PLUS Extended Coverage on Disinfecting and Sanitizing ■ The Conundrum of Cannabis-Infused Products

Volume 24 Number 4
AUGUST/SEPTEMBER 2017

Food Quality & Safety

FARM TO FORK SAFETY

FIGHTING AGAINST FOOD PATHOGENS

New microbiological technologies help industry keep up with increased government scrutiny

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From The Editor

The agriculture sectors are applauding the EPA's move in late June to formally repeal the 2015 Waters of the U.S. (WOTUS) rule. Rather than viewing the rule as an aid to ensure clean water, the industry saw it as burdensome and confusing—negatively impacting America's businesses, farmers, and land owners. As a result, Scott Pruitt, EPA administrator, signed a proposed rule on June 27 to rescind the rule and re-codify the regulatory text defining "waters of the U.S."

"We are taking significant action to return power to the states and provide regulatory certainty to our nation's farmers and businesses," said Pruitt. "This is the first step in the two-step process to redefine 'waters of the U.S.' and we are committed to moving through this re-evaluation to quickly provide regulatory certainty, in a way that is thoughtful, transparent, and collaborative with other agencies and the public."

Bill Kovacs, senior VP of environment, technology, and regulatory affairs, U.S. Chamber of Commerce, approved the move to fix WOTUS. "The final WOTUS rule issued by the last administration was unworkable, a fact acknowledged by courts around the country, and amounted to a massive grab of regulatory authority by an EPA that was overreaching," he said. "We look forward to working with Administrator Pruitt and his team to craft a rule that protects public health and the environment, while giving clarity and certainty to our nation's farmers and job creators."

The American Soybean Association agreed. "Farmers cannot operate without clean water, and each of us takes his or her role as a steward of that resource very seriously," said John Heisdorffer, VP and Iowa farmer. "The WOTUS rule, however, subjected the creeks and streams and ditches that crisscross our operations under an overly broad, one-size-fits-all regulatory definition that made no sense for our individual farms."

Further, Zippy Duvall, president, American Farm Bureau Federation, argued the original rule was never really about clean water. "It was a federal land grab designed to put a straightjacket on farming and private businesses across this nation. That's why our federal courts blocked it from going into effect for the past two years...EPA should ditch this rule once and for all, go back to the drawing board, and write a new rule that protects water quality without trampling the rights of businesses and the states."

The proposed Definition of "Waters of the United States" rule is open for public comment until Aug. 28, 2017, so be sure to add your two cents via www.regulations.gov.

Marian Zboraj
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FARM TO FORK SAFETY

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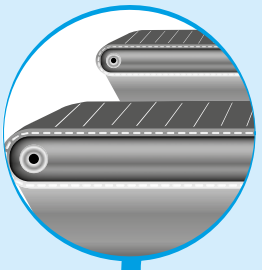

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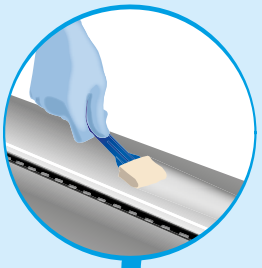

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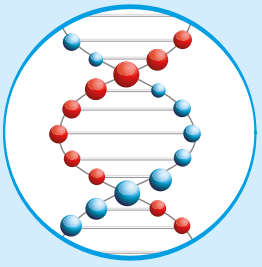

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NEWS & NOTES

Interventions on Farms and Feedlots

The "Food Safety From Farm to Fork" report from the Pew Charitable Trusts examines food safety control measures currently used on farms and feedlots or that might be employed in the future. This report assesses pre-harvest interventions aimed at reducing the level of the major foodborne pathogens—*Salmonella*, *Campylobacter*, and *E. coli* O157:H7—that can lead to the contamination of meat from poultry, swine, and cattle. These pathogens are included in this examination because they account for a substantial proportion of infections linked to meat and poultry consumption, and research on pre-harvest interventions has focused primarily on them.

Business Briefs

Orkla Food Ingredients signs a license agreement with **Renaissance BioScience** to exclusively produce and sell Renaissance acrylamide-reducing yeast in European Nordic and Baltic markets.

New **Nelson-Jameson** facility opens in Amarillo, Texas.

Sterigenics International completes a $16.8 million expansion to its West Memphis, Ark., facility, nearly tripling the facility's gamma sterilization capacity.

NSF International opens office in Bogotá to aid Columbia's growing food industry.

Roka Bioscience enters into a two-year non-exclusive supply agreement with **PURE Bioscience** to market PURE's line of antimicrobial disinfecting and sanitizing processing aids to food industry.

Brexit's Impact on Food in the U.K.

The "A Food Brexit: Time to Get Real'" report published by the Science Policy Research Unit at the University of Sussex suggests that the U.K. is unprepared for the most complex change to its food system, which will be required before Brexit. The paper, by leading food policy specialists Professor Erik Millstone (University of Sussex), Professor Tim Lang (City, University of London), and Professor Terry Marsden (Cardiff University), concludes that leaving the EU poses serious risks to consumer interests, public health, businesses, and workers in the food sector. Its authors claim that this is because there is no government vision for U.K. food or agriculture, yet prices, quality, supply, and the environment will all be adversely affected even with a "soft" Brexit. They warn that British consumers have not been informed about the "enormous" implications for their food, a third of which comes from within the EU.

USDA Deputy Secretary Nomination

President Donald J. Trump nominates Stephen Censky, CEO of the American Soybean Association, to be Deputy Secretary of Agriculture. "Steve Censky has been a strong supporter and vocal advocate throughout his career for agricultural biotech, expanding trade, and increased funding for agriculture research," says Pamela G. Bailey, president and CEO, Grocery Manufacturers Association, in a statement. And according to U.S. Secretary of Agriculture Sonny Perdue, "Our work has only just begun in delivering results for the people of American agriculture, and the experience and leadership skills of Stephen Censky will only enhance our efforts."

U.S. and China Exporting Agreements

The U.S. FDA signs a Memorandum of Understanding (MOU) with the Certification and Accreditation Administration of the People's Republic of China, formally establishing a registration process for U.S. food manufacturers who export certain foods to China. The agency recently published "Guidance for Industry: Establishing and Maintaining a List of U.S. Milk and Milk Product, Seafood, Infant Formula and Formula for Young Children Manufacturers/Processors with Interest in Exporting to China" to further explain what information exporting establishments should provide to the FDA to register under this new arrangement. The FDA will use the information received to establish and update a list of eligible exporters that is consistent with the MOU. List of establishments and products will be updated four times per year.

USDA also reaches agreement with Chinese officials on final details of a protocol to allow the U.S. to begin exporting rice to China for the first time. When the new rice protocol is fully implemented, the U.S. rice industry will have access to this critical market, significantly expanding export opportunities. U.S. rice exports can begin following the completion of an audit of U.S. rice facilities by China's General Administration of Quality Supervision, Inspection, and Quarantine.

In addition, while in Beijing in late June, U.S. Secretary of Agriculture Sonny Perdue formally welcomed the return of U.S. beef to the Chinese market after a 13-year hiatus. The return of U.S. beef and beef products is a part of the U.S.-China 100-Day Action Plan announced by the Trump Administration on May 11, 2017, with the first shipment of U.S. beef arriving in China on June 19, 2017.

Congratulations to our winners!

2017 Annual Food Quality & Safety Award

TreeHouse Foods *and* 5 Generation Bakers

The two companies have been named as winners of the 2017 Food Quality & Safety Award. Private label manufacturer TreeHouse Foods and cinnamon swirl bread manufacturer 5 Generation Bakers were both recognized for employing high product standards and expectations. For the complete story behind each company's success, check out the October/November 2017 issue.

Innovative Tech

Every element of Hillbrush's Total MDX Hygienic Tools product line is metal and X-ray detectable.

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Simplifying Hygiene and Sanitation

The latest tools are designed to empower employees in making a positive impact on food sanitation

BY **LINDA L. LEAKE, MS**

People. It's the title of the iconic song that legendary Barbra Streisand made famous.

And it's the number one consideration in food sanitation.

So says food scientist Ronald Schmidt, PhD, professor emeritus at the University of Florida, Gainesville, and active industry trainer in food safety and hygiene.

"Regardless of the type of processing or food handling operation, it is people who set the rules, follow the rules, and also break the rules of sanitation," Dr. Schmidt points out. "A sanitation program is as good as the attitude, willingness, and efforts of people. That is why the most important aspect of a sanitation program is ongoing personnel training."

It is essential that the full meaning of sanitation and its wide economic scope be accepted by everyone concerned in the food system, including management, Dr. Schmidt emphasizes.

"Personnel training should include appropriate sanitation principles and food handling practices, manufacturing controls, and personal hygiene practices," he elaborates. "Personnel training should instill and nurture an understanding of the desirable hygienic features of food handling facilities, environment, and equipment, the processing steps and technologies for each product manufactured or handled and where potential problems exist, and create a keen desire to satisfy and guard the consumers' interests."

Hand Hygiene

To that end, the SaniTimer handwashing timer is proving to be an effective tool for enhancing hand hygiene protocols in commercial food facilities, according to Charles Abraham, marketing director, SaniTimer, Fort Worth, Texas. "Our clients represent fast food chains, restaurant chains, and food processing facilities including dairy, meat, poultry, and nuts," Abraham says.

"Installed quickly and easily on handwashing faucets throughout food establishments, the patented SaniTimer offers employees a visual and audio aid for assistance in meeting the CDC time requirement of a minimum of 20 seconds for handwashing each time," Abraham points out. "SaniTimer raises compliance rates for hand hygiene up to 90 percent."

Introduced commercially in 2016, the SaniTimer is slated to be included in a new study gearing up at Purdue University on changing behaviors to enhance food safety, Abraham notes.

Abraham says Elite Spice, an industrial seasonings manufacturer, was one of the companies selected to use the SaniTimers on a trial basis starting in 2015.

"We installed SaniTimers on all the handwashing sinks at the entrances to our production areas," says George Meyer, manager of the 160,000-square-foot Elite Spice headquarters, Jessup, Md. "Before we had SaniTimers, it was a challenge to train our employees to wash their hands for the correct amount of time each time. And it was difficult to document that training. Even with instructing employees to sing recommended songs like 'Happy Birthday,' handwashing times were not consistent."

Meyer reports that SaniTimers have taken all the guess work out of handwashing time for his entire team. "SaniTimers are simple and straightforward to use," he relates. "You turn on the water, you see the timer right in front of you, you wash your hands. When the timer goes off, you know you have been washing for 20 seconds and

you turn the water off. Now with this tool our employees know exactly how long to wash their hands every time, so consistency has improved dramatically. Using SaniTimers has been incorporated into our handwashing training protocol."

"We are on a mission to correct the misstep of improper hand hygiene in food safety, while raising food safety standards along the way," Abraham says. "We have found that providing a tool for food safety professionals to use in accomplishing this goal is getting all components of the industry close to constant compliance standards for hand hygiene. We are pushing the FDA review board to require handwashing timers as a tool to ensure the current hand hygiene code that requires employees to wash for a minimum of 20 seconds is complied with."

> "A sanitation program is as good as the attitude, willingness, and efforts of people."
>
> —**RONALD SCHMIDT**, *PhD, professor emeritus at the University of Florida*

Brush Brigade

Addressing cleaning and foreign object contamination concerns is Total MDX Hygienic Tools, a line of fully metal detectable brushes introduced in the U.S. in 2015 by Hillbrush Company Ltd., Mere, Wiltshire, England, a manufacturer of cleaning tools for hygiene sensitive environments.

"These brushes compliment our other metal detectable cleaning tools, including scoops and scrapers, which were first available to the U.S. in 2010," says Mike Rutt, Hillbrush's quality manager. Hillbrush's portfolio includes Resin Set DRS (Dual Retention System) and Anti-Microbial Hygienic Tools, all commercially available in the U.S. since 2010.

