



CERTUS System offers same-shift swab-to-result.



Listeria samples being loaded onto the Solus automated platform.

temperature, duration, pH, and water activity, in addition to the potential levels of cross-contamination from the environment,” Dr. Anand relates.

This is important, Dr. Anand says, because recent cases of *Listeria* in frozen foods that have resulted in recalls, ranging from frozen vegetables to ice cream bars, have reinforced the need for better methods of gauging the risk of foodborne pathogen contamination in processing plants.

“*Listeria* contamination has been recently traced to niches in the food processing environment that harbor the bacteria,” he points out. “For example, *Listeria* contamination in one commercial ice cream plant was traced to bacteria on the spout of an ice cream freezer. This is not surprising, since *Listeria* is a cold-loving microorganism. Pasteurization and cooking kill this organism, but the bacteria can grow at temperatures 40 degrees Fahrenheit and above in refrigerators and can even survive freezing.”

Neha says that, although injured *Listeria* cells are not known to cause illness, they may have the ability to recover and repair themselves.

To better understand the risk from injured cells, she looked at the organism’s behavior in different types of ice cream mixes with total solid levels ranging from 36 percent to 45 percent. She spiked the samples with three levels of a nonpathogenic *Listeria* strain before pasteurization.

“Results showed that injured *Listeria* cells did not recover in the ice cream mix itself under the normal conditions of mix handling,” she reports. “Studies are currently underway to evaluate the influence of any handling abuse on the recovery potential of injured cells.”

To address the issue of cross-contamination in the manufacturing environment, the next step is to determine how *Listeria* builds up in the environment, what characteristics make this possible and how it resists cleanup. This phase of the study starts later in 2018, Neha notes.

New Lab Assay

On July 9, 2018, Solus Scientific, Mansfield, U.K., launched commercial availability of Solus One *Listeria*, a new pathogen detection system.

“Solus One *Listeria* is an assay offering next-day detection of *Listeria* species in environmental samples,” says Ray Wakefield, CEO of Solus. “This assay provides a negative or a presumptive positive result from a single enrichment step in less than 25 hours.”

The whole process is a selective enrichment followed by an immunoassay, Wakefield explains. “If you break this down, the enrichment incubation is 22 hours and the immunoassay is 2 hours and 45 minutes, hence a total of 24 hours and 45 minutes,” he elaborates.

According to Wakefield, benefits of Solus One *Listeria*, which is AOAC certified, include a significant reduction of technician hands-on time. “High sample throughput can be achieved with a single instrument, giving the laboratory the ability to cope with fluctuating sample volumes, and also improving capacity to grow,” Wakefield relates.

Same-Shift *Listeria* Results

Expected to be commercially available on Sept. 15, 2018 is a new in-house pathogen testing system from CERTUS, Chicago, Ill., that offers real-time detection and same-

shift results. To start, the CERTUS System is focusing on environmental *Listeria* detection, according to John Coomes, company president.

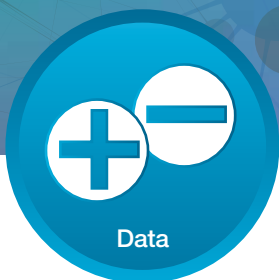
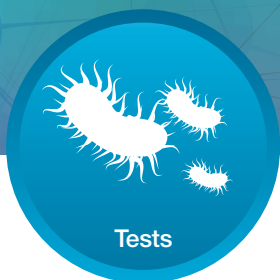
“The CERTUS System utilizes surface-enhanced Raman spectroscopy nanoparticle technology,” Coomes relates. “As part of its path to AOAC validation, which is expected in August this year, the CERTUS System recently underwent an intensive battery of performance-based tests proving detection of *Listeria* species at 10^4 colony forming units (CFUs) during a standard eight-hour work shift. Results also show that 1 CFU of *Listeria monocytogenes* can be detected in as little as 18 hours from swab to result.”

Coomes says tests demonstrate the CERTUS System’s ability to detect *Listeria* in produce wash samples known to have high bioburden. “With a range of matrices that include stainless steel, ceramic, plastic, and concrete sample sites, the CERTUS system provides 98 percent accuracy, which is equivalent to other commercial pathogen detection systems that are much more complex, have longer prep times and require expensive laboratories and technicians,” he points out. “Moreover, inclusivity and exclusivity test results have demonstrated that all challenging strains of *Listeria* are accurately detected with the CERTUS System, and interfering bacteria are excluded from results.” ■

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For extended coverage on *Listeria*, go to the August/September 2018 issue on www.FoodQualityandSafety.com.

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FOOD GENOMICS GOES GLOBAL

WGS and related technologies must become more widespread as the world's food supply gets more interconnected

BY **TED AGRES**

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Advancements in food genomics, particularly high-throughput or next-generation sequencing, are allowing scientists and regulators to detect and identify foodborne pathogens with unparalleled speed and accuracy. By the end of this year, laboratories at FDA, USDA's Food Safety and Inspection Service, and the CDC will rely almost exclusively on whole genome sequencing (WGS) as their main surveillance tool to differentiate strains of bacteria and identify related clusters of infections.

But as the world's food supply becomes increasingly interconnected, there is also a growing recognition that WGS and related technologies must become more widespread, particularly in economically developing food-producing countries. The U.S., for example, imports foods from about 200 different countries, including 90 percent of our seafood and at least half of our fresh fruit, depending on the season.

"This is why we've focused on developing and using advanced technologies and science to enhance our efforts in preventing food safety problems and improve our response time when incidents occur," says FDA Commissioner Scott Gottlieb, MD. "We need to invest even more in these efforts, and in the tools to track and trace contaminated food in the supply chain."

Today, high-throughput sequencing "has become progressively faster and cheaper, providing higher quality and longer and larger number of reads, resulting in better resolution and reproducibility," says Behzad Imanian, PhD, research assistant professor at the Institute for Food Safety and Health (IFSH).

"The food industry is showing great interest in this technology and many of its members have already invested in, experimented with, or even implemented it in their research and development procedures," Dr. Imanian tells *Food Quality & Safety* magazine.

But expanding food genomics will require overcoming numerous challenges, including cost, training, and data handling and storage. There are also unresolved legal, privacy, and technical standards issues, some of which still persist in the U.S. Nevertheless, governments and private researchers are working to expand WGS and related technologies domestically and internationally.

"In the future, most likely a global WGS system will enable very specific and almost real-time identification of all microorganisms," says Jorgen Schlundt, PhD, steering committee head of Global Microbiological Identifier (GMI), a consortium of private scientists and clinicians from more than 40 countries. GMI advocates for a worldwide, interconnected platform of genomic databases to create "one harmonized and revolutionary tool supportive of international health regulations and global public health."

Researchers at FDA's Center for Food Safety and Applied Nutrition (CFSAN) are making WGS bioinformatics tools and data



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.

freely available through an open-source, cloud-based platform called GalaxyTrakr. This new platform "provides a user-friendly and cost-effective solution for industry and other partners to address their bioinformatic needs," says James Pettengill, PhD, a biostatistics and bioinformatics geneticist at CFSAN. Currently about 140 researchers in 42 locations worldwide are using GalaxyTrakr, with 15 new users signing on each week.

WGS BENEFITS

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. "Just as the Hubble telescope revealed previously unsuspected star clusters in the darkest areas of the sky, so public health surveillance using methods with better resolution can identify clusters of infection that were previously missed," says Robert Tauxe, MD, director of CDC's Division of Foodborne, Waterborne, and Environmental Diseases.

Prior to WGS, scientists used tools such as polymerase chain reaction (PCR) and pulsed-field electrophoresis (PFGE) to genotype microorganisms for diagnostic subtyping. In addition to difficulties in standardization, "these pre-WGS techniques were often laborious and time consuming, required highly trained personnel, and expensive equipment," says David J. Lipman, MD, former director of the National Center for Biotechnology Information (NCBI) at the National Institutes of Health. "WGS overcomes many of these old problems."

In PulseNet, the CDC-run network that connects public health and food regulatory agency laboratories nationwide, WGS

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The World Health Organization and other international groups have been encouraging wide adoption of WGS technology to help manage infectious diseases, including food-borne ailments.

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this year has replaced PFGE as the primary method for detecting and investigating *Listeria* outbreaks. In the coming months, WGS will also be used for *Salmonella*, *E. coli*, and *Campylobacter*, says Heather A. Carleton, PhD, leader of the bioinformatics team at CDC's Enteric Diseases Laboratory Branch.

Partially driving this change are the local and state clinical labs that increasingly supply data to PulseNet from culture-independent diagnostic tests (CIDTs), such as immunoassays and nucleic-acid amplified tests. While CIDTs are cheaper, faster, and easier to use than WGS to detect bacteria in sick patients, they are unable to determine the DNA subtype ("fingerprint") or other characteristics necessary for PulseNet to detect outbreaks, track antibiotic resistance, or monitor disease trends.

Because of this, "PulseNet is preparing for a future without isolate culture," Dr. Carleton told an IFSH symposium on food safety and high-throughput sequencing in May. First, researchers will employ a technique called core genome multilocus sequence typing, which can determine a bacterial isolate from the internal fragments of a small number of "housekeeping" genes. Second, they will use shotgun sequencing to identify and subtype both known and unrecognized pathogens. "The latter approach will leapfrog pathogen discovery and likely the identification of known and novel pathogens causing outbreaks of unknown etiology," Dr. Carleton explained.

The U.S. government has also been upgrading public health laboratories that contribute data to PulseNet by equipping facilities with WGS equipment and training personnel. So far, more than 100 scientists in 46 states have been PulseNet trained and

certified, Dr. Carleton said. "By the end of 2018, we anticipate that WGS will be the main PulseNet surveillance tool for detecting dispersed outbreaks caused by *Listeria monocytogenes*, Shiga toxin-producing *E. coli*, and *Salmonella*," Dr. Tauxe said.

Further, the analytic methods have been harmonized with those used in FDA's GenomeTrakr food testing network, Dr. Tauxe added. GenomeTrakr currently contains more than 200,000 pathogen genome entries in its open-source portal, housed at NIH's NCBI, with more than 5,000 isolates being sequenced and added monthly. FDA is currently working to expand GenomeTrakr's distributed network of laboratories internationally and make its reference database more widely available in other countries.

Other current food genomics efforts include characterizing pathogens from CIDTs using metagenomics (cataloging all the species in an environmental sample) and using rapid WGS platforms to mine pathogen adaptations that directly contribute to preventive controls requirements for industry. "Taken together, it is apparent that the role for WGS in microbiological food safety continues to grow as it integrates more and more into pathogen analytic workflow," says Eric Brown, PhD, director of FDA's Division of Food Microbiology.

WGS LIMITS AND CHALLENGES

The extent to which WGS and similar technologies will truly mitigate foodborne illnesses remains to be seen. As the ability to identify outbreaks has improved due to new technologies, "paradoxically, the number of outbreaks may increase since we are now able to identify problems that had previously been invisible to us," Dr. Gottlieb said in a recent statement.

Indeed, improvements in pathogen and risk detection technologies are partially responsible for the more than doubling in the number of food recalls during 2004-08 compared to 2009-13, according to an April 2018 report from USDA's Economic Research Service. As CDC's Dr. Tauxe puts it, as WGS matures, "more dispersed outbreaks will be detected and investigated, and that on average, each will involve fewer cases."

But improvements in WGS and genetic testing are not substitutes for traceability, as illustrated by this year's *E. coli* outbreak linked to romaine lettuce. Researchers used WGS to link the strain of *E. coli* O157:H7 that sickened at least 210 people and killed five in 36 states to lettuce from the Yuma Valley region of Arizona. The bacterium, however, was never actually found on lettuce in fields or in commerce. Indeed, only after the outbreak was declared over in late June did Dr. Gottlieb announce that canal water used for irrigation appears to have been the source of contamination. How *E. coli* got in the water remains a mystery.

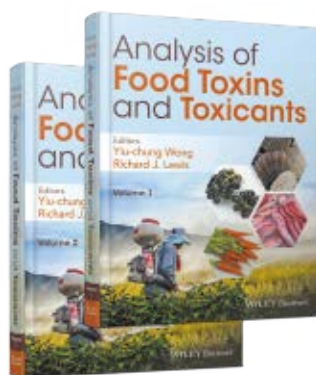
"The genetics does not help in determining the source, or which field it came from, or when it happened. That requires old-fashioned traceability and epidemiology," says David Acheson, MD, former FDA associate commissioner for foods. "If you don't have the bacteria on the commodity, the genetics doesn't help you," he tells Food Quality & Safety.

Also mystifying is that the contamination went totally undetected. "Given the amount of testing that occurs in the industry, both pre-harvest and throughout the supply chain, how could something have such a wide public health impact but not have

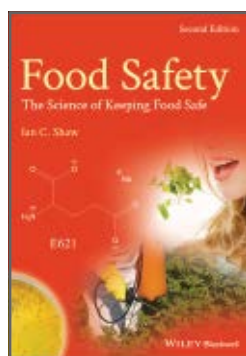
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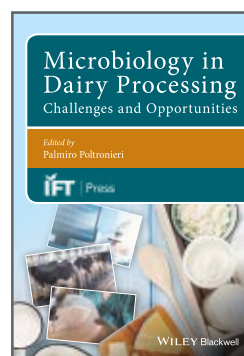
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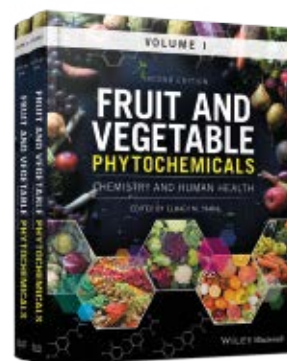
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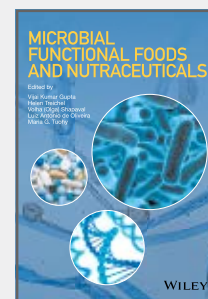
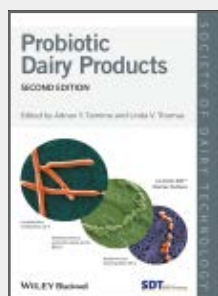
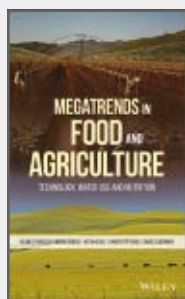
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Another challenge to adoption lies in data sharing—who can access potentially sensitive information derived from WGS, including information on virulence factors and antibiotic resistance.

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been detected through testing?” asks Jennifer McEntire, PhD, vice president for food safety and technology at the United Fresh Produce Association.

“In the quest for more rapid tests that often have shorter enrichment times, are we limiting our ability to detect microorganisms? I don’t know, but I feel like the question needs to be asked,” Dr. McEntire tells Food Quality & Safety.

WGS GOING GLOBAL

The World Health Organization and other international groups have been encouraging wide adoption of WGS technology to help manage infectious diseases, including foodborne ailments. While industrialized countries are using WGS for food safety management, its application in developing and transitional countries has been limited. According to a 2016 report by the United Nations Food and Agriculture Organization, barriers include cost, data storage, infrastructure requirements (such as high-speed Internet), legal issues, data ownership, sharing, and intellectual property rights, and sustainability.

Several of these issues are not unique to developing countries, and present challenges to the U.S. and other developed nations. “Food producers, researchers, and regulators are each affected by the current absence in standards around laboratory preparation and bioinformatics methods,” explains Kristen Beck, PhD, technical lead for the Consortium for Sequencing the Food Supply Chain and a research staff member at IBM Research-Almaden. “This makes standardization and comparative analysis very challenging,” she tells Food Quality & Safety.

An additional limiting factor is the cost of culturing microbial samples. “This will need to be orders of magnitude less than today’s per-sample cost to be usable at the scale of current routine testing,” Dr. Beck says. But as costs decline, this will become less of an issue and “will further enable technologies, such as culture-free sequencing of food microbiomes for hazard detection.”

Another challenge to adoption lies in data sharing—who can access potentially sensitive information derived from WGS, including information on virulence factors and antibiotic resistance. “How will these data be used and interpreted, and who will have access?” asks Claudia Narvaez, PhD, professor of food safety at the University of Manitoba. “And how will regulatory agencies interpret the findings, and how could this affect current regulations?”

While policymakers and regulators wrestle with these issues, researchers and equipment manufacturers continue to make advancements in genomics instrumentation. For example, researchers at the University of Georgia Center for Food Safety have developed a portable device that can shorten pathogen sequencing time from one or two days to one or two hours. Instead of culturing the sample, which can take 24-48 hours, the USB drive-sized device uses tiny magnetic beads coated with antibodies to separate pathogen DNA from the sample. It then amplifies the DNA and sequences it in real time.

In another example, researchers at Pittsburgh State University have created hybrid nanosensors composed of special iron oxide particles blended with optical dye, plus antibodies that specifically latch onto *E. coli* O157:H7 cells. By combining magnetic resonance imaging technology with fluorescence emission, they can quickly detect the pathogen in fluids, such as milk or lake water.

Even PCR technology, long a mainstay of food industry testing, is being upgraded. Bio-Rad Laboratories’ Droplet Digital PCR (ddPCR) technology allows for sample partitioning. “In traditional PCR, a single measurement is performed on a single sample. In ddPCR, a single sample is partitioned into thousands of nanosized droplets, allowing thousands of independent, single amplification events within that sample,” explains Mike Clark, the company’s international PCR group manager. This can help determine whether a single *E. coli* cell contains the virulence genes making it pathogenic or if those genes are just present in different cells within a food sample.

Advances are also occurring in metagenomics and food microbiome sequencing. “From sequence data of a single microbiome sample, you are provided with pathogen information, a microbial community snapshot, antimicrobial resistance, and host/food matrix composition,” explains IBM’s Dr. Beck. “When you compare multiple microbiomes, you are able to observe deviations in your supply chain that can indicate a hazard before it is allowed to become an issue.”

Expanding this concept, FDA’s One Health framework “holds that a connection exists between the environment and animal and human health,” says Eric Stevens, PhD, an FDA staff fellow. One Health encourages the sharing of WGS data across the various sectors related to food. “WGS can be used within supply chain management that could identify problem areas on the farm to fork continuum,” Dr. Stevens told the IFSH symposium. ■

Agres is an award-winning writer based in Laurel, Md. Reach him at tedagres@yahoo.com.

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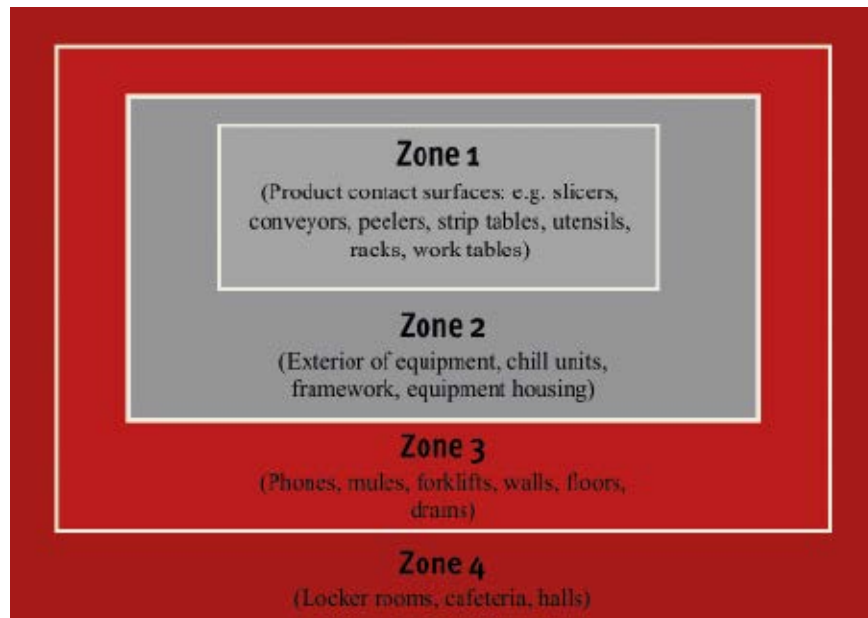
ENVIRONMENTAL CONTROL

Getting Value from Your Environmental Monitoring Data

Analyzing EMP data, rather than simply collecting and filing it, can provide actionable results to improve food safety protocols

BY TIMOTHY A. FREIER, PHD

Figure 1. Environmental sampling zones.



In the past 25 years, there has been a great evolution in the food and feed manufacturing industries, from a reliance on finished product testing, to intensive environmental monitoring programs (EMPs). These programs can take many forms, ranging from very generic indicator monitoring (testing for ATP or aerobic plate counts), to specific pathogen EMPs, with the most common being *Listeria spp.* and *Salmonella*—organisms that are uniquely qualified to take up residence in food manufacturing plants. While these programs can look very different, they all

generate data that can be used to improve food safety protocols.

Most EMPs that look for broad indicator groups are quantitative. With ATP testing, most detection platforms provide quantitative data in the form of relative light units. If using aerobic plate count data, this too is quantitative, yielding counts typically reported as colony forming units per sample. Other quantitative indicator groups used in EMPs include yeast and mold, coliforms, and *Enterobacteriaceae*. Over time, statistical process controls can be used to determine when

counts are trending upward or when there is a sharp spike in counts from the established baseline data, indicating a potential problem.

In contrast, most pathogen EMPs are based on qualitative testing. In other words, results are reported as either positive or negative. One of the limitations of this type of testing is that it is unknown whether there was a single cell present on the sample, or if there were thousands, as both can result in a positive result.

Getting Complicated

EMPs have gotten much bigger and more complicated, often testing for multiple pathogens in multiple areas of a facility. For example, in the early days of *Listeria* EMPs, many programs sampled only drains in the ready-to-eat (RTE) area. If a drain was positive, it was re-sanitized and re-tested. Today, it is not uncommon for a food or pet food manufacturing facility to test for quantitative indicator groups at pre-op to verify the effectiveness of sanitation (mainly on product contact surfaces), and also test for specific pathogens in multiple sampling zones (see Figure 1) and in multiple hygienic zones of the facility (see Figure 2). This increasing complexity of EMPs also means that the data evaluation becomes more complex.

In addition to these complexities, EMP data can come from several different types of testing. Routine monitoring is the backbone of most programs. It is the daily, weekly, or monthly testing that is conducted in a relatively steady manner to verify the efficacy of multiple prerequisite programs, such as sanitation, employee practices, hygienic design, and hygienic zoning. Quarterly sampling is not recommended since the time between testing is too great should a positive be found and a corrective action implemented. If the routine monitoring indicates that there is a problem, another form of testing kicks in, the investigational sampling. This testing is conducted to try to find the root cause or origination of the contamination. Investi-

gations can be completed with just a few samples, but more realistically, hundreds or thousands of samples may need to be processed to solve a pathogen contamination issue. Another type of testing that can generate valuable data is special cause sampling. This includes the “extra” testing that is done to help verify control during unusual events, such as construction projects, inclement weather, power interruptions, or even periods of unusually high production volumes.

Testing Positive

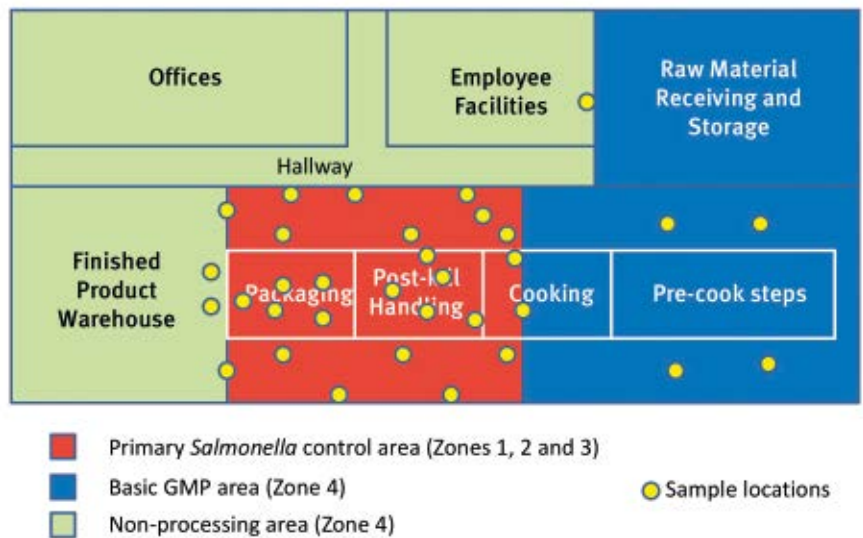
It is now nearly universally acknowledged that a good EMP will sometimes generate positive results and should be viewed as a win/win situation. Most regulators and auditors understand this, and the focus of

Being able to visualize which sites have been sampled and which have tested positive or negative is extremely valuable in helping to solve contamination issues and continuously improve the EMP.

their attention often becomes the appropriateness of the investigation and the corrective actions. This is where a good data management system is especially critical. The first important component of an investigation is understanding what should trigger an investigation. With a quantitative program, it may be triggered when a gradual but real increase in counts has occurred or when a spike above the usual background level occurs. For a qualitative pathogen EMP, the trigger may be a single positive on a Zone 1 site (direct product contact), or a repeat positive in this same area. It could also be a general increase in the number of positives in an area or zone.

Once an investigation has been triggered, a multidisciplinary team (probably the same team that devised the routine monitoring program) should meet and discuss what is known and what is unknown about the issue. This team should include members who can inject critical

Figure 2. Hygienic zone sampling example.



viewpoints in the investigation, often experts from production, sanitation, quality assurance, maintenance, engineering, or any other areas that might contribute to the investigation. This team should interview other employees and check records to determine if any unusual events happened before or during the contamination event. For example, were there any unusual moisture events, such as a roof leak, power failure, construction, formulation or process change, etc.? Answering these types of questions often leads to multiple theories that need to be followed up with additional testing and fact finding.

As EMPs began to mature, many groups found that mapping is a critical part of data management. Being able to visualize which sites have been sampled and which have tested positive or negative is extremely valuable in helping to solve contamination issues and continuously improve the EMP. Mapping can range from a simple drawing pinned on the wall with multiple Magic Markers to indicate positive and negative findings, to sophisticated computer programs (see Figure 3). A map will typically show two dimensions, but it is also important to somehow capture the dimension of time. Being able to look back over a year’s worth of data to see if certain areas or related practices are linked to a higher occurrence of positives can help pinpoint problems. It is also important to have historical references. Many facilities unfortunately have high turnover of personnel. Having maps and other docu-

mentation to help illuminate past issues, investigations, and corrective actions can be important to prevent history from repeating itself.

Every environmental positive is not created equal. The reaction to a positive in a Zone 3 drain, far away from exposed RTE product will be much different from the reaction to a Zone 1 product contact positive. The EMP team needs to have a system that knows when to initiate and escalate the investigation and corrective action activities commensurate with the risk implied by the positive sample finding(s). Being able to visualize a series of positives in relation to the physical layout of the facility, process flow, and employee activities can greatly aid in informing the direction of the investigation and corrective actions and help keep the pathogen out of the finished product. The concept of “seek and destroy” means that the EMP teams seek out the target in the most likely places, sampling areas that are difficult to clean and sanitize (and therefore also difficult to reach for sampling). This often involves very complete and careful disassembly of complex equipment while sampling each part. Then the team destroys the target organism or growth niche by seeking the root cause, implementing a permanent fix, and then verifying that the issue truly has been permanently eradicated.

Sharing EMP data between similar facilities has played an important role in helping facilities improve their EMPs.

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Some of the earliest data sharing efforts were between facilities owned by the same company. It then expanded to supplier groups, meeting at a common customer, and then various trade associations. Understanding where similar facilities have found environmental pathogen problem areas have allowed EMPs to greatly accelerate their effectiveness.

Another important tool in environmental pathogen investigations is the use of strain tracking. One of the earliest examples of strain tracking was the use of serogroup or serotype data to track individual strains of *Salmonella*. Today we

During investigations and corrective actions, it has often been found that the process flow has contributed to a contamination issue.

can differentiate to an even higher degree using methods such as ribotyping or whole genome sequencing to differentiate between closely related targets. The ability to determine whether a facility has a house pet (an environmental pathogen that is well-adapted to the facility conditions and is isolated routinely and over long periods of time) or house pests (transient strains that are introduced from outside the facility and are then eliminated) can be key. Regulators that find repeat occurrences of a house pet may determine that the facility is operating under insanitary conditions, with very serious consequences to continuing operation of that facility. Many companies are incorporating strain tracking into their EMPs to understand persistence and better protect public health.