"Resin Set DRS brushware directly answers the number one brush related concern for food processors, 'How do I prevent filament loss?'" Rutt says. "Resin Set DRS brushware is manufactured using FDA-approved materials and contains food grade, stainless steel staples to hold filaments securely into place. Antimicrobial epoxy resin is then floated into every part of the brush back, locking the filaments into position."

According to Rutt, Anti-Microbial Hygienic Tools get to grips with the second biggest brush concern of food processors: how to prevent bacterial contamination. "If bacteria are unable to grow on the brush, scraper, or squeegee, they cannot reproduce and will therefore die," Rutt points out. "This product line meets ISO standards and contains silver-ion technology, which actively inhibits the growth of bacteria for the lifetime of the product."

Hillbrush's Total MDX Hygienic Tools are made with Resin Set DRS technology, including antimicrobial resin, so they are metal detectable and filament locking.

(Continued on p. 14)

(Continued from p. 13)

Ford Gum & Machine Co., Akron, N.Y., a manufacturer and distributor of gumballs and gumball machine banks, as well as a private label confections manufacturer, has been using the Hillbrush Total MDX products in its facility since early 2017.

"Not only are these Hillbrush products more durable than other brands of hygiene tools we previously used, we consider their metal detectable capabilities a real food safety advantage," says Kevin Dunnigan, Ford Gum's quality assurance manager.

Knowledge-Based Services

In early 2017, Sealed Air launched several new hygiene solutions in its suite of Diversey Knowledge-Based Services, including CIPTEC, which offers precise clean-in-place (CIP) monitoring so CIP cycles can be shortened; and Dynamic Flow Monitoring, an advanced water management improvement program.

SaniTimer offers employees a visual and audio aid to ensure proper handwashing.

These offerings augment the company's provision of services, such as CIPCheck and AquaCheck, that have been in place for many years, says Roger Wagler, director of technical services for Diversey Hygiene North America, Charlotte, N.C.

"Our Knowledge-Based Services offer a holistic approach to help food and beverage manufacturers measure, monitor, and improve operational efficiency and food safety throughout their operations," Wagler relates. "These services are designed to streamline processes, increase efficiency, and reduce food safety risks, all while closely managing costs and pursuing the efficient use of resources."

CIPCheck. Diversey CIPCheck focuses on the technical, environmental, and economic optimization of CIP installations to help a plant discover if its CIP system is underperforming, says Eric van der Beek, a Diversey Hygiene sector specialist.

"While CIP systems are designed to automate a plant's cleaning process and efficiently clean and sanitize enclosed processing equipment, we have found that more than 50 percent of CIP systems run unvalidated, using the original settings," van der Beek points out. "With today's emphasis on improved resource management, it's important for food and beverage processors to consider a detailed analysis of their CIP system to determine whether incremental improvements like balancing out line capacity or adding a recovery tank to re-use water will improve efficiency or resource use."

For the CIPCheck process, the Diversey service team conducts a detailed probe into the CIP system to assess the system design; audit current cleaning procedures; map the current water, energy, and chemical usage; and measure cycle time.

"As necessary, we conduct additional assessments into the cleaning result, microbiological standards, and specific soils or allergens," van der Beek relates. "Clients get an analysis benchmarking their plant's performance against industry standards and a detailed report identifying areas of improvement."

CIPTEC. Diversey CIPTEC harnesses the power of light to monitor a CIP system in real time. A series of patented CIPTEC spectrophotometers are placed through the CIP system to measure light traveling through the liquids inside a CIP system, van der Beek explains.

"Typically, CIP cycle times are based on empirical averages, generally resulting in cleaning cycles that are too long," he points out. "In some cases, however, even these long cycles can fall short, impacting the safety of a product or the efficiency of an operation. We have found that the majority of CIP systems are over-washing by as much as to 50 percent.

"The light spectrum more accurately measures the contents of the CIP system, and CIPTEC data can tell the difference between water, chemicals, or milk residues, which conductivity can—but not to the level that CIPTEC can," van der Beek elaborates. "CIPTEC systems and our statistical data analysis methods calculate the optimal regime to eliminate over-rinsing and over-washing. In many cases, we're able to reduce cycle times by more than 50 percent, while maintaining a safety margin at Six Sigma level."

The Diversey CIPTEC can provide users with precise CIP monitoring to allow for shortened CIP cycles.

SEALED AIR

Dynamic Flow Monitoring. Diversey Dynamic Flow Monitoring provides an ongoing water use monitoring and management program that facilitates process improvement opportunities based on the day-to-day impact of open plant cleaning (OPC). It's the next generation of water management improvement programs built from the Diversey AquaCheck model, says Barry Sperling, a global applications expert for Diversey Hygiene.

AquaCheck is a three-step program that audits, quantifies, and analyzes. It also recommends holistic improvement for water use optimization. "AquaCheck sets a baseline strategy and defines goals, then Dynamic Flow Monitoring digs deeper into day-to-day operations to let a client know the impact of water use during all OPC events, and shows their water usage in real-time," Sperling explains. "With Dynamic Flow Monitoring, food processors get real-time, 24/7 monitoring of water consumption which allows operations to more easily define or adjust best practices, as well as validate the water conservation levels achieved." ■

ZACHARY EDDY

Leake, doing business as Food Safety Ink, is a food safety consultant, auditor, and award-winning journalist based in Wilmington, N.C. Reach her at LLLeake@aol.com.

For bonus content, go to August/September 2017 issue on FoodQualityandSafety.com and click on "Simplifying Hygiene and Sanitation Practices."

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Industry Insights

The Cannatourism Conundrum

Food safety considerations for off-site marijuana consumption | BY **JASON S. CETEL** AND **ANNA M. WIAND**

The U.S. has reached a tipping point with respect to legalizing marijuana. Cannabusinesses and gangapreneurs, along with advocates across the country, have created a billion-dollar industry in the face of federal prohibition. Whether from a medical or recreational perspective, the question facing patients and adult users is where and how one can consume marijuana and cannabis-derivative products.

Marijuana tourism, or "cannatourism," is the hospitality industry trend of people traveling to states to participate in the new and legal cannabis industry. While it may be legal to purchase marijuana, public consumption is illegal. Public use typically includes any place where the public or a substantial group of people has access. The biggest impediment to a successful cannatourism market is identifying places where it is permissible to consume the products that are purchased.

The prohibition on public consumption is a concern for all facets of the hospitality industry, including restaurateurs who wish to develop cannabis-infused menu items. Consumers will have to wait for regulatory changes before they can enjoy a cannabis-infused restaurant meal.

Cannabis use requires private spaces. Without access to a private space, there are limited options for consuming legally purchased cannabis products. It's something that states will grapple with in the coming years to resolve the cannatourism conundrum.

The Alaska Alcohol & Marijuana Control Office has been considering rules to allow a designated area for onsite consumption within a licensed retail marijuana store. This would make the on-premises consumption of marijuana a legal reality by creating the first regulated, commercial cannabis consumption locations. It could be a first step toward allowing restaurants to serve cannabis-infused meals.

The Popularity of Edibles

Part of the recent debate in the Florida Legislature over implementing the new constitutional amendment expanding Florida's medical marijuana industry focused on smoking marijuana. Since smoking is the most common form of consuming marijuana, why is there controversy surrounding this practice?

The process of smoking involves the burning or igniting of marijuana and inhaling the smoke. With public health perceptions aimed at mitigating harmful tobacco smoke, it is natural to understand the reluctance to encourage smoking marijuana. Florida legislators decided that alternative methods of consumption were safer, including commercially-produced food products. The concept of edible cannabis appears to be more palatable for politicians. On the recreational, adult-use front, as marijuana use has become destigmatized, smoking cannabis is facing competition from other forms of consumption, such as edible cannabis products.

Creative entrepreneurs are producing various edible products made with extracted marijuana oils containing cannabinoids: active chemicals such as tetrahydrocannabinol (THC) or cannabidiol (CBD). Once the cannabinoids are extracted into liquid form, they can be incorporated into ordinary food. Because the stomach absorbs and processes the cannabinoids slower than the lungs, the oral method of consumption involves a prolonged release of cannabis into the system. The slow metabolism of marijuana-infused edible food is a benefit for recreational users who want a long, continuous high. Similarly, these products can be a critical part of a medical patient's cannabis-use regimen because the medicine is absorbed and metabolized slowly through the digestive system.

A more extended release of the drug can have palliative outcomes for patients with certain ailments that may benefit from a more sustained therapeutic effect.

But the cannatourism conundrum means there are no opportunities for on-premise consumption of edible food. Restaurants cannot obtain licenses to produce marijuana-infused products or sell edibles to consumers. The future of the U.S. marijuana industry may eventually see marijuana bars or restaurants. One can imagine a multi-course meal at a gourmet restaurant involving low-dose infusions for each course. While this *joie de vivre* experience may fit well with the foodie cultural revolution, we are not there yet.

Private Caterers

A work-around solution involves private catering. To avoid the public use prohibition, social consumption may involve such private use as catered medicated meals in states with medical use only laws, or cannabis-themed dinner parties in recreational law states. These events are more frequent as connoisseur- or pharmaceutical-grade cannabis is seen as a luxury experience, like drinking fine wines.

Social cannabis use is taking cues from the food and beverage industry. Marijuana-infused food pairings, like wine dinners, are becoming part of the overall cannabis experience. Under this scenario, chefs or caterers may be hired to prepare meals at private residences in accordance with the jurisdiction's laws.

Of course, facilitators of cannabis dinners must be mindful of how the intoxicant may influence diners. They must understand how edibles are metabolized, and that the resulting intoxicating effect is different from smoking. If the cannabis dosage is not incorporated into the recipe in moderation, or if the food is improperly prepared, the meal can result in overdoses or foodborne illnesses, which could trigger potential liability.

Cannabis Food Safety

The popularity of cannabis-infused edibles may be an even greater food safety risk than catered dinners because of the number of consumers such products may reach. Companies recalling marijuana-infused edible products for ordinary food safety reasons has become a common practice. Such recalls have ranged from failing to meet packaging requirements to prevent foodborne illnesses to producing products found to contain potentially dangerous (to humans) pesticides, which are banned for cannabis cultivation. Other problems have resulted from erroneous or misleading labels that do not reflect accurate dosages, ingredients, or potency.

Third-party independent testing laboratories and standard operating procedures that incorporate Hazard Analysis and Critical Control Point, i.e. HACCP, plans and current Good Manufacturing Practices are necessary for the production of safe marijuana-infused food products. State laws and regulations are evolving to incorporate these food safety principles.

In Florida, cannabis is approved only for medicinal uses, but cannabis production facilities are still subject to food safety requirements. These new requirements mandate that licensed medical marijuana treatment centers demonstrate that their processing facilities have established a food safety Good Manufacturing Practice (such as the Global Food Safety Initiative) with oversight and inspection by a nationally accredited certifying body. Florida has taken this a step further by initiating the development of regulations tailored to these products. For example, the Florida Department of Agriculture and Consumer Services must assist the Florida Department of Health in developing testing requirements for contaminants in edibles, including sanitation rules that apply to the storage, display, or dispensing of edibles.

> The proposed rules mandate that manufacturers must ensure that all personnel complete a food handler course accredited by the American National Standards Institute.

In April, the California Office of Manufactured Cannabis Safety released proposed rules that address food safety concerns. The rules prohibit edibles that contain potentially hazardous food, including products that must be temperature controlled, perishable bakery products that must be maintained in cold temperatures to prevent the growth of microorganisms, and dairy products. Also, no ingredients other than cannabis extracts or concentrates can be used to manufacture edibles unless they are FDA-approved. Licensees are prohibited from infusing alcoholic beverages with cannabis, and edibles cannot contain additives (like nicotine or caffeine) that would increase their potency or create an unsafe combination with other psychoactive products. The proposed rules mandate that manufacturers must ensure that all personnel complete a food handler course accredited by the American National Standards Institute.