Improving Protocols

During investigations and corrective actions, it has often been found that the process flow has contributed to a contamination issue. For example, mapping may indicate that a higher level of *Salmonella* positives has been found on the floor in the hallway leading to a trash compactor. After

Figure 3. Screenshot mapping example from EnviroMap software.



further investigation, it is found that there is moisture from rain events that is entering the trash compactor, causing growth of *Salmonella*. Steps in improving this situation include, better staging of garbage, having special footwear dedicated to the area, and applying a dry floor sanitizer powder. A more permanent fix can then be worked on, going to the root cause, and fixing the problem with the ingress of moisture into the area.

Sanitation is another key prerequisite program that can be improved based on the results of EMPs. If elevated levels of indicators are found during pre-op sampling, the sanitation practices can be changed to fix the problem. Examples include retraining of personnel, changing types or concentrations of detergents or sanitizers, modifying water conditions (hardness), changing water pressure or temperature, or increasing the frequency of sanitation. These same changes can also be implemented in response to finding pathogens in a pathogen EMP.

Hygienic design improvements can be made (and the capital expense justified) by the EMP results. Equipment design has been greatly improved as industries have identified growth niches or harborage points within equipment. Elimination of difficult-to-clean areas, such as hollow support structures, hollow conveyor rollers, door gasket material, conduits, poorly sealed control panels, etc., have helped eliminate environmental pathogen problems, and have secondary benefits, such as reduced spoilage issues and more efficient cleaning and sanitation. Designing equipment with integrated clean-in-place

sanitation systems, or access points that can be reached without the use of special tools, has also led to great improvements. In addition to equipment, the facility itself can be improved through better hygienic zoning, air flow changes, and the prevention of moisture or pests, etc.

Results of EMPs have also led to changes in products being produced. Changing products at high risk for environmental pathogen issues to those at low risk can be the most bulletproof way to reduce the overall public health risk. For example, the reformulation of RTE meat and poultry products with listeristatic antimicrobials, such as lactate and diacetate, has moved many of these products into a lower risk status by preventing the growth of *Listeria* during shelf life.

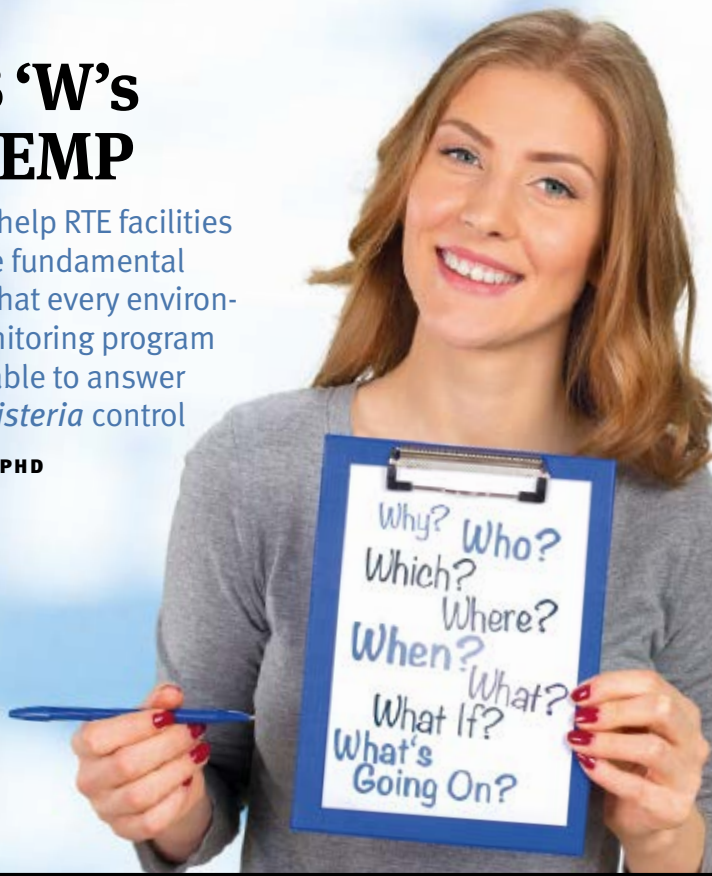
Finally, the EMP itself can be improved based on the EMP results. In fact, EMPs should always evolve as our knowledge about the pathogen, product, process, and facility evolve. When an EMP, process, product, or facility is new, the EMP needs to be rather extensive because the EMP team will be exploring, looking for where potential problem areas might be. With the collection of months' or years' worth of data, the EMP can be fine-tuned, moving from reactionary to preventive. Often this means that individual samples can be better optimized to give the most value. Positives should become very rare, and when found, they are welcomed as a way to improve the system. ■

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The 8 'W's of an EMP

These 'W's help RTE facilities address the fundamental questions that every environmental monitoring program should be able to answer regarding *Listeria* control

BY RUBY LEE, PHD



Ready-to-eat (RTE) food safety recalls and outbreaks due to product contamination of *Listeria monocytogenes* from the environment are devastating to affected consumers and their families, the originating food plants, and the food industry. RTE food plants must develop a risk-based environmental monitoring program (EMP) that covers the eight "W"s: why, who, which, where, when, what, what if, and what's going on.

Why

The goals of an EMP are to verify the effectiveness of *Listeria* control and to seek and destroy the pathogen and harborage sites (if present) for regulatory compliance (e.g. FDA Food Safety Modernization Act), recall prevention, audit readiness (e.g. Global Food Safety Initiative), brand protection, and customer and consumer satisfaction.

Who

Although the food safety team develops and implements an EMP, successful im-

plementation relies on the senior management team. This team commits to nurture food safety culture so the EMP is not the flavor of the month to pass an audit.

Which

Listeria spp. is the most suitable indicator and includes psychrotrophic *Listeria monocytogenes* with relatively low infective dose to cause listeriosis but with relatively high mortality rate in high-risk populations (e.g. young, old, pregnant woman, and immunocompromised patients). For low water activity foods, Enterobacteriaceae and *Salmonella* spp. are the target indicators.

Where

A master list is required to document Zone 1 food contact surfaces (FCS), Zone 2 non-food contact surfaces (NFCS) in close proximity to FCS, Zone 3 more remote NFCS that are in or near the processing areas and could lead to contamination of Zones 1 and 2, and Zone 4 NFCS in remote areas outside of the processing area from which environ-

Samples should be taken several hours into production or preferably just prior to cleanup, which allows time for *L. monocytogenes* (if present) in harborage sites to contaminate the sampling sites.

mental pathogens can be introduced into the processing environment.

During routine sampling, it is recommended to sample and test at least 10 FCS and 10 NFCS per RTE line in a larger food plant. Within a defined period of time, all sites in the master list are sampled and tested.

When

Samples should be taken several hours into production (e.g. three to four hours) or preferably just prior to cleanup, which allows time for *L. monocytogenes* (if present) in harborage sites to contaminate the sampling sites. Frequency should be based on risk, regulation, and industry best practices. According to FDA's draft guidance for "Control of *Listeria monocytogenes* in RTE Foods," higher risk products do not receive a listericidal treatment to adequately reduce *L. monocytogenes*, are not formulated to prevent the growth of *L. monocytogenes* or be lethal to *L. monocytogenes*, and are handled extensively after the pathogen reduction step and prior to packaging. They also do not receive a listericidal control measure in the package, support the growth of *L. monocytogenes* under normal storage conditions, and have a relatively longer refrigerated shelf life. During routine sampling, high-risk RTE lines should be tested weekly on a random production day. Low-risk RTE lines can be tested at a lower frequency.

What

An approved sampling and testing method with proper application needs to be followed by an accredited laboratory (e.g. the FDA's 2015 "Testing Methodology for *Liste-*

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ria species or *L. monocytogenes* in Environmental Samples”). A 1 foot x 1 foot area should be sampled if applicable. Proper neutralizing buffer (e.g. D/E neutralizing broth) should be used to neutralize residual sanitizer on the sponge, if applicable, to prevent false negative results.

What If

A finding of *Listeria* spp. in the RTE processing environment should trigger corrective actions such as intensified cleaning and sanitizing, intensified sampling and testing, comprehensive investigation and root cause analysis, “hold and test” procedures, and preventative measures. Corrective actions should be risk-based (e.g. NFCS versus FCS, low- versus high-risk line, routine versus intensified sampling phase, and isolated versus persistent findings) in reference to regulatory policy and industry best practices. Advances in molecular technology tools (e.g. ribotyping and whole genome sequencing) facilitate definitive root cause analysis.

What’s Going On

Trend analysis is conducted to review the past, take actions today, and improve the future. Trend analysis is conducted to verify *Listeria* control via time and/or spatial patterns by observing if *Listeria* findings are increasing in particular sites or areas, increasing in the same area on multiple but non-consecutive sampling occasions,

Trend analysis is conducted to review the past, take actions today, and improve the future.

increasing in overall percentage, and/or moving from NFCS to FCS. Statistical methods (e.g. Pareto analysis) should be applied in trend analysis and root cause analysis. Management review should be performed regularly to assess the prevalence of *Listeria* spp., identify their fluctuations over time (especially at sites with sporadic positives that may have gone unnoticed previously), detect trends, and verify corrective actions.

In terms of improving from average to best, the average plants file the laboratory reports after reviewing. The good plants summarize *Listeria* findings in a table with when and where they occurred. The better plants assemble a multidisciplinary team to take actions. Some better facilities color-code routine, intensified, and investigative vector *Listeria* findings on plant schematics with areas, zones, and equipment, and overlay these with transparent flow diagrams (e.g. people flow, product flow, and drainage flow). The best plants go one step further by taking a science-based and systematic seek and destroy (S&D) approach to identify, control, and eliminate *Listeria* growth niches proactively.

Development of growth niches is facilitated by equipment design problems (e.g. slicing equipment or hollow areas of equipment) and unsatisfactory operational conditions (e.g. food debris gets into difficult-to-clean locations, mid-shift cleanup, and high-pressure cleaning). If growth niches are not designed out of the process, they should be controlled by minimizing their contamination potential. The best plants validate the sanitation standard operating procedures to prevent biofilm formation in the growth niches. Tools for biofilm detection should be used during pre-operation to verify sanitation efficacy, and during and after investigation to verify corrective actions. There are two steps in S&D. Firstly, the team disassembles equipment to a routine daily sanitation level, inspects the disassembled equipment for organic buildup and growth niches, conducts microbiological tests if growth niches are identified, and evaluates the sanitation method during pre-operation. Secondly, the team repeats step one on the completely disassembled equipment.

Are you ready to use the eight “W”s to improve your risk-based EMP from average to good, better, or best RTE food plant status for regulatory compliance, recall prevention, audit readiness, brand protection, and customer and consumer satisfaction? ■

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4 Food Safety Training Challenges and How to Overcome Them

Incorporating technology and innovative tools on the floor go a long way toward building a culture of food safety

BY LAURA DUNN NELSON

Food manufacturers face several challenges when it comes to training their frontline workforces. Inherent struggles include heavy turnover, a dearth of skilled workers, high production quotas, tight timelines, and maintaining consistent behavior across all lines, shifts, and locations. Add federal regulations and compliance rules to the list, and training employees well enough to routinely apply correct behavior on the floor becomes a bigger challenge.

However, even the most complex problems can be overcome with the right tools and an open mindset. Training shouldn't be designed as "one and done." Effective training is continuous. Studies show an integrated training solution that combines interactive training, continuous reinforcement, and one-on-one coaching can elevate food safety training—while resulting in a lift in production and efficiency on the food production floor at the same time.

Conducted by Alchemy Systems and its research partners, the Global Food

Safety Training Survey is an annual study and comprehensive industry benchmarking tool that determines the efficacy of food safety training programs across the globe. More than 1,400 food safety professionals in more than 20 food industry sectors participate in the study to determine best practices for overcoming common industry challenges. Some significant issues uncovered by last year's survey were scheduling time for training, keeping the message to employees consistent, creating engaging training, and verifying training for compliance—and these pertained to companies of all sizes. When examining solutions, it was clear that incorporating technology and innovative tools on the floor went a long way toward overcoming training challenges and building a culture of food safety.

Challenge #1: Scheduling Time

It should come as no surprise that finding time for training has been the No. 1 challenge identified each year in the Global Food Safety Training Survey. High quo-

tas and tight schedules often leave safety managers and floor supervisors competing for employees' time.

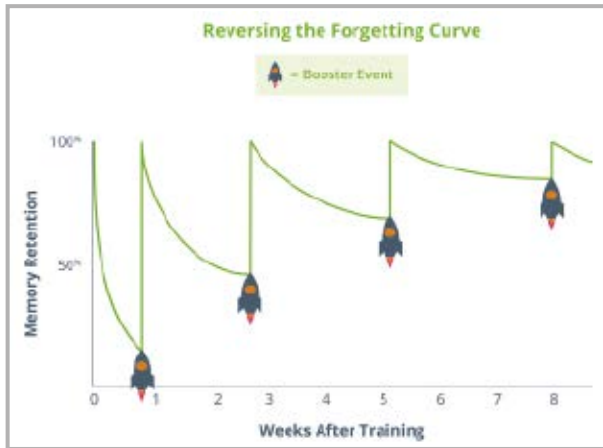
The most effective onboarding programs are short and engaging, relatable, and include knowledge checks at every step to assess comprehension. However, according to a phenomenon called the "forgetting curve," even the most compelling onboarding training can be forgotten—up to 80 percent—if that training isn't continuously reinforced. Building quick three- to five-minute "refreshers" into daily operations that complement training can reinforce and keep material fresh.

It can be difficult to squeeze in refreshers amid busy schedules. Luckily, the research is in our favor. Studies show the most effective refresher training is short and interactive. Rather than hour-long sessions, five-minute sessions punctuated with questions that prompt understanding and retention are more effective. Adult learning experts agree on the importance of recognizing a tenured employee's level of knowledge by using brief refreshers as opposed to sitting through the same training as a new employee year after year. These short learning "bursts" take less time and fewer resources, so production can remain humming while employees learn and re-learn on the job. Strategically placing communications tools in high-traffic areas, like posters and video, also helps employees internalize concepts through repetition without taking time off the floor.

A mobile coaching app designed for the food production floor is another way to save time training. When frontline workers receive one-on-one coaching, they're able to ask questions that create an invaluable dialogue and help them apply safety on the floor. A mobile coaching app conducts formal observations and corrective actions, as well as automatically records and stores observation and remediation data for future audits—which is a must for compliance. Many companies have seen success using such a tool designed for food manufacturing.

"Our mobile coaching app has helped us improve the performance of our workers by allowing us not only to provide the ini-

(Continued on p. 30)



ALCHEMY SYSTEMS

Implementing booster events that complement training in daily operations can reinforce and keep material fresh, helping to reverse the “forgetting curve.”

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tial training, but to go out onto the floors any time of day, any shift, and verify that the learning that they achieved in the classroom has been sustained and continues,” says Robert Munoz, learning and development training manager at JBS.

Challenge #2: Ensuring Consistent Messaging

A significant challenge to consistency in many companies is having dozens or hundreds of supervisors, each with their own way of doing things. Not all leaders possess the same strengths, and some supervisors may be less experienced or engaging. Ensuring messaging is strong and consistent, regardless of who’s in charge, is imperative for keeping operations firing on all cylinders.

The right training tools can drive consistency. One way to ensure messaging stays consistent is to create learning plans for employees based on department or role. Learning plans function like playlists and allow training leaders to “plug and play,” empowering employees to take ownership over their own training. When employees all receive the same training, messaging stays consistent.

Shift huddle guides can also help drive consistency among supervisors by keeping everyone on the same page, literally. Not only do the effective communications make relaying messaging easier, it also saves supervisors time by eliminating the need to reinvent the wheel each shift.

“It helps me sleep peacefully at night because whether it’s my third shift, my second shift, or my day shift, I know that if training is happening, they’re watching that same courseware. They’re watching that same video, and it is going to be communicated across all shifts, all departments. It doesn’t matter who the facilitator is...it is going to be the same message across the board,” says James Hatch, operations training supervisor at Idahoan Foods, a potato production company.

Consistency post-FSMA (Food Safety Modernization Act) is also crucial amid evolving regulations. Implementing company-wide communications, like eye-catching posters and looping digital videos in break rooms, can engage employees throughout the day, reinforce compliance, and keep operations consistent.



ALCHEMY SYSTEMS

Interactive training courseware that pauses to test learners’ knowledge and requires participation and feedback has proven more effective than the old-school ways of training.

“Since we’ve launched the communication program, consisting of monthly topics that are reinforced with visuals throughout the facility, people are thinking about these topics more often,” says Amanda Moss, HR manager at Chudleigh’s, a commercial bakery. “The coordinated posters, the digital videos, the huddle guides, along with the training that we do monthly, really reinforces the topics that we cover, and again, drives that safety culture throughout the organization.”

Challenge #3: Make Training Compelling and Memorable

It’s difficult to jazz up food safety and operations training. One way to cut through training white noise is to examine the different ways your food safety training is delivered. Long gone are the days of thick training manuals and boring hours-long videos. Today’s workers learn best when training material is delivered quickly and to the point, mimicking the visual and digital ways in which they experience the world.

Food safety training that moves beyond generic training material and imagery (i.e., stock photography in office-centric settings) is necessary to make an impact. Interactive training courseware that pauses to test learners’ knowledge and requires participation and feedback has proven more effective than the old-school ways of training. When learners’ attention spans are short and distractions are many, quick, succinct training courses make an impact.

The Global Food Safety Training Survey reports that 76 percent of food companies that responded still rely on reading materials and on-the-job instruction to deliver training. But for many front-line workers, reading complex safety procedures and standard operating procedures can be difficult.

More effective means of communication that encourage interaction can keep workers engaged and paying close attention. Research also shows when workers recognize themselves or their work environments in training materials, they’re more likely to remember what they have learned.

“When we customize the programs, it takes it out of a generalization and puts it in a real-time format for the employees so

that they can recognize the different scenarios to help them better perform their positions,” says Cindy Fedde, training coordinator at Dorada Foods, a large poultry processor.

Workers tend to glaze over generic content when it doesn't resonate, failing to commit important concepts to long-term memory. Incorporating food production-specific imagery and video from your workplace, even featuring your employees, can be an effective training method, which then translates into correct action on the floor. Advance course authoring software makes this easy to do with little to no technical background.

Challenge #4: Verifying Training Occurred and Was Understood

Here's the deal with food safety training: Just because it happened doesn't mean you're in the clear. It's one thing to get all employees onboarded, but documenting that training occurred—and was understood—presents a new set of challenges entirely. Tracking training manually can be time-consuming and invites inaccuracies. Yet, according to the Global Food Safety Training Survey, 66 percent of the food companies that responded say they still use paper-based documentation to track training, and more than half use Excel.

Furthermore, tracking training occurrence doesn't account for verifying comprehension. “Active learning” that requires learners to participate and answer questions not only increases engagement, but a modern learning management system can also document those answers. An automated recordkeeping system can also track when remediation was necessary, that it occurred, and that the employee followed through with correct behavior on the floor.

When it comes to audits and inspections, this defensible data is critical. Having a central learning management system that can scale across multiple shifts and locations is the most effective way to ensure food safety across your entire operations.

“When an auditor comes and asks for a specific training document, I'm able to pull that record digitally within a matter of minutes. I have documentation for hundreds of employees, and I can provide that to auditors in a snap of a finger,” says Tony Salazar, training manager at Ventura Foods, a leading food manufacturer that uses an automated recordkeeping system.

Yet 35 percent of large companies still don't have such a system in place, and as many as 80 percent of small companies don't. As compliance regulations continue to tighten, airtight data management will become more crucial than ever. A learning management system that can sync up records on or offline will be necessary for many production environments.

Food companies that are willing to incorporate new methods of training, including a central learning management system that can deliver timely, consistent training and document data for compliance, mobile coaching tools, and meaningful communications, will be the companies that can transcend the current challenges to create a strong frontline workforce. And since the success of any food company is directly tied to the knowledge, skill, and strength of their workforce, these relatively modest investments in training tend to pay remarkable dividends. ■

Dunn Nelson is vice president of food safety and global alliances at Alchemy Systems. Reach her at laura.nelson@alchemy.com.



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California Coffee Could Be Exempt from Cancer Warnings

What recent Proposition 65 developments mean for coffee roasters and retailers

BY MALCOLM WEISS, SHANNON OLDENBURG, AND ALEXANDRA HAMILTON

California coffee drinkers may no longer see cancer warnings along with their morning caffeine fix. The coffee served to consumers has not changed, but a recent proposed regulation by California's Office of Environmental Health Hazard Assessment (OEHHA) would exempt coffee from cancer warnings required for many consumer products in the state. OEHHA's proposal comes shortly after a statement of decision by the Los Angeles Superior Court this spring that found that brewed coffee sold at retail stores contains levels of acrylamide that require a warning.

The case was consolidated from two suits filed in 2010 by a Proposition 65 citizen enforcer called the Council for Education and Research on Toxics (CERT), alleging that more than 90 businesses selling brewed coffee had violated California's Safe Drinking Water and Toxic Enforcement Act of 1986—better known as Proposition 65—by failing to provide warnings to consumers based on the exposure to acrylamide.*

Under California's Proposition 65, businesses with more than 10 employees must provide "clear and reasonable" warnings for products, including food, that may ex-

pose consumers to unacceptable levels of any of more than 900 chemicals listed as known by the state to cause cancer, birth defects, or other reproductive harm. Acrylamide has been on the Proposition 65 list since 1990 as a carcinogen. The International Agency for Research on Cancer identifies acrylamide as a "probable human carcinogen" and the U.S. EPA characterizes it as "likely to be carcinogenic to humans."

Acrylamide is not a chemical added to coffee. Rather, it occurs naturally during the roasting process as a result of the Maillard reaction (the same chemical reaction that creates browning when searing a steak, for example). Acrylamide is produced when starchy foods like toast, potatoes, or many snack foods are cooked above certain temperatures.

Years of Litigation

Los Angeles Superior Court Judge Elihu Berle's recent ruling came after nearly eight years of litigation. The decision is-

**Council for Education and Research on Toxics v. Starbucks Corp. et al., No. BC435759, and Council for Education and Research on Toxics v. Brad Barry Company Ltd. et al., No. BC461182, both in the Superior Court of the State of California for the County of Los Angeles.*

sued on May 7, 2018, affirming an earlier preliminary decision, marked the end of Phase II in the litigation, which addressed coffee sellers' Proposition 65 affirmative defense based on an Alternative Significant Risk Level (ASRL) assessment. The court previously rejected several other affirmative defenses during Phase I, including those based on the First Amendment, federal preemption, and the statutory No Significant Risk Level (NSRL).

Both the ASRL and NSRL are affirmative defenses that can be used to demonstrate that no warning is required. Under the NSRL approach, warning requirements do not apply if a defendant can demonstrate "that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer." Essentially, the defendants argued during Phase I that no warning was required for coffee because consumers' exposure to acrylamide was less than the 0.2 micrograms per day NSRL that OEHHA has set.

To prevail on the NSRL defense, a quantitative risk assessment must be performed to prove that exposure to acrylamide is below 0.2 micrograms per day level. Defendants, however, focused on presenting evidence showing that coffee as a whole does not increase cancer risks. Judge Berle agreed with the plaintiff that defendants' evidence on the cancer risks of coffee as a whole, a mixture of numerous substances, was insufficient to meet their burden to assert the NSRL defense. Instead, he found that a quantitative risk assessment to determine the risk from just acrylamide exposure from coffee, not the drink as a whole, was required.

Phase II of the trial, on the other hand, focused on the ASRL affirmative defense, which is based on interpretation of the Proposition 65 implementing regulations. Effectively, there is no duty to provide a warning even if an exposure exceeds the established NSRL, "where sound considerations of public health support an alternative level," such as "where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination." Defendants argued that coffee fits within these "sound considerations" because cooking—roasting—is required to render brewed coffee palatable for consumers.

In Phase I, the court rejected an argument by CERT that, to qualify for an ASRL, defendants must take measures to reduce acrylamide levels to the lowest possible level. The court also found, however, that defendants had failed to meet their burden to qualify for an ASRL defense because their quantitative risk assessment focused on coffee as a mixture rather than just the acrylamide in it. In Phase II, Judge Berle again rejected defendants' proposed ASRL defense because the revised quantitative risk assessment was based on acrylamide generally and was not specific to acrylamide in coffee.

The court likewise rejected defendants' arguments in favor of setting an ASRL 10 times greater than the NSRL for acrylamide, despite expert testimony from a former commissioner of FDA, that FDA had regulated certain carcinogens in food at a more lenient risk level (10-4 instead of the typical 10-6 standard), and a former OEHHA proposal to regulate acrylamide in bread and cereal at that same 10-4 risk level. The court rejected both rationales as "inadequate grounds for an alternative risk level." Moreover, the court found that some of the product testing the defendants relied on was scientifically unreliable and inadmissible.

A number of the coffee companies in the case responded to Judge Berle's proposed ruling issued on March 28, 2018, by arguing that they did prove that acrylamide in coffee is not present at dangerous levels and they need not comply with the warning requirement. Judge Berle nonetheless finalized his decision. CERT filed a motion seeking permanent injunction in light of the court's ruling. A hearing is scheduled in the case for the end of July

to address CERT's motion for permanent injunction and the companies' motion to stay.

Regulatory Intervention

On June 15, 2018, OEHHA issued its proposed regulation to provide that coffee does not pose a significant cancer risk based on the naturally occurring carcinogens in it, and thus Proposition 65 does not require cancer warnings for coffee. OEHHA relied on a report issued in June 2018 by the World Health Organization's International Agency for Research on Cancer, which reviewed over 1,000 studies to determine that "inadequate evidence" linking coffee consumption to cancer exists, and that coffee drinkers experience strong antioxidant effects that are related to a reduction in cancer risk. Under the proposal, most brewed coffee would be exempt from Proposition 65 warning requirements, but only for those chemicals that occur naturally in the roasting and brewing process (i.e. not for exposures related to listed chemicals that are intentionally added to the coffee or enter the coffee in some other fashion).

Warning Fatigue?

Coffee is not the first food product to be the focus of a Proposition 65 suit over acrylamide exposure. Previous suits alleged failures to warn of acrylamide exposures in some potato products. A suit against Kentucky Fried Chicken for failure to warn of acrylamide in its fried and baked potato products was settled in 2007, as was a similar suit against potato chip manufacturers the following year.

Although OEHHA's proposed regulation may obviate the impact of Judge

Berle's decision for coffee sellers, his decision could hold meaning for businesses outside the coffee industry. In particular, it demonstrates the incongruous nature of Proposition 65 decisions and the resulting difficulty for businesses to avoid burdensome litigation. For instance, the weed-killing product Roundup need not bear a Proposition 65 warning pursuant to a recent ruling by a federal judge, but as a result of this decision, coffee must.

Moreover, that this case has been litigated for the past eight years evidences the cost and difficulty involved for businesses to deal with Proposition 65 claims and to successfully defend against them. That difficulty is compounded since the burden of persuasion falls to the defendant to prove a defense—even as in this case, where the defendants believed they had a preponderance of evidence to support that coffee on balance has more health benefits than harms. In light of these defense considerations, compliance up front is the best approach for businesses.

The recent decision in the coffee case is a salient example of a common criticism of Proposition 65 that it leads to warning fatigue. As consumers are faced with more and more warnings, the warnings become less and less effective, even when the threat may be significant. Some have argued that warnings do not change consumer behavior at all, meaning that coffee drinkers are unlikely to stop ordering their regular beverage even if it comes with a cancer warning. ■

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Prop. 65: What It Is and What Companies Need to Do

Suppliers and retailers not actively working toward compliance risk more than just a slap on the wrist

BY RANDY FIELDS

There's a lot of buzz right now around California's Proposition 65, which leaves many suppliers and retailers wondering how it affects them, what they should know, and what to do about it to ensure compliance. Proposition 65, also known as the Safe Drinking Water and Toxic Enforcement Act, was enacted in November 1986 and requires businesses to give warnings to California consumers about exposures to chemicals that cause cancer or birth defects and reproductive harm. These exposures can come from facilities, equipment, and/or consumer goods. By requiring warnings of exposures, the law suggests that California consumers are better equipped to make informed decisions about the places they visit and the products they buy.