Although these regulations are designed for the commercial production of cannabis-infused edibles, the overall food safety concerns are relevant for the unlicensed, off-site preparation of cannabis-infused meals in private settings.

Food Safety Recommendations

The FDA Model Food Code, which is adopted across the country, is designed to ensure proper food handling and production to avoid contamination and foodborne illness. Five major risk factors have been identified as leading to foodborne illness including: 1) improper holding temperatures, 2) inadequate cooking, 3) contaminated equipment, 4) food from unsafe sources, and 5) poor personal hygiene.

The risks underlying traditional food safety concerns are magnified when one considers that many consumers of cannabis foods are using the products for medical purposes and, therefore, may be immune-compromised individuals. For example, a common food safety requirement is that food handlers ensure proper temperature controls and food that hasn't been closely monitored cannot be served to highly susceptible populations, which include many medical marijuana patients.

Caterers must be especially cognizant to ensure that food safety protocols are in effect, particularly for contaminated equipment and poor personal hygiene, as these are avenues for contaminants to get into food making it unsafe.

Best practices go above the minimum regulations to ensure food safety through-

(Continued on p. 54)

FSMA Update

Reducing Risks with Automation and Information Systems

Modular automation and information technologies can address risk-reducing strategies for food processes to better comply with FSMA | BY **GLENN RESTIVO**

Food industry quality manufacturing requirements are stringent, and the FDA's Food Safety Modernization Act (FSMA) is aimed at preventing purposeful adulteration from acts intended to cause wide-scale harm to public health. The preventive controls rules require facilities to develop and implement written food safety plans as they will be held accountable for monitoring their facilities and identifying any potential hazards in their products as well as preventing those hazards.

In a recent feature on the FDA website Joann Givens, co-chair of the FSMA Operations Team Steering Committee, addressed the question, "What is the best thing covered food facilities can be doing now?" She writes, "They should look at the big picture, at areas in which they could be vulnerable and proactively take action. Promptly responding to problems, even if they aren't yet violations, can prevent them from getting to the point at which there is a concern about the safety of the food." She also suggests that facilities should set up a thorough system for documenting what they do. "The better the records, the more a company can demonstrate that it is meeting the legal standard...and consider having some redundancy in the system so that if one measure fails, another can take its place," she writes.

FSMA requires that companies implement safety plans that detail points in the manufacturing process that could be risky, but the question remains whether technology automation and information systems could play a role in helping manufacturers comply with the new regulations.

All About Data

Most food manufacturers have automation and information hardware and software systems, including PLCs, DCS, HMI SCADA, Batch, Data Historians, OEE, MES, WMS, and ERP. While these systems are necessary, some are legacy systems (meaning they are not supported anymore), most systems are from multiple vendors, and many are not connected. So, how can your company meet the intent of the FSMA and extract the required information that lies within these multiple, disparate systems? Extraction is not always easy, as some information is paper-based or tied up in ERP, WMS, Data Historian, or MES systems. Getting data out of disparate automation and information systems is time consuming, inefficient, and even inaccurate.

Then what's the better solution? Data, data, and more data! Many food companies collect data in multiple ways—automatically, via operator entries, on chart recorders, etc.—and lots of it. Whether your company is automated or not, your laboratory information management systems (LIMS) may be the most important system providing data on food quality as they collect quality data from raw materials to final product. Once your company has this data, what do you do with it? Can it be retrieved in a timely manner, and can you make use of it during and/or after the product is manufactured? If your LIMS aren't integrated in the automation and information layer of the company, they should be! LIMS data, combined with automation and information data, enables true manufacturing and process knowledge.

Quality by Design

In the life science industry, the Quality by Design (QbD) initiative from the FDA provides guidance on pharmaceutical development to facilitate design of products and processes that will maximize the product's efficacy and safety profile while enhancing product manufacturability and control. QbD is defined by the European Medicines Agency as "a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding based on sound science and quality risk management." The FDA has proposed in its guidelines for industry a definition for process validation that is "the collection and evaluation of data, from the process design stage throughout production,

which establishes scientific evidence that a process is capable of consistently delivering quality products."

A food manufacturer requires a complete understanding of its management's responsibility to drive a culture, which ensures that the facility, its production processes, and its employees understand expectations throughout the production chain. The company should analyze and document what automation and information systems exist (if they do not already know), generate a risk-assessment plan, and prioritize next steps. Cost of implementation is always a part of the equation, so the fact that increased knowledge can also increase product quality and improve the production methodology—hence reducing the production costs—is an important argument to get buy-in from management.

Integrated modular automation and information systems, when designed and configured properly, address product quality, compliance, productivity, information accuracy, process repeatability, human error, human safety, product traceability, downtime, and operational efficiency.

So how do you collect process, batch, and quality data today? Kjell Francois, industry software delivery manager, Siemens, comments, "It is not just a matter of combining your process and batch data, it's also the move from sample-driven lab data to process-driven online measurements, which will increase the product quality monitoring abilities and process knowledge. The idea is to move QA from the lab to the line. This is an approach that is now already applied, for example, in some dairy companies."

Within your manufacturing process, do you know your key production critical-to-process and critical-to-quality data points that, when out of spec, can adversely affect final product quality? Do you collect all data or just key data, and what are you doing with it? Are you just storing it? A high rate of quality data has been collected in LIMS environments over the years. Typically, trend charts are made and key performance indicators (KPIs) are followed over time, often based on sample data from samples collected in the production lines. Integrated data—process, batch, and quality—would enrich the (near-) real-time dashboard information displayed.

How do you retrieve this data if it is requested? Are you recording data automatically, and/or on paper? Are you still using chart recorders in certain areas? Are you doing any statistical analysis? If yes, is it off-line and after-the-fact, or is it on-line, at-line, in-line, and proactively making real-time corrections to your process? Can you predict final product quality by proactively controlling around these key data points? Today's technology enables you to meet these on-line/at-line/in-line sampling goals, allowing you to more accurately predict your final product quality.

Finally, how do you handle an investigation? When it comes to your final batch report, is it a hodgepodge of paper and electronic data that requires too much time to assemble, then analyze? Is your batch report retrievable in a timely manner? In today's investigations, it might take a significant amount of time to find and extract the necessary data, but it doesn't have to. FSMA makes it clear that the FDA would ideally like the information in under 24 hours, and emerging technology will allow you to meet this goal.

Putting It Into Practice

Today's modular automation and information systems, including LIMS, collect a lot of raw data. Are you simply collecting this data (rendering it basically useless), or are you merging collected data to allow full contextualization? Once combined or merged, this information can be made available to the employees in real time, enabling them to make timely decisions. KPIs can be generated and utilized by all manufacturers, and these metrics can be managed and measured. These KPIs are able to address many common challenges that companies face, as well as uncover points in the manufacturing process that could be risky. In addition, this information can be made available to the entire business for deeper analysis, and the results used to help a company make better decisions when addressing potential risk.

Dave Sharpe, global industry director, CPG for Rockwell Automation, notes, "An enterprise-wide approach that embraces information-enabled technologies and automation can help address food safety across operations while increasing productivity. The right technology can help apply a more proactive approach to your food safety program. Beyond compliance, a food safety program can be used to improve product quality, asset utilization, yield, and energy usage. By taking advantage of technologies that improve asset utilization, you can meet demanding production goals and support fast changeovers while also maintaining high product quality."

Tracking and tracing your supply chain from raw ingredients to finished goods also addresses potential risks that can adversely affect a company's brands' final product quality. Having the ability to document, track, and retrieve all informational ingredients that make up the batch aligns with FSMA and is becoming more important to customers and consumers. Quickly accessing the information that was used to make a specific product will save time, effort, and potentially a customer. For most food manufacturers, it is not a question of if they will need to provide this information, but when. Having a solution that provides the least disruption to production and shipping can often provide enough of an ROI to offset the cost incurred by the adaption of this type of solution. It also ensures brand protection and loyalty when consumers in today's markets are quite fickle.

Ultimately, increasing the use of modular automation and information systems and fully integrating your LIMS and quality data directly address the increasing need for traceability, food safety, and competition. If you fully and proactively integrate data from disparate automation and information systems, it will allow your company to meet the intent of FSMA, which in turn will fuel growth, protect brand integrity, and meet current and new national and international regulations.

What's the bottom line? Automation and information systems not only help your company meet the regulations of FSMA, but they also enable consumers to feel confident in their purchase of your product. In an age where up-to-the-minute information is at the consumer's fingertips, your company can proactively market that it has taken the steps necessary to meet the latest food safety government regulations.

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FIGHTING AGAINST FOOD PATHOGENS

New microbiological technologies help industry keep up with increased government scrutiny

BY **TED AGRES**

In the world of virulent foodborne pathogens, *Campylobacter* and *Salmonella* have become the chief culprits, responsible for nearly 70 percent of all such illnesses in the U.S. last year. Detecting these and other bacteria in the food supply is a matter of growing urgency for both government regulators and the food industry. As the food chain expands globally, manufacturers are being held increasingly responsible for preventing outbreaks under the Food Safety Modernization Act (FSMA).

"We are making progress in detecting and responding more quickly to foodborne illness, but our priority remains preventing illnesses from happening in the first place," says Susan Mayne, PhD, director of FDA's Center for Food Safety and Applied Nutrition (CFSAN).

Campylobacter is commonly associated with consumption of raw or undercooked poultry and meat, while *Salmonella* is an issue in many types of food, including eggs, meat, poultry, fruits, vegetables, spices, and nuts. Both bacteria can cause mild to severe illness, from uncomplicated diarrhea to severe systemic infections, such as Guillain-Barré syndrome (*Campylobacter*), an autoimmune disease that can cause paralysis, and reactive arthritis (*Salmonella*), which can cause acute, debilitating joint pain.

"In order to decrease the likelihood of these pathogens in the food chain, it is essential to analyze the raw material, the environment where the food is produced, and food products at different manufacturing stages; for example, niches where *Salmonella* could be harbored in the environment that could cause cross-contamination," says Claudia Narvaez, PhD, professor of food science at the University of Manitoba, Canada.

Advances in laboratory and onsite testing equipment are allowing manufacturers to more easily and economically sample their raw ingredients, environment and facilities, and finished products for evidence of bacterial contamination, thus greatly reducing the potential for a recall, or worse. These developments include time-of-flight mass spectrometry, bacteriophage-based assays, novel biosensors, as well as advances in traditional techniques, such as polymerase chain reaction (PCR).

"Test methods continue to improve, with many methods now available that give results within 24 hours of sample receipt by the lab," explains Timothy Freier, PhD, vice president for scientific affairs and microbiology at Mérieux NutriSciences (North America). But he also urges caution. "With these faster turn-around times, test methods are walking the line between incubation time and detection capabilities, so careful validation of these ultra-rapid methods is crucial," Dr. Freier tells Food Quality & Safety magazine.

Accurately detecting and eliminating pathogens is increasingly essential for industry because advances in whole genome sequencing (WGS) are allowing public health agencies and government regulators to identify and trace foodborne contamination, such as *Salmonella*, back to specific growers and processing plants with increasing accuracy, faster and more cheaply than ever before.

"This is raising the bar for the food industry, as new food-illness associations are found," Freier adds. "A combination of ingredient testing, finished product testing, and environmental monitoring are typically needed to control this hazard."

Illnesses and Deaths

While exact numbers remain unknown, the CDC has estimated that about 48 million people in the U.S. get sick from a foodborne illness, 128,000 are hospitalized, and 3,000 die annually. The World Health Organization notes that *Campylobacter* is the world's most common foodborne bacterial cause of diarrhea, responsible for more than 95 million illnesses and 21,000 deaths annually, according to a 2015 report.

In 2016, surveillance from labs in 10 U.S. states confirmed about 24,000 foodborne infections, more than 5,500 hospitalizations, and nearly 100 deaths caused by nine enteric pathogens commonly transmitted through food, according to the CDC's latest Foodborne Diseases Active Surveillance Network (FoodNet) report, published in April.