Proposition 65 is administered by the Office of Environmental Health Hazard Assessment (OEHHA), part of the California EPA. OEHHA determines which chemicals meet the scientific and legal requirements for placement on the Proposition 65 list, which must be updated annually and has grown to include more than 900 chem-

icals since it was first published in 1987. OEHHA also publishes maximum permissible exposure levels above which written warnings are required. These include No Significant Risk Levels (NSRLs) for carcinogens and Maximum Allowable Dose Levels (MADLs) for chemicals causing reproductive toxicity.

The Warning

Under the current law (effective until Aug. 30, 2018), if the use of a food product sold to California consumers will expose them to a Proposition 65 chemical at levels exceeding the NSRLs and/or MADLs, then the food product label must contain a warning or there must be a warning on the shelf where the product is stocked. Under the upcoming revisions to Proposition 65, if the use of a food product sold to California consumers will expose them to a Proposition 65 chemical at levels exceeding the NSRLs and/or MADLs, then the food product label or shelf sign must contain a new statement:

"WARNING: Consuming this product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California

to cause cancer and/or (as appropriate) [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food."

Proposition 65 was designed to be enforced by the California Attorney General Office and/or any district or city attorney for cities whose population exceeds 750,000. In the event a consumer food product is discovered to contain chemicals at levels that exceed the permissible NSRLs and/or MADLs, and the consumer product does not have a warning, these officials could bring a lawsuit against the offending companies. Because of the vast number of potential exposures and violations, consumer advocacy groups, private citizens, and law firms are also allowed to enforce Proposition 65 on the government's behalf.

Need to Know

Because of the Proposition 65 changes, food manufacturers should continuously stay abreast of new notices to ensure that the types of food products they are manufacturing are not being targeted. Manufacturers should also consider testing their products against the standards established under Proposition 65 to ensure they are compliant. If not, they will require a warning.

Food retailers should also read the new notices to ensure that the food products they sell are not being targeted. Retailers should send notices to their suppliers inquiring about whether the products they are purchasing may contain Proposition 65 chemicals exceeding the established NSRLs and/or MADLs and, if so, whether they require warnings. Each of these inquiries and responses should be carefully managed and documented.

Bottom line for the new Proposition 65 regulations is that retailers and suppliers not actively working toward compliance risk more than just a slap on the wrist. California is a litigious state and if executives doing business there are not compliant they could wind up out of business. ■

Fields is CEO of ReposiTrak and Park City Group. Reach him at randy@parkcitygroup.com.

When Food Meets Faith

Meeting ingredient labeling criteria to ensure religious dietary compliance | BY JUDY SEBASTIAN



Answering the question, “What’s for dinner?” unvaryingly leads to more questions. The modern food culture web is continuously branching and growing in complexity as dietary preferences of consumers worldwide are being influenced by geographic location, protein choices, lifestyle trends, ethnic backgrounds, seasonal availability, and a factor that directs one’s inner compass—religious beliefs.

With over 4,000 (and growing) religions being observed, several sects and doctrines bridge food with faith and spirituality. Devout followers of influential religions such as Islam, Christianity, Judaism, Buddhism, Jainism, and Hinduism, to name a few, make intentional food choices to satisfy their nutritional requirements and respect the religious laws. This impacts food safety and quality management systems from harvesting, slaughtering, or sourcing to food packaging and labeling.

Religious-Based Diets

There is a growing need for food businesses to ensure religious compliance, apart from meeting established health and safety standards. A few revered religion-based dietary labels include the following.

Halal. Followers of Islam observe two broad food categories, namely halal (Arabic for those that are permitted) and haram (those that are forbidden). While halal and

haram are universal terms that apply to all facets of a Muslim’s life, this categorization is commonly used in relation to food and beverage products, food contact materials, cosmetics, and pharmaceuticals. Haram foods include pork and porcine byproducts, alcohol, and products that may contain enzymes or emulsifiers made from haram animal fats such as lard, porcine gelatin, or fats derived from animals not slaughtered following the Islamic laws. Food products fermented by yeast and that contain hints of alcohol also fall under the haram category. The way in which an animal is slaughtered prior to processing is pivotal according to religious guidelines and needs to be carried out by a skilled and trained Muslim slaughterer. In addition to this, meat, poultry, and seafood need to be derived from animals and fish fed vegetarian feed for them to be certified as halal. According to the report released by the World Halal Forum in 2015, halal foods account for 16 percent of the global food industry and this number is expected to grow significantly by 2020.

Kosher. Jews recognize certain types of food products as permissible (kosher, Hebrew for pure) and prohibited (treif). Kosher food certification and labeling is slightly more complicated as it branches out further based on elaborate Biblical regulations. Moreover, it is prohibited for meat and dairy products to mix with each other, from farm to fork. The three sub-cat-

egories of kosher food include meat, dairy, and pareve—food products that are neither meat nor dairy. Cleaning activities, production utensils and equipment used, preparation steps, processing, and food packaging procedures need to adhere with the religious requirements as well. Kosher food products that are neither meat nor dairy may lose their pareve status if they are processed in meat or dairy production facilities that lack a physical separation from the rest of the operation or when additives have been employed—meaning, the purity has been compromised.

This rule is meticulously practiced by observant Jews even when it comes to handling cooking utensils, food contact surface, and food storage containers. Some may run the extra mile of following separate cleaning cycles for utensils used to prepare dairy products and those utilized in cooking meat and poultry products.

When it comes to wine, a separate set of guidelines dictate production and processing. Even if all the ingredients in the produced wine are of kosher origin and the equipment used is kosher compliant, it will be certified and endorsed as kosher only if the production was carried out solely by Torah-observant Jews.

Jain. Jains or the followers of the ancient Indian religion, Jainism, presumably observe the most stringent diet. The core philosophy of Jainism is to respect all living things—including microorganisms and practice non-violence or “ahimsa.” This limits their dietary options to a strict vegan diet that excludes dairy, meat, seafood, poultry, and vegetables such as onions, potatoes, and garlic as they grow beneath the ground. Followers of this faith also find themselves cooking each meal fresh, as they refrain from consuming food that is a day old or older and may be harboring other living beings such as microbes. Staunch followers don’t eat before sunrise and after sunset to ensure what they eat is “visible” to them. This practice dates to pre-artificial light days when it was difficult to navigate in the dark.

A common predicament most Jains face is the permissible levels of insect fragments or rodent hair, described as insect filth and rodent filth respectively,

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highlighted by the U.S. FDA and other international food safety agencies. Per the FDA an action level is required only if an average of 30 or more insect fragments per 10 grams of food product is detected. In an ideal environment, there ought to be zero presence of any extraneous substances in food products. However, keeping realistic scenarios and risk levels in mind, foreign contaminants such as bug parts and microbes are bound to enter the food system. This explains why devout followers of Jainism find it hard to choose reliable and trustworthy dining options or purchase food and beverage products.

Although there isn't a formal inspection or certification agency in place to validate food brands that offer Jain-friendly dietary options, a few sectors of the hospitality industry such as the aviation sectors have taken proactive steps to include these options as a part of their in-flight offerings.

Hindu. Hinduism is a religion based on co-existence and interdependence of sentient beings. The Hindu diet also is predominantly vegetarian-based to reflect the community's belief in non-violence. Higher Hindu castes such as Brahmins follow a strict vegetarian diet with rigor and discipline. Traditional Orthodox Brahmins may choose to clean the entire household and engage in a cleaning ritual should they learn that one of their guests had consumed meat or poultry products prior to entering the household. Clarified butter, or ghee, is of importance to the Hindus as it is rich, flavorful, and is often associated with a sign of prosperity.

Depending on the level of adherence, beef is forbidden for the most part as cows hold a sacred status and are revered as well. Pork and pork byproducts may be prohibited, depending on the caste or sect. This is why Hindus around the world are pressing for more transparency when it comes to food ingredients and nutrition labeling. Bovine and/or porcine gelatinous additives cannot be a part of a typical Hindu diet.

Religious Food Labeling Challenges

Food codes established by federal food safety agencies around the world primarily focus on public health and safety—the

approach is unbiased and universal. While countries that are governed by religious laws, such as nations within the Middle East, find it easier to mandate food labeling requirements and parameters, other countries that are more secular cannot stipulate similar, if not the same, ingredient labeling criteria. Although voluntary efforts are being made by certain food brands to reduce this gap, a few challenges still exist.

Lack of cultural and religious understanding. The world is more interconnected now than before. Ethnic and cultural diversity is becoming more common and is influencing food culture globally. Efforts need to be made to understand the needs and wants of the current demographic. This can be augmented by investing in data analyses to understand the current population and economy better. The four major religion-based diets previously mentioned illustrate that we are simply scratching the surface when it comes to understanding cultural differences on a global level, and the various diets they follow.

Disjointed global compliance systems. Enhanced international trade regulations and import/export tariffs have made it easier to source ingredients from around the world. While the commercial side is benefitting from this, communication and compliance are two other major areas of improvement. Food brands that engage in major export activities need to be mindful about their customers overseas and ensure the language is translated, if needed, with each ingredient specified, where possible. Unfortunately, food labeling requirements of one country may not necessarily match that of another. In addition, more efforts are usually made to meet the minimum export compliance requirement versus maximizing communicating information pertaining to the product to the end user.

Religious food processing standards are more rigorous. Both halal and kosher slaughtering processes require time, manual labor, and more operational space to effectively and accurately carry out the religious requirements. The standards set in place are based on ancient, traditional religious texts that emphasize on caring for the animal prior to slaughtering it and treating the carcass with respect

during and after the slaughter. These labor-intensive processes are hard to sustain nationwide and are more expensive to maintain.

Food security gets negatively impacted. When ingredient and/or nutrition labeling requirements are not met by the point of export, the point of import must temporarily hold the product before choosing to dispose of it or return it to the supplier. With costs involved, supply chain regulations, and customs requirements to consider, most countries choose to dispose of food products that do not match the local food labeling requirements. This adds to the problem of food wastage and negatively impacts food security.

Opportunities for Improvement

Analyzing quality data surrounding dining and food purchasing patterns of the current demographic will help food brands gauge what their action items are to gain a competitive edge. Though labeling every ingredient appears to be the obvious solution, there are certain limitations as complex compounds may be a derivative from two or more sources.

Religious-based food product certification and accreditation bodies could introduce economical certification programs to support small-scale food businesses that usually are founded by people who have identified a specific need of an ethnic community.

Regulatory authorities need to make an intentional decision to include the needs of other ethnic groups, especially if their population size is significant. For example, gelatin can be obtained from meat, poultry, and pork products and is often used in food, cosmetic, and personal care products. Forward-thinking food brands are voluntarily disclosing ingredients such a pork- or beef-derived gelatin. One might make the argument that this disclosure may negatively impact sales. The other perspective that often gets missed is consumers can recognize brands that are transparent and therefore feel safe trusting them. ■

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In The Lab

RAPID METHODS



A Valuable Tool for Quantitative Analysis

qNMR is an under-used technique that is becoming increasingly popular due to its reputation for making analysis easier

BY MICHAEL FREY, PHD, AND TAKAKO SUEMATSU, PHD

The food industry is subject to intense scrutiny throughout the supply chain due to the vital requirement to verify the safety and authenticity of foods. Many traditional analysis techniques are limited in their capabilities, and in a high-throughput environment like a food testing laboratory, rapid methods for non-specific analysis are required.

Nuclear magnetic resonance (NMR) has long been a preferred method for organic compound analysis, but it's quantitative NMR (qNMR) that's making waves in a field that has so far been reliant upon chromatography for its quantitative analysis requirements. Although NMR has a quantitative performance in principle, it has previously been considered big, ex-

pensive, low-sensitivity, and altogether complicated when compared to chromatographic methods. However, that's all changing, with qNMR attracting attention from a variety of fields for the reliability of the results it can achieve.

qNMR Catches On

Traditionally a research method, NMR is increasingly becoming an analytical tool that has particular merit in the food industry. NMR methodology enables primary and secondary metabolites to be identified and quantified, delivering high-throughput spectroscopic and structural information on a wide range of metabolites simultaneously.

A key benefit of using NMR for food testing is that samples can be analyzed ei-

ther in solid or liquid state, negating the requirement for complicated sample preparation, and facilitating efficient sample screening for multi-component mixtures (i.e. foods).

A major feature of qNMR is that it does not require a standard reference material (RM) that is identical to the analyte. Hydrogen within the molecules can be observed and measured with NMR, so even if the molecules are different, the presence of hydrogen means that quantitative analysis is possible. This is extremely useful for quantification of new compounds and means that calibration curves are not required for this analysis.

False Food Claims

Food characterization is becoming increasingly important due to food fraud scandals around the world and changing consumer attitudes toward what's in their food. As a result of consumers' rising interest in this, there's also increased regulation regarding substantiation of health benefits in order to police false claims. The two together have led to much more scrutiny of labels, and consumers are becoming more confident in reading food packaging, and understanding it and what it means for their health.

Food testing labs are validating that the claims manufacturers are making on their packaging are correct, and the technology available is making this process much easier than it has been in the past.

Traceability is crucial to the global food supply chain as companies are under mounting pressure to understand and implement ways to track and trace their products throughout the food chain and prove authenticity and place of origin. This pressure comes in a bid to improve food safety, but also to ensure security and avoid a public health disaster or negative economic impact.

RMs are indispensable for accurate analysis of hazardous substances in food; however, regulators have not been able to keep pace to provide RMs for the growing number of organic compounds that might require analysis.

Case Study

In collaboration with JEOL Ltd, the National Metrology Institute of Japan im-

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Figure 1. qNMR can allow for quick and accurate quantification of analytes from natural sources when obtaining a reference material is difficult.

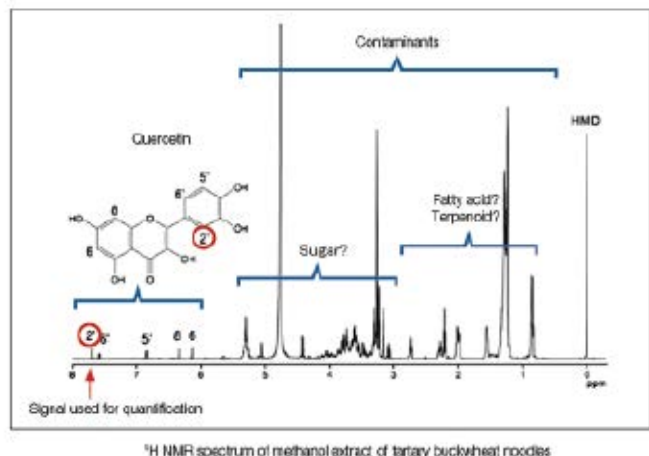
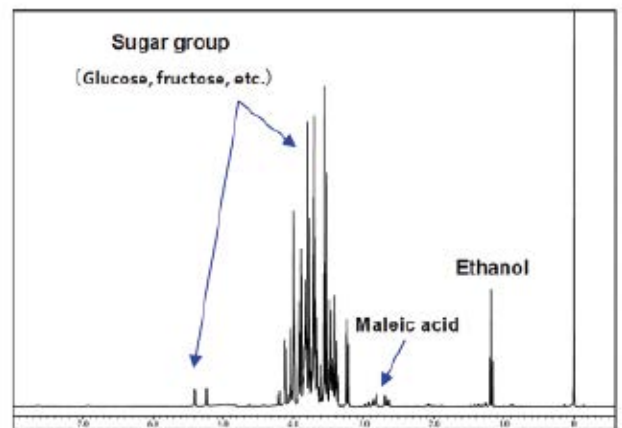


Figure 2. ¹H-NMR spectrum of apple juice.



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proved the ¹H NMR method to perform precise comparisons of signal quantities from protons at different chemical shifts. This enabled quantitative analysis at an acceptable level of uncertainty for a variety of organic RMs by using a primary RM for protons.

NMR thus allows for accurate (and rapid) quantification of analytes derived from natural sources when it is difficult to obtain RM for quantification. Tartary buckwheat contains large amounts of rutin as a functional flavonoid. Quercetin, a flavonoid, can be detected as a degradation product of rutin in samples because there are rutin degrading enzymes in Tartary buckwheat noodles. An NMR system was used to quantify the amount of quercetin found in a sample of noodles, using hexamethyl disilane as an internal reference standard. It was determined that the content of quercetin was 1.58 ± 0.14 mg per gram of Tartary buckwheat. Figure 1 shows the ¹H NMR spectrum of methanol extract of the sample.

The Challenge of Counterfeiting

The USP (United States Pharmacopeia) Food Fraud Database lists hundreds of incidents of economically motivated adulteration, substitution, counterfeiting/mislabeling of food products (e.g. olive oil and milk powder), and some adulterants such as melamine. Techniques like chromatography can provide a detailed profile of food but require a lot of sample prep and manual processes, which means they're expensive and time-consuming.

The food industry needs quick methods for non-specific analysis.

NMR reveals multiple components of food on a single spectrum, with high-throughput analysis. Measurement of the ratio of components can address the issue

A major feature of qNMR is that it does not require a standard reference material that is identical to the analyte.

of adulteration—with qNMR, it is possible to confirm the proportion of a target component in a sample and to determine the absolute amount of the component of interest.

Figure 2 shows a ¹H-NMR spectrum of apple juice, with the signals of ethanol and sugars clear. In this sample, the signals can be viewed separately, allowing for the extraction of both quantitative and qualitative information in an efficient manner, without having to change measurement conditions.

NMR analysis, together with chemometrics, has allowed some important characteristics of food such as geographical origin, genotype-phenotype relation, quality, and authenticity to be investigated. Olive oil is a good example of this application. Complex interactions between the variety of olives, pedocli-

matic conditions, fruit ripening, and agronomic factors make up the composition of extra virgin olive oils. NMR can characterize them in terms of geographical origin, genetic origin, authenticity, and quality.

The Future of Food Testing

Because foods are so diverse and complex, with different compounds and chemical structures, concentrations, solubility, and nutritional values, the technique used for detailed analysis is crucial. With so many challenges around proving the authenticity of food, it's clear that qNMR is a valuable tool for analysis and, importantly, a time-saving technique for food testing laboratories. As food research and development progress and become ever more innovative, the need to prove authenticity, safety, and quality of foods grows in importance.

Although it might be new to many in the food industry, qNMR isn't a new tool for analysis; rather it's an under-used technique that's becoming more popular among analytical chemists due to its growing reputation for making analysis easier.

As industries employing NMR techniques invest in technology capable of ever more complex research and analysis, it's entirely possible that NMR will become a standard method for quantitative analysis in the future. ■

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Manufacturing & Distribution

PACKAGING



HPP: Everything Old is New Again

With its seeds planted in the 1600s, high pressure processing is one of the ‘coolest’ innovations taking food and beverage packaging by storm | BY LINDA L. LEAKE, MS

For Chris Staudt, high pressure processing (HPP) is a key that has opened new doors, professionally speaking. As CEO of Chairman’s Foods, LLC, Staudt oversees production of custom fresh and frozen products for food service and retail customers in a 40,000-square-foot plant at the company headquarters in Nashville, Tenn. and a 38,000-square-foot facility in Columbus, Ga.

“HPP is nothing new,” Staudt says, “but it has opened doors for us, allowed us to provide solutions for our customers that traditional methods would not allow.”

Simply put, HPP is a technique by which food and beverage products, already sealed in final packaging, are introduced

into a vessel and subjected to a high level of hydrostatic pressures (43,500-87,000 pounds per square inch) transmitted by cold water.

Acknowledged by USDA and FDA as a kill step, HPP is a natural process that inactivates *E. coli* O157:H7, *Salmonella*, *Listeria monocytogenes*, and other foodborne pathogens, with minimal impact on a consumable product’s taste, texture, appearance, or nutritional value.

Tracing its roots back to the 17th century, HPP is also called pascalization, as an homage to the French scientist Blaise Pascal who studied the effects of pressure on fluids; bridgmanization, after physicist Percy Williams Bridgman who won the 1946 Nobel Prize for Physics for his work on the physics of high pressures;

and high hydrostatic pressure, abbreviated as HHP.

In June 1899, Bert Holmes Hite published a bulletin entitled “The Effect of Pressure in the Preservation of Milk,” which first documents pressure being used as a food preservation method. Hite is credited as the first person to conclusively demonstrate the inactivation of microorganisms using pressure.

Founded in 1976, Chairman’s Foods started using HPP in 2011. Examples of the company’s products include kettle cooked fillings for chicken pot pies; sous vide cooked proteins; ready-to-eat chicken salads and other prepared items for food service delis and steam tables; and assorted co-pack queso dips for several grocery store chains, including Whole Foods.

Emphasizing chicken salad, Staudt is quick to mention that HPP has helped Chairman’s Foods attract new customers to the wildly popular comfort food.

“Many companies make chicken salad, but, thanks to HPP, we can make it using fresh ingredients, with a longer shelf life, and a clean label with a short list of ingredients void of powders and preservatives,” Staudt explains. “Since we are not stuck with old processing traditions, we have new opportunities.”

Chairman’s Foods utilizes the HPP services of Universal Pure, shipping products to the latter’s facilities in Villa Rica, Ga., Coppell, Texas, and Lincoln, Neb. From those locations, Chairman’s arranges shipping to its customers once HPP is completed.

HPP is typically used to enhance food safety and extend product shelf life, which is the technology’s biggest economic impact, says Mark Fleck, an HPP consultant for Universal Pure. “Because HPP addresses typical spoilage organisms such as bacteria, yeast, and mold, producers realize significant shelf life increases often a two to four times improvement,” he relates. “More times than not, HPP becomes a critical control point in a food produc-

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er's Hazard Analysis and Critical Control Points (HACCP) plan."

Another benefit, Fleck mentions, is that HPP can also serve as a package leak detector. "HPP uses simple water pressure which is applied uniformly (isostatic) to the packages," he notes. "If the package integrity is faulty, operators can remove the defective packages post HPP, thereby delivering 100 percent quality packaged products to their customers. Food producers can reduce or eliminate credits and chargeback expenses."

According to Fleck, the added shelf-life benefit of HPP produces savings across the production and distribution spectrum. "Manufacturers may be able to produce the product less frequently and in larger batches, thereby making their operation more efficient," he explains. "Logistics may have the option to ship full truckloads rather than LTL (less than truckload) shipments, thereby obtaining better rates. And, extended shelf life helps retailers reduce stocking frequency and minimizing out of code date products."

Impact on Food Packaging

"The first and major consideration when selecting packaging for HPP is that the package will be submerged in water during the process," Fleck says. "Secondly, some flexibility must be a part of the package."

Fleck notes that these requirements can be addressed by selecting a plastic bottle, bag, stand-up pouch, or utilizing form-fill-seal packaging technology. "Many semi-rigid cups with heat sealed lidding films perform well," he points out. "And there are a variety of peelable lidding films available to make the package more consumer friendly."

From a material perspective, there are numerous options to choose from, Fleck says. "For example, PET (polyethylene terephthalate), HDPE (high-density polyethylene), and PP (polypropylene) are excellent choices," he relates. "If barrier properties are desired, EVOH (ethylene vinyl alcohol) or nylon can become a layer in co-extruded films."

Label type is another important element of successful HPP, Fleck adds. "Think in terms of non-paper-based labels suitable for food packaging," he advises. "Don't forget to take in to account



An employee loads meat, sealed in its package, into the HPP canister where it will be subjected to isostatic water pressure.

Another benefit, Fleck mentions, is that HPP can also serve as a package leak detector.

that the label adhesive will also be exposed to moisture. A popular alternative is to print the label directly on the food package or one can apply the label post HPP."

Grant Lorsung, president of True Fresh HPP, Buena Park, Calif., says the effect of HPP on food packaging has been monumental. "While speaking recently with a large supplier of plastics, they mentioned that just five years ago they were not going to waste time on developing specific resins or packaging offerings for HPP," he relates. "But HPP is revolutionizing the food packaging industry, and even this particular plastics supplier has since developed a full catalog of films and containers of all sizes and shapes designed specifically for HPP."

Packaging manufacturers focus on understanding the design to handle the HPP process, Lorsung mentions. "To that end, special fitments on spouts, welds on edges, and shapes to withstand HPP pressures are being incorporated into HPP packaging," he says.

Offering HPP services since 2015, True Fresh HPP operates four Hiperbaric 525 processors, with a total annual capacity of 100 million pounds. The portfolio of food products that True Fresh HPP processes includes hummus, salsas, deli meats, marinated meats, cold-pressed juices, sauces, vegetables, spreads, milk, nut milks, cheese, sausage, cold coffee drinks, baby food, and pet food.

In March 2018, True Fresh HPP launched a partnership with NutriFresh Services, Edison, N.J., an HPP and cold-pressed juice manufacturing facility. By combining True Fresh's four Hiperbaric HPP machines with NutriFresh's three Hiperbaric HPP units, the merger creates a HPP tolling enterprise with a capacity of 200 million pounds annually.

"This is a process that is just in the infancy stages," Lorsung emphasizes. "As the U.S. consumer begins to realize just how much better it is for food safety and quality, HPP technology will continue to grow at an exponential rate. Because HPP is a cold process, it does not alter the food product, and no artificial preservatives or additives such as color or flavor are needed. Vitamins and minerals remain intact after HPP, and taste, texture, and appearance all remain the same."

HPP Validation Center

Cornell University opened the HPP Validation Center at its Geneva, N.Y., campus on Feb. 1, 2017.

The CPC has developed a High Pressure Certified logo that members can use after their HPP process, HACCP plan, and validation studies are verified by a third party audit...

According to Randy Worobo, PhD, a professor of food microbiology in Cornell's Department of Food Science, three types of customized services are offered at the 1,500-square-foot Center: HPP safety validation studies, microbiological shelf-life studies, and physicochemical evaluations. The Center features a 55-liter commercial Hiperbaric HPP unit.

"We do the full range of validation studies for bacterial pathogens and protozoan parasites," Dr. Worobo relates, noting that since the Center is designated biosafety level 2, *Clostridium botulinum* is not tested there. "Our pathogen validation studies are conducted with 5-strain cocktails using isolates that are from similar sources. We can perform HPP pathogen validations and shelf life determinations for a variety of foods that include juices, meats, purees, wet salads, etc. Due to the HPP unit being part of a biosafety level 2 laboratory, no processing for commercial sale is permitted."

In just over a year, more than 100 pathogen validation studies have been performed at the Center for a whole gamut of products, Dr. Worobo reports. "Many of these products are already commercialized and being sold in the marketplace across the U.S.," he notes.



The CPC's High Pressure Certified logo can be used by members after their HPP process, HACCP plan, and validation studies are verified by a third-party audit.



The state-of-the-art Hiperbaric HPP machine at Cornell's New York State Agricultural Experiment Station.

Cold Pressure Council

In March 2017, the Cold Pressure Council (CPC) was launched with a mission to lead, facilitate, and promote industry standardization, user education, and consumer awareness of HPP, according to Joyce Longfield, MS, vice president of product innovation, Good Foods Group, LLC, Pleasant Prairie, Wis., and CPC chair.

Managed by PMMI, The Association for Packaging and Processing Technologies, Reston, Va., the CPC was formed by nine member companies that contributed time, talent, and financial resources to establish the Council on a firm footing, Longfield says.

"Currently boasting more than 20 members, the CPC includes companies that have and use HPP equipment, such as machinery manufacturers and processors; suppliers of materials associated with HPP, including packaging; and regulatory and academic professionals," she relates. "Our long-term goal is to be a global organization." Good Foods and Universal Pure are two of the founding members.

The CPC has developed a High Pressure Certified logo that members can use after their HPP process, HACCP plan, and validation studies are verified by a third-party audit, and after paying the CPC licensing fee of \$250 per stock keeping unit per year. Brands that recently started using the logo include Good Foods, Evolution Fresh, and Suja Juice, Longfield notes.

The logo program reflects the goal of the Council, which has always been twofold, Longfield says. "First, we want to create uniformity among the HPP industry through consistent use of the technology that meets regulatory requirements," she points out. "To do so, we provide guidance on using HPP as either a CCP or for shelf life extension. This led to creating the logo program for companies that wanted to demonstrate support for consistent validation for use of the technology. The logo program also provides organizations support in bringing awareness to the consumer."

Second, the Council strives to grow consumer awareness of the benefits of HPP food, and ultimately consumer demand for these food and beverages, Longfield continues. "The website for the logo, expected to be up and running by the end of the summer of 2018, will be separate from that of the Council and will have the look and feel similar to that for non-GMO products, where the information provided is to educate the consumer on HPP benefits," she says. "The logo website content will not be overly scientific, but rather will be information that's easier to digest." ■

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For extended coverage on HPP, go to the August/September 2018 issue on www.FoodQualityandSafety.com.