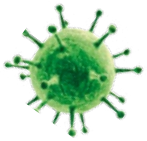
Among the bacteria, *Campylobacter* and *Salmonella* led the pack, being responsible for 8,547 and 8,172 illnesses, respectively. The remaining pathogens were distant finishers, from *Shigella* (number three on the list with 2,913 illnesses) to the parasite *Cyclospora* (number nine with only 55 illnesses). While *Listeria* was close to the bottom in terms of prevalence (127 cases) it was the most virulent of all, with 97 percent of its victims requiring hospitalization and 13 percent of them dying.

Because FoodNet collects data from public health departments in 10 states, representing only 15 percent of the U.S. population, the nationwide numbers are much larger. Additionally, the actual number of foodborne illnesses always exceeds the number reported because many people who get sick do not seek, or necessarily require, medical treatment.

Not only does the FoodNet report "provide important information about which foodborne germs are making people sick in the United States," says Robert Tauxe, MD, director of CDC's Division of Foodborne, Waterborne, and Environmental Diseases, but "it also points out changes in the ways clinicians are testing for foodborne illness and gaps in information as a result."

In particular, FoodNet counts infections diagnosed both by traditional, culture-based methods as well as those diagnosed using newer, culture-independent diagnostic tests (CIDTs). CIDTs, such as immunoassays and nucleic-acid amplified tests, can be faster and easier than traditional culture-based methods, which also require use of trained personnel. CIDTs can identify a general bacteria type within hours without having to culture, or grow the pure bacteria strain (or isolate) in a laboratory, a process that typically takes days.

But without the isolate, public health scientists are unable determine the DNA subtype ("fingerprint"), its resistance pattern, or other characteristics necessary to detect outbreaks, track antibiotic resistance, monitor disease trends, and ultimately prevent outbreaks, CDC says.



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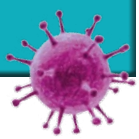
For instance, PulseNet, the CDC-run network that connects public health and food regulatory agency laboratories, relies on the collection of DNA fingerprints of bacteria taken from sick patients to identify local and multistate outbreaks. The growing use of CIDTs is endangering PulseNet's effectiveness. "Without a DNA fingerprint of the bacteria, CDC and public health labs will not be able to find, monitor, and prevent foodborne disease outbreaks, track antibiotic resistance, or follow trends to know if prevention policies are working," CDC says.

Problems with Culturing

Regulatory bodies in both U.S. and the European Union are emphasizing the reduction of *Campylobacter* and *Salmonella* while increasing testing requirements, says Mike Clark, International PCR group manager, Food Science Division, Bio-Rad Laboratories. "Industry must be equipped to respond to these changes with testing solutions that are fit-for-purpose," he tells Food Quality & Safety magazine.

PCR techniques are based on amplification of the DNA of target pathogens. As the cost and complexity of genetic testing began to come down in the 1980s, PCR became commonplace in government and company labs. Today, it remains among the most widely used approaches to detecting foodborne bacteria.

Among the bacteria, *Campylobacter* and *Salmonella* led the pack, being responsible for 8,547 and 8,172 illnesses, respectively.



But because PCR also requires culturing, identification can still take many days. Advanced PCR tests, including quantitative and real-time PCR, can produce results more quickly by using probes and primers designed to target highly-conserved regions of the target genome.

"Many laboratories are using conventional methods combined with molecular methods for detecting these two foodborne pathogens," Dr. Narvaez explains. For example, PCR is often combined with immunomagnetic separation (IMS) that uses antibody-antigen interactions to detect very low levels of pathogens. "These are probably among the most-used methods used by industry and academia, and are approved by regulatory agencies," she explains.

However, even these are not fast enough because they can take upwards of 24 hours, including enrichment, to produce definitive results. "Scientists are working on developing detection methods that can be sensitive and specific but also faster, ideally less than one hour with no enrichment, to obtain definitive results," Dr. Narvaez says.

New Technologies and Approaches

Among the many developments in laboratory and onsite testing are advances in established approaches such as time-of-flight mass spectrometry; the invention of novel biosensors and assays using bacteriophages, enzymes, antibodies, nucleic acids, cell receptors, or polymers; nanotechnology-based sensors; and other rapid detection methods. Below are summaries of a few of these approaches.

MALDI-TOF. Matrix-assisted laser desorption/ionization-time of flight mass spectrometry can determine the unique proteomic fingerprint of a bacterium relatively quickly and inexpensively. It compares the bacterial protein profile obtained from a culture to a library of known patterns. "Typically no more than an isolated colony from a culture plate or a small aliquot from a broth is required," explains Daniele Sohier, PhD, business development manager, industrial microbiology and diagnostics at Bruker Daltonik GmbH. "The entire method takes only a few minutes for a single sample, with results up to 24 hours faster than traditional methods," she tells Food Quality & Safety.

Bacteriophage-based assays. Bacteriophages are viruses that infect bacteria. Because they are highly specific, interact quickly, and are harmless to humans, bacteriophages can be incorporated into novel assays and biosensors to detect, and in some cases even eliminate, foodborne pathogens.

Novel biosensors. These biosensors use biological elements, such as small molecules, proteins, or cells attached to a sensor surface to recognize or bind to specific targets or components of bacteria. Detection methods include label-free sensors, immunosensors, fluorescence-based, and carbon-nanofiber sensors.

Rapid microbial detection methods. These typically use fluorescent DNA markers to identify pathogens rapidly and accurately. These culture-independent platforms use fluorescent *in situ* hybridization, fluorescent microagglutination, and filter cytometry. Other rapid approaches include low-cost test strips to indicate the presence of a particular pathogen within hours. For example, paper- or film-based assays using stencil-printed carbon electrodes are able to detect *E. coli* and other bacteria within 4-12 hours.

WGS Still King

Despite these and other advances, WGS or next-generation sequencing, remains the gold standard for pathogen detection because of its high precision. As the cost declines, officials expect small WGS sequencers to proliferate among state and local public health agencies, as well as among private labs and manufacturing companies.

"We are looking at some very small sequencers that could fit in the pocket," says Marc Allard, PhD, CFSAN's research area coordinator for genomics. "We could have a lab in a briefcase that could go out to the consumer safety officer and actually do field testing. This is the future vision," he says.

But because of its current complexity, cost, and other requirements, the food industry has largely steered clear of WGS. "The science and technology behind WGS are new and might seem a bit more complicated than the ones that have been in use by the industry for many years," said Behzad Imanian, PhD, WGS project leader at the Institute for Food Safety and Health (IFSH) at Illinois Institute of Technology.

The amount of data produced by WGS can be "overwhelming," Dr. Imanian told an IFSH symposium in May. The data analysis requires a proficiency in bioinformatics, which could be problematic for industry, while data interpretation "is far from simple, even for

trained bioinformaticians," he added. Thus, while U.S. and international food safety regulators are increasingly embracing WGS, the food industry has been reluctant. A notable exception has been the Consortium for Sequencing the Food Supply Chain, an initiative started in 2015 by IBM Research and Mars Inc. Recently joined by Bio-Rad Laboratories, the consortium is sequencing the genetic material of food and soil samples in order to create a "microbial baseline" to better understand the factors behind contamination and foodborne disease.

Interagency Collaboration

In 2011, the CDC, FDA, and USDA's Food Safety and Inspection Service established the Interagency Food Safety Analytics Collaboration (IFSAC) to improve coordination of federal food safety analytic efforts and address cross-cutting priorities for food safety data collection, analysis, and use. In addition to *Campylobacter* and *Salmonella*, IFSAC's efforts have been directed at *E. coli* and *Listeria monocytogenes*.

During its first five years, IFSAC developed a new food categorization scheme, which CDC now uses to classify food implicated in outbreaks, as well as an agreed-upon method for estimating sources of foodborne illnesses. In its latest strategic plan, IFSAC outlines three goals for 2017-2021: 1) improve the use and quality of new and existing data sources, 2) improve analytic methods and models, and 3) enhance communications about its analytic products.

1. Data sources. Current sources, such as for foodborne illness outbreaks, are valuable but also incomplete and inconsistent. To address this, IFSAC will acquire additional data sources such as regulatory sampling data and WGS information. IFSAC will also work with state and local public health and regulatory agencies to obtain more and better outbreak reporting.

2. Analytic methods. While there's been progress in applying new methods and models for attributing foodborne illnesses, no best data sources or approaches have been identified. IFSAC will expand its scientific exchanges to identify gaps, develop ways to incorporate sporadic illness surveillance data, and integrate multiple data sources into estimates and analyses.

3. Enhance communications. Because foodborne illness attribution is complex and constantly changing, effective communication with health practitioners, academics, industry, and the public is important. IFSAC will improve and expand these relationships.

"It is always positive to see different parts of the government collaborating on food safety issues, although, as always, the issues are lack of funding and lack of time to move things forward," says David Acheson, MD, founder and CEO of the Acheson Group and a former FDA associate commissioner for foods. "But we should always be looking to do more because there is always more to do," he says.

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Real-time titration of sanitation chemicals prior to use helps ensure products are effective and comply with audit requirements.

Are Your Sanitation Chemicals Audit-Ready?

Cleaning chemicals are core elements of any sanitation program and need to be documented for inspectors

BY **MATT PRINE**

Cleaning chemicals are at the core of any plant sanitation program. Successful production depends on using chemicals properly to clean and sanitize all processing areas. There's little room for error when it comes to managing sanitation products—especially when auditors come calling.

Audits are ever-present in the food industry. Some are industry driven, such as Global Food Safety Initiative and Safe Quality Food audits. Government regulations trigger USDA, FDA, and Occupational Safety and Health Administration (OSHA) inspections. And customers may require yet another round of audits and inspections at your plant.

Each of these audits may cover different aspects of food production, but regardless of the type of inspection, you can expect plant sanitation and chemicals to come under scrutiny. The best way to prepare for a potential audit is to always follow chemical handling best practices and document them religiously from start to finish.

Chemistry 101

The basics of chemical handling are simple—use the right chemicals, at the right place, and in the right amount. It's critical to adhere to the chemical product label, which specifies what the product is to be used for and how it should be mixed and stored.

Make sure your operation doesn't have in-plant "chemists" who create their own cleaning concoctions. For example, mixing bleach and quaternary ammonium together can be an effective detergent for removing tough colored soil, like tomato-based sauce. However, the bleach label does not allow it to be combined with other chemicals. Any product mixing that's not listed in label directions will be a red flag in case of audit. Plus, mixing incompatible chemicals, such as chlorine with acid, could produce toxic gases and safety hazards for employees.

All cleaners and sanitizers must be used for the purpose on the label—not to clean the parking lot, for example. Always stay "on-script" to stay audit-ready.

Some's Good, More's Better? Not.

This old-school saying would be a definite red flag for auditors. Always stay within concentration ranges specified on the chemical label for the product and how it's being used. Lower concentrations may not effectively sanitize the food production area, while higher concentrations would be wasteful and costly.

Also keep in mind that the U.S. EPA classifies disinfectants and sanitizers as pesticides because they control microbes in the environment. Using a higher-than-labeled chemical concentration could risk EPA action against your plant—and risk food contamination.

The only way to know for sure that you are using correct chemical concentrations is through titrations to verify products have been mixed with the proper amount of water. Titration data is one of the key metrics that inspectors will look for during an audit of your chemicals.

Real-time titrations are recommended. Here's why: If you mix and use a chemical product on a Monday and don't run titration tests until Wednesday, you may have spent two days using the wrong concentration. That could jeopardize food safety as well as raise issues at inspection time.

Even before mixing and titration, make sure to use chemicals only from a li-

censed chemical blending facility. Look for a company that provides technical support and supplies high quality dispensers and foamers to ensure proper product application. Also, ask your chemical supplier about its quality control procedures. Ideally the chemical manufacturer or blender should test each lot for purity and potency prior to shipment.

Don't Overlook Your H2O

An often-overlooked factor in sanitation chemical efficacy is water quality. Test water at least once a year and anytime your municipality notifies you of changes in the water supply.

Water hardness is one of the key factors affecting cleaning products. Between zero and 4 grains is considered soft water and above 7 grains is considered hard water. Chemical labels will outline the product's effectiveness based on different hardness levels.

Mineral-based impurities also adversely affect cleaning and sanitizing. Iron, manganese, chlorides, and silica can cause staining, corrosion, or filming.

Expect an auditor to test a water sample from the chemical mixing area to verify your chemical program aligns with onsite water conditions. To be prepared, work with your chemical supplier to adjust your chemicals or water supply as needed for optimal efficacy.

Storing Chemicals

Storage is another issue for inspectors, from efficacy as well as worker safety standpoints.

To ensure efficacy, always store chemicals in securely locked containers to prevent product tampering, contamination, or degradation. Store chemical drums and totes in well-ventilated, well-drained areas. Keep them away from sunlight or heat, which can cause oxidation that in turn reduces product potency.

Make sure all chemical containers are labeled. Every bucket or jug used to mix chemicals must have a tag identifying the product or product mixture that it contains. Frequently tour your plant and look for unlabeled materials. Any chemical container without a label is a food and worker safety risk because it creates the potential for its contents to be used improperly.

Ensure worker safety by storing different types of chemicals in separate areas to prevent cross-contamination or toxic mixtures.

Don't forget to monitor secondary containment—pallets or other structures meant to control spills or leakage from chemical drums/totes. The secondary containment should be rated appropriately for the materials being stored and have no dents, cracks, or punctures to cause product leakage. Be aware of local requirements regarding secondary containment, as regulations can vary from state to state.

Training for Success

You want your plant clean and sanitized for the next day's production. And above all, you want your sanitation crew to go home safely. Regardless of whether you have an in-house sanitation crew or use a contract sanitation supplier, make sure all workers have a clear understanding of cleaning procedures and how to use chemicals safely and correctly.

Training should cover chemistry basics, including proper storage, mixing, and labeling. Help workers understand the importance of personal protective equipment and how to respond in case of an accident or product spill. Include training on how to operate eyewash stations and showers.

As much as possible, make these training sessions interactive with hands-on experiences. Keep language barriers in mind and translate materials into Spanish or other languages appropriate for your sanitation employee population.

Once workers are trained, they must be well supervised in the food facility to ensure that all chemicals are handled and applied safely and completely.

Even after training has taken place, continue with frequent, ongoing refresher sessions to avoid procedural drift. Document each session, what it covered, and who participated.

Audit-Readiness Means Safe Food

A modern, compliant food facility depends on the often-complex world of sanitation chemicals. Following sanitation best practices at all times will not only keep your plant audit-ready, you'll have satisfied customers and a productive work force. And when an inspector shows up at your door, keep in mind that audits are really for your benefit—to ensure you can continue to supply your customers with safe, high-quality food products.

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Prove It with Paperwork!

From an auditor's perspective, if a procedure isn't documented it never happened. To stay audit-ready, keep the following sanitation program documents on site and available for inspection.

- Master Sanitation Schedule that details the timetable for cleaning food production areas.
- Safety Data Sheet (SDS) for every cleaning product, posted where workers can see them. The SDS lists important safety information, including precautions and potential hazards that employees should be aware of.
- Technical Data Sheet from the manufacturer that includes product specifications and instructions for use and disposal.
- Cleaning Procedure Manual, describing how to clean the facility and what chemicals are used. This manual should also document how employees are trained to handle and apply chemicals.
- Chemical Inventory Record, documenting chemicals on hand and titration data showing they are used in legal, safe ranges.
- Letter of Guarantee from the chemical supplier to certify the company delivered the correct products to the facility.

Most food processing plants maintain these documents as paper copies, usually in a binder. Others are moving to electronic copies for ease of updating. It might still be a good idea to print out hard copies because auditors may not have easy access to your computer system to view the digital files.—*M.P.*

A Closer Look at Resistance

Understanding how different types of resistance may impact the effectiveness of sanitizers and disinfectants

BY **DALE GRINSTEAD, PHD**

Resistance is the ability of a microorganism to exhibit reduced sensitivity to an antimicrobial treatment that's effective against other organisms. There are several kinds of resistance, including intrinsic, phenotypically acquired, and genetically acquired.

Intrinsic

Intrinsic resistance is ability of organism to be insensitive to an antimicrobial condition due to the nature of microorganism. Some microorganisms form bacterial spores enabling them to survive conditions like extreme temperatures and drying, as well as exposure to disinfectants and sanitizers. Non-oxidizing antimicrobials, such as phenolics, alcohol, and quaternary ammonium chloride (QAC), cannot penetrate a spore coat. And with oxidizing biocides, it takes higher levels and exposure times to inactivate a spore compared to a normal microorganism. For example, it may take 5,000 parts per million (ppm) and several minutes to inactivate a spore compared to 50 ppm of chlorine and 30 seconds.

Another form of intrinsic resistance is displayed by mycobacteria, which have a cell wall that is very hydrophobic and contains a lot of natural wax. This can prevent many biocides, especially non-oxidizing biocides, from penetrating the cell wall. This barrier can be overcome but it requires a higher level of biocide, longer exposure time or the use of other ingredients.

Intrinsic resistance is generally a very stable trait and is closely linked to the basic structure of various microorganisms. In general, the intrinsic resistance of microorganism to biocides is, from most resistant to least resistant: spores>mycobacteria>non-enveloped viruses>gram negative bacteria>gram positive bacteria>enveloped viruses.

Phenotypically Acquired

The ability of microorganisms to become insensitive to an antimicrobial treatment as a result of how and where the organism grows is considered phenotypically acquired resistance. An example is biofilms, complex communities of microorganisms like bacteria, yeast, molds, protozoa, and viruses. Biofilms attach to surfaces and secrete a material that strengthens and protects the biofilm. Organisms in a biofilm are far more resistant to antimicrobial agents than organisms that are freely in suspension. This increased resistance occurs because antimicrobial agents can't physically reach the microorganisms through the secreted material or they are inactivated by the material.

Organisms that are on a soiled surface or even in solution with a heavy soil load are also often very resistant to biocides. As with biofilms, this is a result of the biocide being inactivated by the soil or physically prevented from reaching the organism.

Unlike intrinsic resistance, phenotypically acquired resistance is not a stable trait of microorganisms. If the organisms in a biofilm are suspended in solution so they are no longer protected by the secreted material, the organisms are as sensitive to a biocide as an organism that was not in the biofilm. Or, if the soil is removed, the organisms will become sensitive to biocides. This is one reason why it is important to clean a surface before sanitizers are used.

Acquired Genotypic

Genetically acquired resistance is insensitivity to a biocide that a microorganism gains either via a mutation or through a transfer of resistance genes from one organism to another. A mutation is a change in an organism's DNA, and on rare occasions, can make a microorganism resistant to biocides. Exposure to antimicrobials at sub-lethal levels over time can encourage this kind of mutation. Thus, it's critical to use all sanitizers and disinfectants at the recommended concentrations and in proper way. It's also important that biocides drain properly. Pooling or standing solutions of antimicrobials diluted to below lethal levels increase chances of developing a mutant resistant to that biocide.

Organisms can also acquire a genetic resistance to a biocide by acquiring a resis-

tance gene from another microorganism. There are different modes of transfer, but the end result is an organism that was previously sensitive to a biocide can suddenly acquire the genes to be resistant to the biocide or even multiple antimicrobial agents.

This increased resistance occurs because antimicrobial agents can't physically reach the microorganisms through the secreted material or they are inactivated by the material.

Oftentimes this kind of resistance is not stable. A mutation or resistance gene may only offer a survival advantage as long as the biocide is present. For instance, a mutation in a binding site that makes it less likely for a QAC to bind to a microorganism may also interfere with the binding of nutrients that are critical for cell to survive. While the QAC is present, the mutation acts as a survival advantage but once the QAC is removed, the mutant is still not able to absorb nutrients easily and may disappear from a population once the biocide is gone.

The Impact of Resistance

Many people get concerned about genetically acquired resistance to sanitizers, yet this is one of least relevant forms. The confusion may result from legitimate concern over genetically acquired resistance to antibiotics. However, antibiotics and the biocides used in sanitizers and disinfectants are different compounds used in different ways. Antibiotics often have a single binding site on a target microorganism and a single site at which they are active. They're also used at levels very close to lowest possible level at which the antimicrobial is effective, referred as minimum inhibitory concentration (MIC). That means a mutation in a single binding site or active site in a microorganism can make that organism nearly immune to an antibiotic, especially if antibiotic is used near MIC levels.

Biocides can kill microorganisms in many ways. In some cases, there may be hundreds or even thousands of binding sites or places in a bacterial cell where the biocide is active. Even if a cell mutates so a site on its surface no longer binds a biocide, it may have a very limited effect on the biocide's effectiveness. Another factor is use levels. A sanitizer or disinfectant is often used at many times the MIC for that antimicrobial. For example, the MIC for a typical QAC against many organisms is 0.5-2 ppm. An organism with resistance to a QAC might tolerate 2-5 times that much QAC to survive 1-10 ppm. But QAC is used at 200-800 ppm in many applications, so this level of resistance has little or no effect.

Intrinsic resistance is also not a particularly relevant resistance as long as due care is taken when selecting sanitizers and disinfectants. Because this characteristic is stable and is inherent to the nature of target microorganisms, the effectiveness of an antimicrobial can be tested against the microorganism and the antimicrobial's label will indicate which microorganisms the treatment is effective against.

Often the most serious form of resistance is phenotypically acquired resistance, or organisms growing in biofilms or those protected by soil. The most important step for controlling these kinds of organisms is good cleaning practices. Yet when there is a microbial problem, many people change sanitizers on the assumption that organisms have acquired a genetic resistance or use the sanitizers at higher than recommend concentrations. Unfortunately, because most sanitizers and many disinfectants are poor cleaners and because the chemicals are often prevented from physically contacting microorganisms in biofilms or soil, such responses are ineffective. The correct response to this kind of resistance is to clean better.

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Ensuring the Adequacy of Your Cleaning Process

Using the right tools and applying standards and verification methods will help comply with QA criteria and mitigate risks to public health | BY **ROLANDO GONZÁLEZ, PHD**

Every day, food processors must make the high-risk decision to begin production, and one key factor in that determination is the effectiveness of the most recent cleaning and sanitation of their manufacturing environment. These judgment calls usually need to be made quickly and under tight schedules. Therefore, it's critical to have a hygiene monitoring and testing program that can be relied on to efficiently provide both accurate and precise results. While no sampling method is capable of recovering 100 percent of the contaminants and organisms present, food processors and industry professionals still need to be as confident as possible before they begin production that the surfaces they are working on are sufficiently clean in order to comply with QA criteria and reduce the risk of potential food contamination.

While QA compliance may seem like enough of a motivator, the risk factors go beyond mere failure to comply. Improper cleaning can result in cross-contamination with spoilage or pathogenic organisms that may impact product quality or safety, respectively, sometimes even resulting in product recalls and unwanted media attention. After factoring in potential financial toll and regulatory agency involvement, it becomes clear just how important ensuring the cleanliness of surfaces and equipment should be to an organization.

Cleaning vs. Sanitizing

One of the first things a plant operator can do is to take a step back in understanding the difference between cleaning and sanitizing; they are not one and the same, though many assume this to be the case. Cleaning involves the removal of food residue and other types of soils from surfaces. By contrast, sanitizing refers to reducing the number of microorganisms to safe levels. The sanitation typically occurs through heat or chemical processes.