Packaging Smarter

The value of smart machines is being realized throughout the food industry as they address quality, productivity, and security concerns

BY STEVE MULDER



Smartphones and other connected devices have made our lives easier in countless ways. In the industrial world, smart machines are performing a similar feat.

Smart machines are defined by their powerful digital capabilities, like real-time diagnostics, seamless connectivity, and contemporary safety technologies. But what makes the machines revolutionary is how these capabilities make industrial operations more competitive.

In food packaging, smarter and higher-performing machines are helping make operations more flexible to accommodate product varieties and different packaging sizes. They also maximize productivity, improve quality, and enhance safety, even as packaging becomes more complex.

Business Value

Smart packaging machines can help food companies address their most pressing business needs.

For example, smart machines present new ways to protect product quality, especially as packaging operations evolve and become more complex.

Gebo Cermex, a packaging and palletizing equipment maker, recently introduced a modular infeed system to help food and CPG producers meet a key need: mass customization. The system is compatible with any bottle shape and dimension and can feed up to 400 bottles per minute. One challenge was how the system

would group bottles to the packing lines. The traditional “screw” method meant bottles could spend up to 12 seconds in the infeed, resulting in labels or bottles being marked, scratched, or dented.

The company chose to use an intelligent track system with independently controlled movers to help protect bottle and label integrity. The system’s movers are in contact with the bottle for only 0.3 seconds—20 times less than a screw approach. The system also uses intelligent bottle-flow management to avoid products piling up and bumping into each other.

Smart machines can also inherently improve productivity and efficiency in food packaging operations.

They can connect to sensors and devices and use intelligent software to enhance machine control. By combining standardized information reporting with standardized machine functionality, they can help drive continuous improvements in OEE.

But smart machines can also improve productivity in new and creative ways. For instance, a packaging OEM developed a remote-monitoring solution for its packaging equipment. The solution allows customers to monitor equipment statuses both on and off the plant floor using mobile technology. It allows the machine builder to offer remote-monitoring services to better maintain a machine’s health and improve its overall performance.

In addition, smart machines can deliver value with modernized safety. By using contemporary safety technologies that integrate safety and machinery control into one system, smart machines are less prone to nuisance shutdowns than hardwired safety systems, resulting in a more productive machine. They also provide access to safety-system data, which safety and operations professionals can use to better understand risks and improve compliance and reduce safety-related downtime.

Optimizing the Design

The right connectivity and performance levels are paramount in a smart packaging machine’s design.

From a connectivity standpoint, the machine should be able to communicate in real time on an IP-based, standard, and unmodified Ethernet network infrastructure. EtherNet/IP, a trademark of ODVA, Inc., is one example of a proven network technology. It supports a simple network architecture and can handle multiple control and safety applications.

At the system level, a smart packaging machine should make use of the latest integrated control and information technologies. These technologies deliver increased performance, easier access to information, and reduced machine complexity—all of which are ideal for smart machines.

For instance, new control options provide anywhere from 20 percent to 45

percent more application capacity. This can help simplify a machine's design complexity while meeting more demanding packaging applications. Also, these controllers include up to 1-gigabit Ethernet ports to support more data-driven operations.

It's also worth considering how a smart packaging machine leverages device integration to impact everything from design time to maintenance. Smart machines that take advantage of advanced integration between controllers and devices can consolidate controller programming, device configuration, and operation and maintenance activities all into one software environment.

This advanced integration brings benefits to the design stage. For example, it allows packaging machine builders to leverage library management to store, manage, and reuse code, which can reduce development time.

But the benefits of advanced integration also extend into production. It can help operators and technicians with more predictive diagnostics, faster sys-

tem upgrades or replacements, and faster troubleshooting.

Managing Security

Security continues to be top of mind as food companies move to more connected, information-enabled operations.

Indeed, new connections on machines can create opportunities for security threats. And those threats can come in many forms: physical or electronic, remote or onsite, malicious or unintentional.

That's why smart packaging machines should support a defense-in-depth security approach. Defense-in-depth security is a security best practice based on the idea that any one point of protection can, and likely will, be defeated. It uses layers of security to mitigate such threats and help protect intellectual property, safeguard operations, and secure remote-access connections.

Defense-in-depth security spans six different layers of security. Some of these layers, and potential security measures that can be applied within them, include the following.

Application security. Security measures can be used to manage access and prevent changes at the manufacturing application level.

Authentication, authorization, and accounting software can restrict and monitor application access and changes. Tamper-detection capabilities can track unwanted application modifications. And a role-based access control system can limit worker access to critical process functions or require that they enter login information before accessing applications.

Device security. Device authentication and identification can help make sure only trusted devices are used in food packaging.

Food producers can also change the out-of-the-box configurations for embedded devices to help make them more secure. For example, companies can control which tags can be modified from HMIs and external applications. Or they define tags as constants, which cannot be modified by controller logic.

Physical security. In addition to securing access to their plants or facilities,

(Continued on p. 48)

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Did You Know?



While many individuals have helped lower costs and preserve quality, Malcom McLean and Barbara Pratt deserve special mention for creative ways they reshaped and fostered the cold chain | BY **CHUCK DINERSTEIN, MD, MBA, FACS**

The “value” of food can be simplistically quantified by a formula: Value = Quality/Cost. While many individuals have helped lower costs and raise and preserve quality, two deserve special mention for the creative, disruptive ways they helped reshape and foster today’s global food supply.

Cost

Maxton, N.C., was struggling as the Great Depression’s grip on America’s economy tightened in the early 20th century. Settled by the Scottish in the late 1700s, Mack’s Town was shortened to Maxton, a more fitting and proper name for a place that was becoming a railroad center. But as local timber disappeared and farm prices plummeted, even the railroad couldn’t keep Maxton’s economy from the margins.

By all accounts, Malcom McLean was a bright boy with good prospects. But typical of the time, his family’s income was insufficient for him to go on past high school, especially in the mid-1930s. So McLean did what he could, driving a truck,

moving empty tobacco barrels around the state. While family finances limited his educational reach, perhaps they fueled his desire for economic stability, even growth. He and his two siblings formed a small trucking company; McLean still driving, but now bringing cotton up north for export.

With U.S. Highway 1, the main route north more a cobbling of established roads than a real interstate, it took far longer to get to New York’s ports than it takes today. And once he arrived, his trip was only beginning.

The cotton was off-loaded from McLean’s truck only when the stevedores who handled ships’ cargo had a place to put it on the pier, so it could then be hoisted into the ship’s hold. And whether McLean was patient or not, it must have seemed a waste of time for a man in a hurry to “turn and burn.” There had to be a better way.

Maybe it is apocryphal or maybe it’s true, but it’s rumored during his trip up north, McLean asked, “Why couldn’t an entire truck be hoisted aboard ship, for

instance, and then used for delivery purposes at the other end of the line?”

It took McLean another 20 years to realize his vision. Loading an entire truck and its contents wasted too much precious space, so he had to develop containers. And cargo ships had to be redesigned to accommodate these newly created and standardized containers.

Malcom took a World War II tanker and retrofitted its deck to carry his new containers, and in 1956 the first container ship sailed out of Newark, N.J., with 58 containers that six days later were unloaded in Houston. It took some time, but the wake of that shipment was felt globally and it changed the face of the shipping industry, remaking ship and harbor design, creating a new manufacturing sector for containers—while, it should be noted, decimating an established workforce and their union. When all was said and done, the cost of loading a ship was reduced from \$5.86 per ton to 16 cents.

Quality

The history of food refrigeration for transportation dates back centuries. In the early 1800s, Frederic Tudor, “The Ice King” of Massachusetts, developed a means to harvest the ice formed on lakes and ponds during New England’s winter, and subsequently transported the ice to the far warmer climes, even the sun-soaked Caribbean.

At his peak he was sending ice to India, 12,000 or more nautical miles away. Having demonstrated the ability to ship ice, it was only a small step to use ice for protecting perishable produce. Food grown in one part of the country could be packed in ice and transported by rail across to the other. In fact, the name for iceberg lettuce is claimed to come from the piles of ice packed in with the lettuce when it was shipped by railcar.

While containers had lowered shipping costs, they remained less than ideal. Simply placing a refrigeration unit in a container was not working; some goods arrived in good condition, others were ruined. Saving money on shipping only to be lost to spoilage was not a great bargain.

Sea-Land, the company McLean started, needed a better box. It found an answer during the late 1970s in Barbara Pratt, a newly graduated physics major



from Cornell University who spent the next several years in a laboratory investigating what was then the little-known science of refrigerated transportation—otherwise known as “the cold chain.”

Her first project: moldy cocoa beans.

According to Pratt, “What happens typically is when the sun comes up the temperature increases inside a dry container, that would create a mini oven, and that draws the moisture out of the beans...And what happens when sun goes down at the end of the day, the water then condenses out of the air because the air temperature changes. It would then become water droplets [and] drop onto the bags of cocoa beans, and when you have excess moisture you would then have mold growing.”



To investigate what was a “black box” in terms of actual conditions in containers, Pratt made use of a unique laboratory: another container.

A 40-foot container (evidently the standard of its time) was retrofitted with living quarters on one end and laboratory space, computers, and sensor cabling occupying the rest. The Mobile Research Lab, like any other container, was placed aboard a ship, the cabling connected to sensors in containers carrying perishables and the actual environment within the containers studied at sea.

Pratt’s findings for cocoa beans resulted in changed airflow patterns. In the course of her research, she and her team looked at over 100 commodities and their

findings resulted in new container designs that incorporated customized ventilation, airflow, and temperatures for a range of fresh produce. In many ways, Pratt’s re-designing of McLean’s original containers, now called reefers, made today’s cold chain possible.

An estimated 70 percent of what we eat today passes through the global cold chain. American consumers may not be aware of McLean and Pratt, or of the advances we have made in cold chain logistics. But through their efforts, as well as the work and thoughts of many individuals, the global distribution of fresh food and perishable pharmaceuticals is helping feed the hungry and care for the ill in ways that were unthinkable 50 years ago.

And that is real value. ■

Dr. Dinerstein is a Senior Medical Fellow at the American Council on Science and Health. Reach him at ordinerstein@gmail.com.

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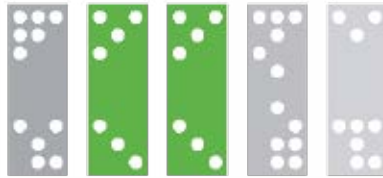
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Listeria PatternAlert assay rapidly identifies molecular patterns from *Listeria* strains to assist food producers in identifying harborage sites for persistent *Listeria* and in tracing back sources of contamination. The assay, which is performed using the fully automated Encompass Optimum workstation, enables users to detect molecular patterns in just six hours directly from a



positive enriched sample, without the need for an isolate. Each result can be matched against a user's specific PatternAlert database to identify their pattern matches across locations and time. Each pattern generated by the assay encompasses a group of strains and may include multiple species of *Listeria*. **Rheonix, 607-257-1242, www.rheonix.com.**

Detectable Rubber Gloves

Powder-free metal detectable gloves are made from natural rubber and the anti-slip patterned finish provides a good grip in wet and dry conditions. Designed for safe use in food processing, the gloves comply with FDA and EU regulations for contact with food. The metal detectability reduces the risk of contaminated products and the bright blue color makes them highly visible if lost in the process area. Gloves have a higher resistance to tearing with a specification for an 0.018-in. thickness. Extra benefits are derived from the bacteriostatic and fungistatic additives that prevent the growth of microbial contaminants. In addition, the low level of soluble proteins reduces the risk of negative skin response. **Detectamet, 844-820-7244, www.detectamet.com.**

Desktop Color Label Printer

With print speed up to 4.5 in. per second, the LX910 can handle labels as wide as 8 in. and as small as 0.75 in. According to the company, banding is virtually eliminated—even on the faster print speeds. Both dye-based ink and pigment ink work interchangeably on the same printer, while a new print head is provided each time the cartridge is changed. Typical applications include product labels for coffee, wine, water, bakery, confectionary, meat, cheese, and other specialty and gourmet foods. The printer is also ideal for manufacturing, laboratory, government, retail, and a wide variety of other markets. **Primera Technology, Inc., 800-797-2772, www.primera.com.**



Mix Proof Valves

Offering minimized CIP fluid losses, the D4 Series of mix proof hygienic valves is used for the separation of dissimilar products across the food and beverage, dairy, and brewing process industries. All D4 valves are fully balanced for dependable operation against pressure spikes and flow in any direction. Automated processing is enhanced with the option of a unique control unit with integrated seat lift detection and no external sensors. Compressed air or lifting tools are not required for removal and service. The D4 range includes the primary D4 model, which meets the basic needs for reliable product separation and seat lift or non-seat lift cleanability, and the DA4 ultra-hygienic model for critical applications requiring enhanced cleanability of all product contact surfaces. For applications where the current generation DA3+ housing is reliably in place, the DA4 can be inserted to provide an efficient upgrade, future-proofing existing installations with minimal disruption and risk. **SPX FLOW, Inc., www.spxflow.com.**



Magnetic Pull Test Kit

The newly designed pull test kit includes an improved polarity indicator to allow users to verify the pole configuration of the separation equipment. Another useful feature of the indicator shows the user how far the magnetic field actually extends beyond the surface of the magnet, which helps determine spacing between cartridges for a given application. The optional version has a digital scale that comes with NIST calibration check certificate. While all industries should utilize a pull test on their magnetic separators, the company emphasizes that with the attention on food safety being so high, it's required in every facility that transports, processes, or packages food. **Bunting Magnetics, 800-835-2526, www.buntingmagnetics.com.**



Rapid Molecular Fingerprinting

The DART QDa System with LiveID is a direct-from-sample analytical system that allows laboratories to answer questions such as: Is the sample authentic? Has the composition of the sample changed? Is the sample quality good or bad? Direct Analysis in Real Time (DART) is a direct and rapid analysis technique for various sample types with minimal sample preparation and no requirement for a chromatographic separation. The source directs heated, ionized gas at the surface of the sample between

the DART interface and the QDa detector where the ionized molecules are detected. The LiveID software provides the user with the capability to train and validate multivariate statistical models using the chemical profile obtained from the DART QDa analysis. The LiveID models can be used to classify the identity of unknown samples, generating results in near real time and a simple yes/no answer in seconds. **Waters Corp., 800-252-4752, www.waters.com.**