Forms of Verification

A critical next step in assessing whether a surface or piece of equipment is clean is comprehending that cleaning is not just a process food safety professionals will complete prior to sanitation, but a process that will be verified before sanitizing takes place. Verification of the efficacy of cleaning is possible with the use of methods such as visual inspection, microbial enumeration, and adenosine triphosphate (ATP) detection. Rigorous industry standards dictate that individuals responsible for this process establish a quantifiable baseline reference, then verify that cleaning has been performed at or exceeding this threshold. In a food manufacturing plant, for example, this process usually involves identifying several test points based on surface and product type, hygiene zone, and risk level that must be verified before production can begin.

Visual inspection allows for the overall assessment of surfaces and equipment, and its definition can be taken at face value: It means visually inspecting an area for cleanliness. Although the method is still used for many reasons, it is limited in that it's subjective, and most importantly, even if a surface appears clean it does not mean that it is. Therefore, visual inspection should be documented and utilized as a supplement to other methods.

Microbial enumeration is a tool to verify cleaning and sanitation that involves estimation of microbial loads through direct counting of colonies in a microbiological medium, and includes indicator organisms in addition to pathogens. While microbial enumeration has an exclusive emphasis on direct estimation of microbial loads on surfaces, its main limitation is the time to obtain results (24-48 hours).

ATP measurement is the most common rapid verification approach used by many facilities. Measuring the levels of ATP on surfaces or in closed systems via rinse water sampling allows for assessing the sanitary conditions after cleaning, and has become an indispensable method over the last several years. ATP is present in all living cells, making it the ideal molecule to test for to verify that no organic material remains on a cleaned surface. Most ATP systems are simple to use and provide an indirect estimation of microbial contamination and residual organic matter that may still be present. Instruments used for the detection of ATP—or luminometers—can be photodiode or silicon-based, among other emerging technologies, and establish a correlation between light emitted from a bioluminescent reaction proportional to the amount of ATP present.

Determining the proper sampling frequency, analyzing the data collected over time, and choosing the right methods and test points are all central elements of a robust sampling, testing, and monitoring

plan. Consistent data is derived from instruments and test kits that are calibrated and tested for accuracy on a routine basis. Individuals who collect the samples are trained systematically in order to reduce, as much as possible, human variability. These individuals know they will be required by both internal and external audits to show their results and demonstrate that proper action took place should a fail occur. For these reasons, having a system that automates retrieval and management of this data is of immense value. For example, the new 3M Clean-Trace Hygiene Monitoring and Management System software provides a versatile platform to support managing and analyzing hygiene monitoring data for informed decision making.

Following Instructions

Food safety managers don't just need their results to be fast; they need them to be precise and accurate. Scientists and engineers have therefore begun focusing on enhancements to improve testing speed, precision, and accuracy. To do that, rather than the standard photodiode and silicon-based instrumentation, top developers have selected photomultiplier detection technology—the gold standard in scientific fields ranging from astronomy to medical imaging and medical device instrumentation to radiation.

Photomultiplier detection technology is about two times faster and 100 times more sensitive to light than photodiode-based solutions. Whereas photodiode-based systems require, on average, 12 to 15 seconds to measure, a photomultiplier-based device, such as the 3M Clean-Trace Hygiene Monitoring and Management System luminometer, requires only 7 seconds. Some photomultiplier tubes are so sensitive that they are able to detect a single photon in one second. By contrast, the human eye can't notice anything smaller than 100,000 photons per second.

Yet even with inspiring technology emerging that promises to make the cleaning verification process more reliable than ever, it remains critical that the food safety professional adhere to protocol and follow instructions. When it comes to the specific technique of swabbing or sponging samples, for instance, the most simple, yet most important thing is to consistently follow the guidance provided by the manufacturer of the product being used. It is this attention to detail that keeps the human element in check during the process of determining whether a food preparation surface or piece of equipment is acceptably clean. Accuracy is critical in hygiene monitoring; precision and reliability mean everything, and "close enough" is not acceptable.

Working with the right tools, understanding cleaning and sanitizing standards and processes, and recognizing the importance of verification will ensure that food safety professionals are effectively mitigating the risk to public health and to their company's brand.

Dr. González is a member of the Global Food Safety Team within 3M. He brings over a decade of food safety and quality management experience across various food platforms, with primary focus on risk mitigation and brand protection. Reach him at rjgonzalez@mmm.com.

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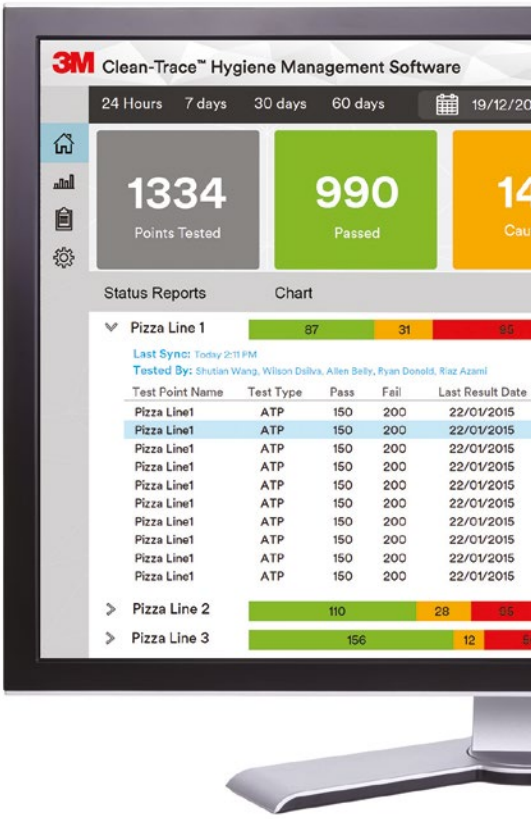

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Contributions OEMs Can Make to Food Safety

What they should know about sanitation and predictive maintenance | BY **JEREMY KING AND JERRY SCHERZINGER**

Some of us can remember from our childhood history classes the shocking story of contaminated food and its impact, particularly on immigrants in the late 19th and early 20th century. In books such as "The Jungle," so-called "muckrakers" exposed the causes and extent of the problem. Their writings led to the creation of the FDA and made food safety an urgent priority.

Recently, bi-partisan leadership took forceful action to mitigate foodborne diseases by passing the Food Safety Modernization Act (FSMA). And its most significant shift, one that cuts directly to the heart of the problem and which has required the urgent attention of food companies and their business partners, is that it changes the mandate from responding to contamination to preventing it.

OEMs and the Food Industry

Many OEMs with long-established relationships in the food industry take pride in their ability to address food sanitation matters even before the government issues food grade requirements. Ryan Edgington, president and CEO of All-Fill, Inc., says, "Cleanliness, sanitation, and ease of access to critical and hard-to-reach areas of the machine are always at the forefront of our standard designs."

At Dorner Manufacturing Co., which designs conveyors for food companies, John Kuhnz, vice president, Engineered Solutions Group, says, "Dorner has platforms designed for application in packaging to direct food contact, products from bakery to proteins, environments from ambient to frozen, and sanitation practices from wipedown to 1500 PSI washdown with caustic cleaning chemicals. As a result, Dorner has been able to meet and exceed the hygienic requirements."

But not all OEMs are prepared. Some are holding back on making the proper adjustments to their machines pending new guidance from the FDA, and smaller OEMs in particular do not always understand the regulations and what they must do to comply. When we at Bimba approach OEM machine builders with new technologies that will monitor machine performance, we are often told by their engineers and maintenance personnel, "Well, that's nice to know about, but I won't add it unless the customer asks."

Recent interviews show customers may indeed want help from OEMs. There is a window of opportunity now open to them, according to the PMMI's (The Association for Packaging and Processing Technologies) "2016 Food Safety Modernization Act Update Report." The report states, "Even though FSMA has created many challenges, most companies have not tried to seek outside help. This is changing quickly as deadlines approach and more companies use OEMs as a consulting resource."

Several service categories for OEMs have been mentioned, such as risk assessment, equipment communications capabilities, machine testing, and validation. One particular area in which OEMs may be able to have a positive impact is through consulting opportunities with smaller food companies. By learning what works and what does not through experience they can then leverage that knowledge as a valuable resource to food companies.

Machines and Contamination

Changes to cleaning processes can often make up for machines with less than ideal food safety designs. It's important to understand the potential of equipment—even equipment specifically manufactured to be as effective as possible against contamination—to have a negative impact on the sanitation of that same equipment if the correct materials are not applied.

For example, when changes to cleaning involve more aggressive chemicals or more frequent cleaning, the surfaces being cleaned may break down more quickly. Localized pitting of those surfaces can create a porous surface that is ideal for the growth of bacteria. Every piece of equipment from screw heads, bends, and joints to the feet of the machinery, can hide contaminants.

So what are the optimal materials and design components for food processing equipment and what cleaning and disinfection options and procedures are best for equipment surfaces?

One key point to stress here is one that may seem counter-intuitive but is nevertheless true: Aggressive cleaning and disinfection solutions pose a significant challenge for machine designers in the food equipment industry. Consider this: Water comprises approximately 95 percent to 99 percent of cleaning and sanitizing solutions, carrying detergent sanitizers to the surface and moving soils or contamination away from the surface. But water that contains impurities can reduce the effectiveness of a detergent or sanitizer. Oxygen and carbon dioxide cause corrosion; bicarbonates such as sodium, calcium, and magnesium cause scaling; chlorides or sulfates are implicated in scale and corrosion.

(Continued on p. 32)

(Continued from p. 31)

Everybody understands the need to prevent food soil from touching food contact surfaces. But soils can be visible or invisible. The primary source of soil is the product being handled. However, minerals from water or cleaning compound residues also contribute to films left on surfaces. And, since soils vary in composition, no one detergent can remove all types.

Therefore, OEMs need to keep in mind that their machines are liable to be exposed to a variety of cleaning chemicals. For instance, acidic cleaners dissolve alkaline soils (minerals) and alkaline cleaners dissolve acidic soils and food wastes. Improper use of detergents can actually "set" soils, making them harder to remove.

Once the type of soil that needs to be addressed has been identified, OEMs need to be aware of the effects that different types of cleaners may have on their equipment. For example, strong alkalis, such as caustic soda, destroy microbes and dissolve protein, but they cause corrosion. Other less powerful alkalis, like sodium carbonate, remove fats but are slightly corrosive. Then there are phosphoric and hydrofluoric acids, excellent for dissolving surface mineral deposits but corrosive to concrete, metals, and fabric.

In short, aggressive cleaning and disinfection solutions pose the greatest challenge for machine designers in the food equipment industry. Their effects can be significantly mitigated by specifying stainless steel for the surfaces of food equipment. Stainless steel provides resistance to corrosive elements, has no negative impact on individuals who handle the material throughout the production process, and is highly reusable and recyclable.

Keeping these considerations in mind, OEMs can add value for their food industry customers by designing equipment that is not only easily cleaned and sanitized, but designed with materials capable of providing extended years of service.

Machine Maintenance

Most players have not been willing to make large investments in new equipment or upgrades. Instead, they find it more economical and equally effective to update cleaning and maintenance procedures on machines. Food companies are looking to OEMs for consulting services, particularly in risk reduction, equipment monitoring, and machine compliance testing.

This reliance on OEM support is strongly reinforced by the results of an independent study for ABB Turbocharging, a global provider in the manufacture and maintenance of turbochargers for 500 kW to 80+ MW diesel and gas engines. The majority (87 percent) of organizations in this study say they work only or mostly with OEMs for maintenance support and spare parts procurement. The reasons should be obvious to all of us who work for or with OEMs. OEMs deliver responsive service, expertise, and knowledge of the market, all of which are essential elements of efficiency. The food industry (or any served by large OEMs) faces economic forces that must be confronted with reduced costs, the reduction of unplanned downtime, and minimal maintenance expenses. This study says, "Minimizing…operational risks is a priority for 66 percent who are focused on eliminating both the potential for damage to their installations and breaching of safety regulations caused by parts failure."

When specifically applying this lesson to food quality and safety, the PMMI concludes, "OEMs should note that the capability to track machine performance issues and downtime and analyze this data with effective tools (has) an immediate and dramatic impact on a company's bottom line. One respondent explained how downtime costs the company more than $10 million per year, and they are more than eager to pay $30,000 per machine for at least 100 machines for user-friendly solutions."

There is a strong link between sanitation and machine maintenance. The fissures in the surfaces of food processing machines will increase the amount of time it will take to properly clean the surfaces, or render them actually "un-cleanable." It may not directly cause downtime in the traditional sense that the machine must be repaired, but additional cleaning time means less time for production.

There are solutions—technology platforms—that enable users to be proactive about maintenance and system optimization by delivering real-time performance data, thereby enhancing productivity without sacrificing quality or efficiency.

The FDA has taken note. It is requesting access to data from remote monitoring tools, reducing the need for workers to access the equipment to check on the condition of wearable components thus saving time and money. By offering Internet of Things-enabled condition monitoring, spare parts, and equipment repair services, OEMs can remotely monitor asset health in their customers' plants, anticipate failures, order the parts, and often execute repairs before the failure occurs. This provides an ongoing, services-based revenue stream for OEMs, while enhancing customer uptime and overall satisfaction.

An increasing number of Bimba's OEM customers are looking to remotely monitor the machines they sell to ensure they are being operated within the design specifications and help reduce warranty claims. Remote monitoring also lets them improve future products because they no longer have to rely on companies using their machines to report how those machines are being used. They can see it for themselves.

With access to a real-time treasure trove of data, food manufacturers can achieve efficiencies on the plant floor and throughout their entire operations. An industrial refrigeration company can, for example, stay on top of equipment health by using sensors to detect unusual vibrations that might indicate a potential failure. This allows them to practice predictive maintenance and eliminates any risk of downtime. A manufacturer of baked goods can use predictive maintenance technology to automatically adjust oven temperature to match the characteristics of specific grains from different suppliers to ensure that quality remains consistent.

In summary, a number of avenues are available for OEMs to both contribute to food safety *and* contribute to their bottom line. Acknowledged thought leaders in the food processing industry exist at larger food companies. By seeking out and listening to what those customers want (longer equipment service life, predictive maintenance and reduced downtime, and serialized process data tracking), savvy OEMs can add revenue streams by sharing their knowledge on a consultative basis as well as improving existing revenues through machine design that meets and exceeds the growing demands of FSMA.

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Ozone as an Added Protection in Food Processing Chain

Ozone technology used in day-to-day food safety protocols for sterilization of bacterial, fungal, viral, and prion contaminants

BY **BRUCE HINKLE**

Every step from farm to fork is fraught with the danger of contamination. Although more is known about the risks of contamination in the food chain from production to plating than ever before, food safety practices have struggled to keep up.

The fact is that chlorine-based chemical sterilization procedures cannot protect food products from all risks, as emerging pathogens demonstrate increasing resistance to customary concentrations of chlorine-based food safety systems.

Ozonated Water to the Rescue

America's largest farm operations, food animal processors, restaurants, grocery stores, wineries, and breweries are all utilizing ozone technology in their day-to-day food safety protocols, achieving almost complete sterilization of bacterial, fungal, viral, and even prion contaminants. Aqueous ozone achieves between 99.99 percent to 99.9999 percent sterilization of food products contaminated by disease causing pathogens, essentially, on contact.

When swimmers in Malibu became ill because of waterborne pathogens from sceptic tank effluent, ozone helped solve the bacterial contamination problem. When a pharmaceutical facility had to shut down because of tenacious biofilm contamination, ozonated water was the solution. Ozonated water technology has solved many other pathogenic and chemical pesticide contamination issues in various industries. Interestingly, disinfection of food products at every stage of the farm-to-fork process presents greater challenges than the problems presented by contamination in these controlled industrial environments as there are simply more food safety variables at play.

Real-World Users

Familiar brand names, such as Whole Foods, The Cheesecake Factory, Kanaloa Seafood, Frank Family Vineyards, Coca-Cola, Sierra Nevada Brewing Co., Halpern's Meats and Seafood, and Fresh Direct, are successfully utilizing aqueous ozone technology to accomplish high levels of food safety.

Companies turn to ozonated water to assure protection of their valuable brands. The Cheesecake Factory has stated in its 2016 annual report "We utilize ozone cleaning systems for certain ingredients in approximately one-half of our prep kitchens, and plan to further roll out this program in order to provide an effective 'green' sanitizing method that is consistent with our sustainability goals."

Dr. Al Baroudi, PhD, CFS, VP, QA, and The Cheesecake Factory's food safety guru, reports, "By killing bacteria on contact, ozonated water disinfection provides the extra needed protection against a cross-contamination event or a deadly *E. coli* outbreak."

Bruno Serato, award-winning chef, and owner of the Anaheim Whitehouse restaurant, installed an ozonated water system in his kitchen and catering facilities. Chef Bruno says, "My ozonated water system is my added insurance policy. Every year there are millions of cases of foodborne illness hospitalizations and deaths due to foodborne bacteria. Ozonated water should be mandatory equipment on food service."

Whole Foods has also endorsed the use of ozonated water going forward, as it has been utilizing the technology in its stores since 2006.

The Benefits

Ozonated water is a cold-water disinfection agent. Currently, chlorine chemical cleaning processes require expensive hot water, and consumes valuable storage space for the chemicals and rinsing solutions. Use of chlorine-based sanitizing systems require frequent deliveries, dedicated storage space, and the training and tasking of employees on how to measure and mix proper proportions of chemical cleaning agents. Chlorine-based systems also require substantial rinsing. Inadequate rinsing can result in the addition of unpleasant bleach flavor to food products.

Conversely, there is no hot water or storage of chemicals needed with ozonated water. Training of food handlers in the use of ozonated water is a one-step process: Immerse the food in ozonated water for at least 30 seconds. The benefits of ozo-

For Further Reading

The book "Ozone in Food Processing" brings together essential information on the application of ozone. This reference includes topics on current trends, regulatory and legislative issues, and specific food applications. The book also discusses operational systems and provides technical studies to confirm the efficacy of ozone. For more information on book, go to http://ow.ly/lKCV30dpmUq.

nated water systems don't stop there: They only require inspection and maintenance once a year, on average; they are environmentally safe as the ozone molecules naturally revert to oxygen within 20 minutes; they don't require dedicated disposal procedures, like chlorine-based products; and they don't leave behind harmful residues.

Tri-atomic oxygen is infused into ozonated water to produce an all-natural sanitizing agent that can be 50 percent stronger than chlorine. It prevents decay and thus extends shelf life by eliminating decomposition agents such as bacteria, yeast, and molds, and enhances food safety by reducing populations of foodborne pathogens, including *E. coli, Salmonella, Listeria*, and *Shigella*.

Ozone can work about 3,000 times faster than chlorine, and requires fewer parts per million to achieve its desired results. It can achieve 4 to 6 log reductions in a short period of time without the by-products of chlorine. For example, a 5-log reduction of *E. coli* population can be accomplished by exposure to aqueous ozone for only 30 seconds. Aqueous ozone is effective against *E. coli* populations whether they are found on the surface of food stuffs, or on the hands of food handlers, who can immerse their hands in ozonated water rinses during food preparation.

Ozone has been approved as a disinfection/sanitizing agent for more than 16 years when the FDA granted GRAS status approval in 2001. Ozone is approved for organics, and is approved by FDA as a food additive. Ozonated water also relieves food operations from burdensome recordkeeping as the EPA does not require reporting in connection with the use of ozonated water.

New advanced ozonated water systems have been designed to integrate into existing food production, processing, and handling facilities. They are scaled from small operations to large industrial operations; that is, something as simple as a sink that dispenses ozonated water from its faucet to larger ozone generators used in the creation of large quantities of ozonated water that can disinfect/sanitize large scale food production processes.

Ozonated water in the wash environment can enhance food safety by killing waterborne and surface pathogens on food products, processing equipment, and contact points of food handlers. Ozonated water systems meet Hazard Analysis and Critical Control Points, or HACCP, requirements by providing automated verification and reporting of control over water usage and disposal. Oxidation-Reduction Potential probes monitor the strength and data logs the readings of the ozone systems while assuring operational status.

Ozonated water breaks down into water and oxygen molecules, leaving no residue. Unlike chlorine sterilizing processes, there is no need for facilities to receive, store, or dispose of ozone.

If you spill ozonated water, get a mop. If you spill chlorine, well, that's a problem you don't need. Ozonated water is the modern, economical, and environmentally benign solution to an ancient problem.

Hinkle is chief technical officer at PureQuest Ozone Technologies. Reach him at bruce@purequestozone.com.

Quality
AUTHENTICITY

Mitigating the Risk of 'Fake' Food

Practical tools and recommendations in creating an effective food fraud prevention program

BY **JEFF CHILTON** AND **KAREN EVERSTINE, PHD, MPH**

Food manufacturing companies are increasing the attention paid to food fraud, which can greatly impact a brand if adulterated food ends up on customers' plates. The rise in consumer awareness drives companies to continually strengthen their food safety and quality programs.

Food Fraud Yesterday and Today

Food fraud issues are not new. Frederick Accum's "A Treatise on Adulterations of Food and Culinary Poisons" from 1820 and Dr. Harvey W. Wiley's Poison Squad of 1902 demonstrate the long-standing concern with adulterated foods and undeclared additives. What has changed is that the health risk due to food fraud (a.k.a. economically-motivated adulteration, or EMA) has become a widely-publicized issue with corresponding increases in regulatory and certification program requirements. What has also changed is the sophistication with which fraudsters adulterate food and the speed of evolution of analytical detection methods.

Food fraud is complex and includes the dilution or substitution of ingredients with an alternate ingredient (this could be an ingredient of lesser quality or even one that is not intended for use in food), the artificial enhancement of perceived quality (such as fraudulently increasing the apparent protein content and "improving" the color with undeclared color additives), the use of unapproved antibiotics and preservatives, misrepresentation of nutritional content, and fraudulent labeling claims (such as organic, cage-free, etc.).

New Requirements

Both the U.S. FDA and the Global Food Safety Initiative (GFSI) have recognized the threat of food fraud in the food supply. As a result, new FDA regulatory requirements and GFSI requirements have been established to ensure that food manufacturing and distribution facilities address food fraud vulnerabilities in their food safety and quality management systems.

The FDA's focus is on EMA that can result in food safety issues, and it requires facilities to identify potential hazards (including those resulting from EMA) during their documented hazard analysis process. When raw materials with relevant potential hazards are identified, appropriate controls should be put in place. Given the nature of EMA, these will most likely be supply chain controls.

Facilities certified under GFSI programs such as British Retail Consortium (BRC), Food Safety System Certification (FSSC) 22000, and Safe Quality Food (SQF) must consider food fraud in terms of both food quality and safety. For companies that will be certified under SQF Edition 8 and FSSC 22000 Version 4—both of which will become effective in January 2018, food fraud vulnerability assessments and mitigation plans will be new requirements of those certification programs.

Risk Mitigation

In contrast with unintended contamination with microbiological, viral, or other agents which may be present in animals or the food production environment, food fraud includes the added challenge of being both intentional and economically motivated. This makes risk assessment a more difficult task. Food fraud is generally addressed from the perspective of vulnerability—in other words, which ingredients in a portfolio may be more vulnerable to fraud due to various specific factors. These include things such as the strength of the supplier relationship, the audit strategy, the effectiveness of the analytical methods, and the known history of fraud for a given ingredient.

The U.S. Pharmacopeial Convention (USP) Food Fraud Mitigation Guidance (www.foodfraud.org) is a publicly-available framework that guides users through an evaluation of nine contributing factors to food fraud vulnerability. It also helps

users consider potential impacts of food fraud, both economic- and health-related, and putting a mitigation plan in place to reduce vulnerabilities. Food fraud history is specifically cited as an important component of vulnerability assessments. USP's Food Fraud Database is a tool that searches and identifies historical records for food fraud along with published analytical detection methods. USP also publishes the Food Chemicals Codex that describes the form, function, and specifications for more than 1,200 food ingredients, along with analytical methods and corresponding reference materials to ensure quality and purity and further establish the identity of food ingredients. Use of public standards can be an important component of a food fraud control plan in addition to being useful in an overall food quality control program.