Monitoring Perishable Shipments

The GO Real-Time Reusable Tracker, a new version of the GO Real-Time Tracker, allows users to recharge and reuse the device. It provides visibility of location and temperature of perishable shipments in real time, via a cellular connection. It's suitable for use in scenarios where customers own their own trucks and/or control both the start and end point of a shipment. **Emerson, 314-553-2000, www.emerson.com.**

Wine pH Tester

The Wine pH tester (HI981033) is engineered to solve the challenge of measuring samples with a higher solids content. The ideal pH tester for wine making, this tester is crafted to measure the pH in juice, must, and wine. The company says the probe features Clogging Prevention System sleeve junction technology that resists clogging up to 20x longer than a standard ceramic frit. A spherical glass tip design allows the probe to come in direct contact with a wider area of the wine sample for a faster pH measurement. Equipped with a glass body, the electrode is easy to clean and chemically resistant. The glass body is also able to quickly reach a thermal equilibrium. **Hanna Instruments, Inc., 800-426-6287, <https://hannainst.com>.**

NGS-Based Platform for Pathogen Testing

Clear Safety is an end-to-end NGS-based food safety platform for high-volume routine pathogen testing. According to the company, by combining NGS sequencing, advanced microbiology, robotic automation, data science, and software analytics, a 99.9% accuracy can be achieved while lowering costs. The platform collects hundreds of millions of data points per analysis to learn everything about a pathogen in a single test. The first release of the platform supports high-volume *Salmonella* testing. *Listeria* and *E. coli* testing will be rolled out in 2019. All tests go from sample to answer in under 24 hours. **Clear Labs, 650-257-3304, www.clearlabs.com.**

X-Ray Source

The XRBHR series of monoblock X-ray sources are designed for OEM applications powering their internal bipolar X-ray tube to 80kV and 100kV at power levels of 100W, 210W, 350W, and 500W. Features such as universal input, compact package size, and standard RS-232 or Ethernet digital interface simplify integration of any XRBHR model into a user's X-ray system. These intelligent power supplies monitor and log over two dozen operations, using a real-time clock to record total X-ray ON time. Each XRBHR model is available with fan (standard) or cone (optional) beam geometries. **Spellman High Voltage Electronics Corp., 631-630-3000, www.spellmanhv.com.**



In Other News

3M Food Safety's Petrifilm Rapid *E. coli*/Coliform Count Plate receives PTM Certificate number 051801 from AOAC Research Institute.

Hygiena's BAX System assays now meet new ISO 16140-2 standard for all AFNOR-approved methods.

NSF International expands its commercially available DNA analysis services for food safety and supply chain management to include NGS techniques.

Q Laboratories now has norovirus and hepatitis A testing in food, water, and environmental samples listed on its ISO 17025 Scope of Accredited Methods.

Gelest's BIOSAFE HM4100 antimicrobial receives certification from NSF International for food contact and drinking water applications.

SGS gets accredited as a Certification Body for the Aquaculture Stewardship Council Certification scheme, which covers standards relating to farming 12 species of seafood and a joint ASC-MSC standard for seaweed.

Packaging Smarter

(Continued from p. 43)

companies also should secure entry points on their physical network infrastructure. Control panels, cabling, and network components, like routers, switches, and gateways, need to be protected against intrusions, tampering, and accidents.

Lock-out devices can prevent the unwanted removal of data and virus uploads by restricting unauthorized access to USB ports. And lock-in devices can keep vital connections in place and

reduce the potential for unauthorized cable removals.

Be Future Ready

As smart machines continue to be embraced by the food industry, it's not only important to consider how the machines will fit into production today, but also in the future.

The number of smart devices connecting to smart machines will only grow, as will the volume of data that smart ma-

chines must handle. That's why companies should make sure the smart machines they invest in today are future-ready, with the capacity to support additional technologies and more information.

After all, technology advances happen quickly. And smart machines will be more relevant and a greater competitive differentiator if they can keep pace with those advances. ■

Mulder is regional segment manager for packaging at Rockwell Automation. Reach him at scmulder@ra.rockwell.com.

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26-29

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Call 301-924-7077 ext. 170
or email CustomerService@aoac.org.

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18-19

Dairy Supplier Food Safety Management Workshop

Rosemont, Ill.
Visit <http://www.usdairy.com/events>
or call 847-627-3249.

25-27

IAFP's 6th Latin America Symposium on Food Safety

Buenos Aires, Argentina
Visit <http://www.iafp-latino2018.com.ar>.

OCTOBER

14-17

Pack Expo

Chicago
Visit <https://www.packexpointernational.com>.

16-18

Food Safety & Sanitation Short Course for Food Manufacturers

Pennsylvania State University
Visit <http://agsci.psu.edu/sanitation>, call 814-865-8301, or email CSC0@psu.edu.

16-18

HACCP Plan Development for Food Processors

New Brunswick, N.J.
Visit <http://www.cpe.rutgers.edu/courses/current/lf0403ca.html>, call 848-932-7234, or email suzanne.hills@rutgers.edu.

23-25

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FEBRUARY

12-14

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SCIENTIFIC FINDINGS

For access to complete journal articles mentioned below, go to “Food Science Research” located in August/September 2018 issue at www.FoodQualityandSafety.com, or type the headline of requested article in search box.



ARTICLE: Shrinkage of Food Materials During Drying

Shrinkage of food materials during drying is a common physical phenomenon that affects the textural quality and taste of the dried product. The shrinkage of food material depends on many factors including material characteristics, microstructure, mechanical properties, and process conditions. Understanding the effect of these influencing factors on deformation of fruits and vegetables during drying is crucial to obtain better-quality product. The main aim of this study is to critically review the existing theoretical shrinkage models and present a framework for a theoretical model for the shrinkage mechanism. It also describes the effect of different drying conditions on material shrinkage, how the diverse characteristics of fruits and vegetables affect shrinkage propagation, and the challenges in developing a physics-based shrinkage model. **Comprehensive Reviews in Food Science and Food Safety, July 18, 2018, online version.**

ARTICLE: Integration of Biomedical Technologies in Meat Processing

Modern-day processing of meat products involves a series of complex procedures to ensure the quality and safety of the meat for consumers. As the size of abattoirs increases, the logistical problems associated with large-capacity animal processing can affect facility sanitation and the meat products, potentially increasing transmission of infectious diseases. And spoilage of food from improper processing and storage increases the global economic and ecological burden of meat production. Advances in biomedical and materials science have led to innovative new antibacterial technologies, which have broad applications in the medical industry. Additionally, new approaches in tissue engineering and nondestructive cooling of biological specimens could improve organ transplantation and tissue grafting. These same strategies may be even more effective in the preservation and protection of meat. This review presents potential applications of emerging biomedical technologies to improve meat safety and quality. Future research directions investigating these new technologies and their usefulness in the meat processing chain along with regulatory, logistical, and consumer perception issues are also discussed. **Comprehensive Reviews in Food Science and Food Safety, Volume 17, Issue 3, May 2018, Pages 615-632.**

ARTICLE: Effects of Gamma Radiation Combined with Cinnamon Oil on Smoked Salmon Slices Inoculated with *Shewanella putrefaciens*

Smoked salmon slices inoculated with *Shewanella putrefaciens* were untreated (CK) or treated with 2 kGy gamma radiation (G), 1% (v/v) cinnamon oil (C), or the combination of them (G+C), and then packaged and stored at 4°C for 10 days. Microbiological and physicochemical analyses were then carried out. This review discusses how all treatments showed a better effect on inhibiting the increase in total viable counts, total volatile basic nitrogen, and thiobarbituric acid-reactive substances than CK, especially the treatment of G+C. It also discusses how the combination treatment also showed a best effect on retarding the reduction in polyunsaturated fatty acids of salmon samples in all treatments. These results indicate that treatments of gamma radiation and cinnamon oil on salmon samples, especially the combination treatment, can be used to maintain the quality of smoked salmon slices. **Food Science & Nutrition, Volume 6, Issue 4, June 2018, Pages 806-813.**



ARTICLE: Microbiological Changes and Their Impact on Quality of Red Hot Chili Pepper Mash During Natural Fermentation

Production of hot sauce may require fermentation of red hot pepper mash in barrels from two weeks up to three years. The purpose of this study is to evaluate the microbiological changes and their impact on quality characteristics of red hot pepper mash during natural fermentation over a period of 18 months. Aerobic plate count, lactic acid bacteria, and yeast counts, as well as changes in pH, acid content, color, and aroma of red hot pepper mash, were analyzed. Lactic acid bacteria and yeast presented a symbiotic association throughout the fermentation process. Significant pH reduction was observed, with an inverse correlation with acid content. Aroma was analyzed based on six volatile compounds that had a significant increase during the first 60 days of fermentation, followed by a significant reduction after 300 days. **Food Science + Technology, Volume 53, Issue 8, August 2018, Pages 1816-1823.**

A row of stainless steel hand dryers is installed in a kitchen sink area. The dryers are sleek and modern, with a cylindrical design. In the background, a person wearing a white lab coat is visible, suggesting a professional or industrial setting. The lighting is bright and clean, emphasizing the hygiene of the environment.

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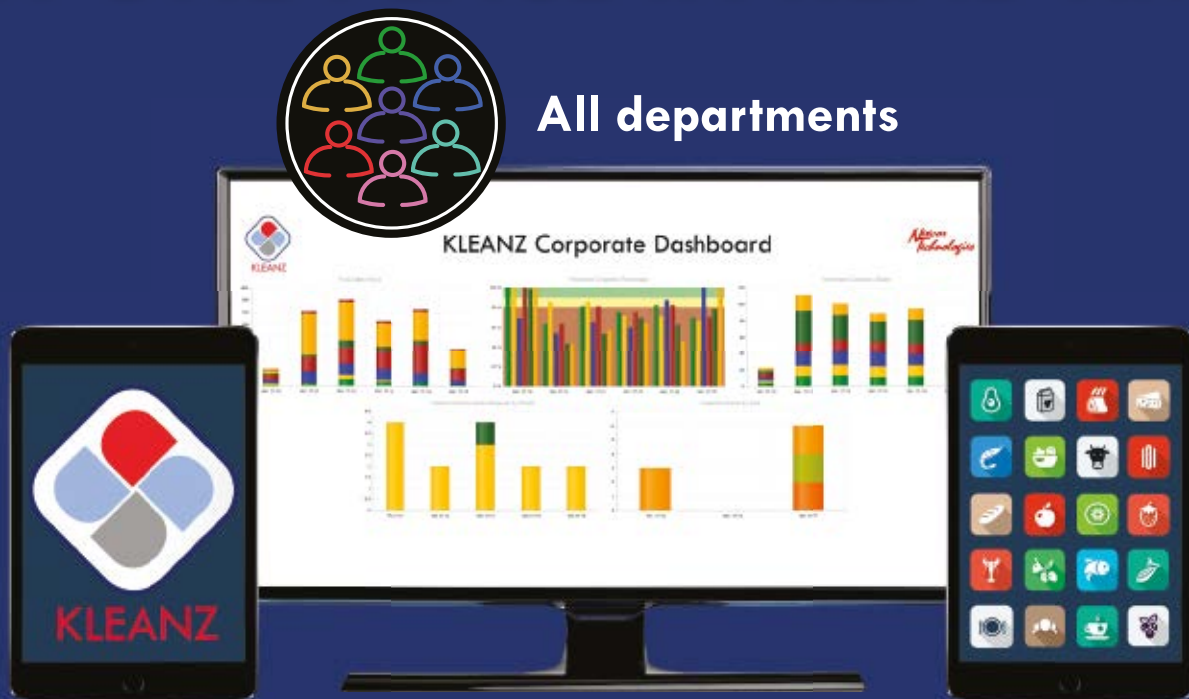
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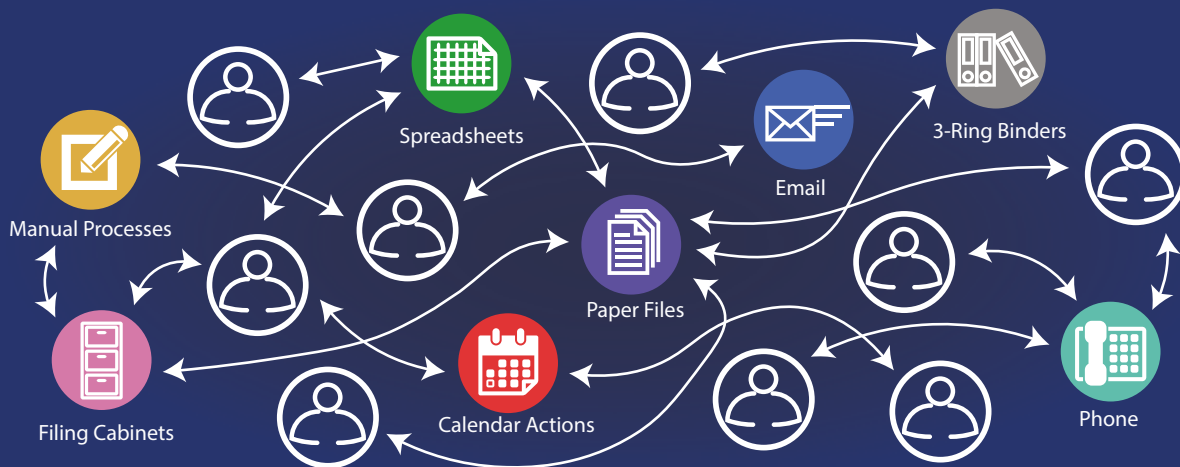
¹Dry time measured using Dyson test method 769 based on NSF P335 using a measurement of 0.1g residual moisture.

²In collaboration with Carbon Trust, Dyson has produced a method to measure the environmental impact of electrical appliances and paper towels. The carbon calculations were produced using GaBi software providing by PE International, based on product use over five years and using the U.S. as a representative country of use. Dry times for products were evaluated using DTM 769.

EVERYTHING FOOD SAFETY IN ONE PLACE IN REAL-TIME

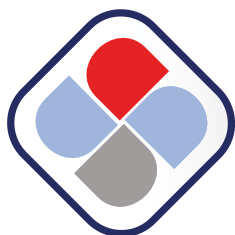


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