Vulnerability Assessments

There are three primary steps to effective food fraud prevention programs: 1) raw material vulnerability assessment, 2) food fraud mitigation plan, and 3) food fraud program sustainment.

The first step in creating a prevention program is to conduct a vulnerability assessment of all raw materials or groups of raw materials. As part of this assessment, food producers must identify the source of their ingredients to determine whether they come from potentially high-risk geographic areas or suppliers. Other considerations include whether ingredients have a known history of adulteration and whether there are economic considerations that would increase the incentive for fraud. Raw materials can then be categorized as low, moderate, or high vulnerability.

The second step in creating a food fraud prevention program is developing a food fraud mitigation plan, which is required by GFSI-recognized certification program owners. Once the vulnerability assessment is complete, the food producer must determine what specific control measures are required. These will depend on the vulnerability level and may include laboratory testing, audits, and any additional measures determined by the facility. At a high level, the following are some general strategies for reducing food fraud vulnerability for sourced ingredients.

Understand your supply chain. This includes the geographic region where the raw material is sourced, the number of upstream suppliers, and what upstream controls are in place.

Know your suppliers and track their performance history. Effective supply chain management programs should include comprehensive supplier approval procedures and supplier evaluation processes. Supplier approval procedures must require potential vendors to submit all relevant information, such as product specifications and third-party audits. Once approved, the supplier evaluation procedures address supplier performance, including tracking of any non-conformities and ongoing evaluations of pricing, service, delivery, and third-party audits completed at least on an annual basis.

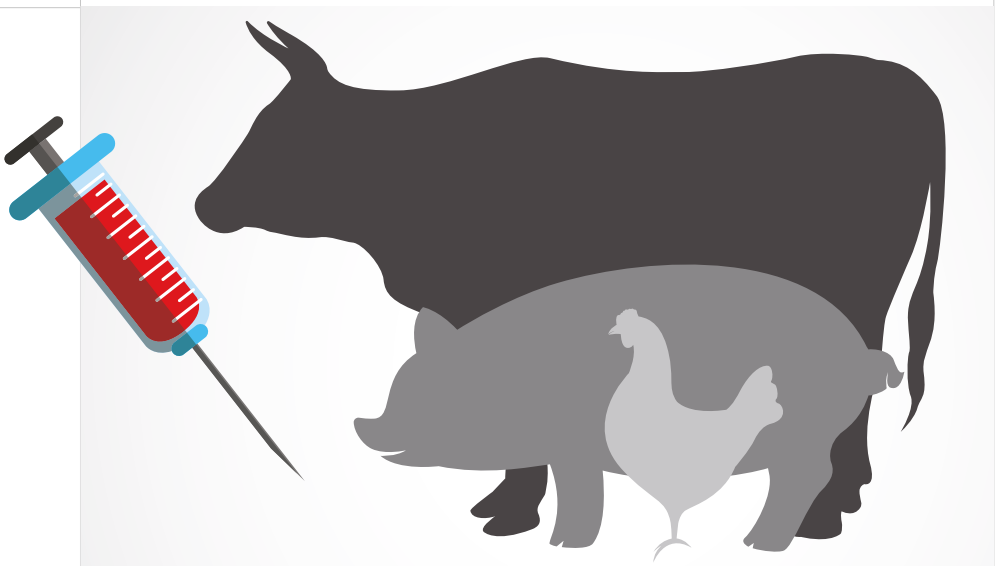
Determine necessary verification processes. This may include audit strategies and specification and testing requirements. Once accurate vulnerability levels have been assessed and determined, appropriate verification methods can be established in the written food fraud mitigation plan. These verification methods will likely differ among raw materials and suppliers based on the vulnerabilities. A trusted supplier of a low vulnerability ingredient may only be required to provide a third-party audit report. Moderate-risk raw materials may require a certificate of analysis (COA) in addition to the third-party audit. High-risk suppliers of high vulnerability ingredients may be required to perform periodic verification testing to validate the results of the COAs they provide.

The last step is to put in place a food fraud program sustainment system to ensure continued compliance and validation of food fraud management systems. These management systems must be kept up-to-date as companies develop products with new raw materials or source raw materials from different suppliers. Quarterly reviews are recommended, as well as an annual validation assessment to ensure the ongoing effectiveness of a company's systems and to meet the annual review

(Continued on p. 54)

Testing

HORMONES/ANTIBIOTICS



Hormone Detection Tactics in Ireland

Screening for growth promoting hormones at the Irish Equine Centre

BY **AISLING TREACY, MSC.**

In Ireland, the European Communities (Control of Animal Remedies and their Residues) Regulations 2009 implement the provisions of Council Directives 96/22/EC and 96/23/EC. They prohibit the import, manufacture, sale, supply, administration, or possession of substances having oestrogenic, androgenic, gestagenic, or thyrostatic action and beta-agonists. Limited exceptions are outlined in 96/22/EC for animal remedies that may contain these substances.

The National Residue Control Plan (NRCP), drawn up in accordance with Council Directive 96/23/EC on measures to monitor certain substances and residues in live animals and animal products, is approved by the European Commission and implemented by the Food Safety Authority of Ireland. The scope of testing under the NRCP, for which the Irish Equine Centre is an official laboratory for part of these analyses, is very comprehensive, covering all 11 animal/food areas and 18 distinct residue groups that fall into four broad categories: 1) banned substances, such as growth promoting hormones; 2) approved veterinary medicines; 3) approved animal feed additives; and 4) environmental contaminants.

Testing carried out under this Plan and the low incidence (less than 0.2 percent) of non-compliant samples during last few years indicate that the controls in place are ensuring the dispensing of banned growth promoting hormones and banned substances to food-producing animals in Ireland remains low, or those illegally using these substances have evaded detection.

Growth promoters, which are tested for under the NRCP, are hormonal and antibiotic substances that may be used in food producing animals to increase the production of muscle meat and the reduction of fat. The type of growth promoter used is dependent on the animal species and mode of rearing. Antibiotic growth promoters are usually added to feedstuffs, such as coccidiostats used in poultry and chlorotetracycline used in the porcine industry.

Human Health

It is not clear what the potential human health impacts of growth promoters are, particularly when it is possible that exposure may be extended over long periods of time. Of the hormonal growth promoters (anabolic steroids) the use of three natural steroids (17β-estradiol, progesterone, and testosterone) and three synthetic hormones (zeranol, trenbolone acetate, and progestin melengestrol acetate) have been banned in the EU since 1988. For all of these six hormones, endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic, and carcinogenic effects could be possible. Of the various susceptible risk groups, prepubertal children is the group that was reported to be of greatest concern by a report on the Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health (SCVPH)—April 10, 2002 (on review of previous SCVPH opinions of April 30, 1999 and May 3, 2000 on the potential risks to human health from hormone residues in bovine meat and meat products). Therefore, from a consumer health perspective, it is essential that testing is carried out for these substances.

Of the antibiotic growth promoters, prophylactic use is common practice in animal feed and can be vital for animal health, particularly with intensified animal rearing. Suppression of disease causing organisms by prophylactic use of antibiotics may reduce the incidence of clinical and subclinical disease, resulting in better animal health and growth. The same classes of antibiotics used to treat humans are given to animals. A 2013 U.S. FDA report revealed the meat industry accounts for nearly four fifths of all antibiotics used. If antibiotics are administered at a therapeutic level (in the absence of prophylactic use), the consumer may be exposed to the antibiotic, particularly if it's not used judiciously with observation of withdrawal times so maximum residue limits (MRLs) aren't breached. This in turn could heighten the issue of antibiotic resistance, which affects all species.

Detection

Due to the economic benefits to be gained from the use of illegal growth promoters, they will continue to be used in animal production. As analytical methods of detection become more sensitive, methods of evasion have become more sophisticated. The ban on the use of steroid implants (which were easily detected upon ante-mortem inspection) resulted in the production and distribution of liquid-based steroid formulations. The use of low-dose multi-compound cocktails, which are below detectable levels but have a synergistic effect when used together, and natural hormone administrations such as 17β-estradiol, make detection and confirmation of these substances difficult. This in turn presents a challenge to regulatory authorities tasked with enforcing their ban.

The Special Investigation Unit (Ireland) provides specialist inspectors for the Department of Agriculture to investigate and deal with the use of illegal substances in animal production. Surveillance for residues of veterinary substances in food-producing animals is regulated by the Directive 86/469/EEC, which offers guidelines for sampling procedures on farms and in slaughterhouses. The category of compounds and species will determine the level and frequency of sampling and this is outlined in the NRCP each year. Sampling intensity increases in response to the incidence of non-compliant samples. This was evident during the bute horsemeat scandal in 2013 with intensified sampling for phenylbutazone in horses, which is a group A prohibited substance under Directive 96/23/EC (Annex I). This also occurred for anthelmintics in sheep/goats and dioxins in all species and food commodities.

Analytical methods of detection have become more sensitive over time due to the requirement to meet detection levels or MRLs outlined in legislation. For some substances, these have been lowered and methods must be sensitive enough to detect very low concentrations of substances in multiple matrices. There are several analytical methods used for detection of drug residues in a sample. Enzyme-linked immunosorbent assay (ELISA) methods usually target one substance and their cross reactants. This methodology works well as a screening tool for targeted screening. The disadvantage of using ELISA-based methods is in the event that a single sample needs to be screened for multiple drug residues since each drug residue has to be tested using a specific kit. The Siemens Immulite, which is an automated chemiluminescent immunoassay, is used for hormone detection such as progesterone and estradiol in serum samples. Again, as for the ELISA, an individual kit is required for detection of each individual hormone.

Randox Food developed another method of biochemical analysis using the Evidence Investigator, which features biochip array technology (BAT) used to perform simultaneous quantitative detection of multiple analytes from a single sample. The core technology is the Randox biochip, a device containing an array of discrete test regions containing immobilized antibodies specific to the drug residues under test—according to the kit type. The Evidence Investigator is a benchtop analyzer housing digital imaging instrumentation that captures the chemiluminescent signal emitted from drug residue conjugates labeled with HRP.

All of these methods are rapid, reliable, and sensitive. Drug residues or hormones can be detected in very small concentrations. The results must be reproducible and all methods must be validated in accordance with the requirements of Commission Decision 2002/657/EC, which determines standards for the performance of analytical methods and the interpretation of results.

Dairy Market

An important area of focus in residue testing is the dairy industry. Because milk and milk products, such as baby milk powder, are a huge export market for Ireland, these products must be screened for growth promoters and antibiotics. It is a legal requirement that raw milk not contain residues, including antibiotics. Each farmer is required to keep a record of all medicines purchased and administered to animals. Milk from dairy cows that are on antibiotic treatment must be discarded and kept out of the food chain until the withdrawal period has been observed. Milk testing programs used by the dairy co-ops are tested at the farm level. If antibiotics are detected, the milk must be discarded and not used for human consumption. Severe commercial penalties ensue for the farmer.

Randox InfiniPlex for milk BAT method using the Evidence Investigator is a possible option that provides a single analysis to screen for all currently monitored residues covered under legislation. It screens for over 120 drug residues, including antibiotics and growth promoters. Technologies like this are essential in an emerging market where consumer health is of paramount importance.

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HRAM for Pesticide Workflows

Full scan pesticide analysis based on high-resolution accurate mass has potential to help laboratories overcome the challenges of today and ready themselves for demands of tomorrow

BY **MACIEJ BROMIRSKI**

Targeted pesticide residue analysis is a well-established and essential part of modern food testing. Labs routinely determine pesticides present in food samples against a specific target list to ensure food products comply with the maximum residue levels (MRLs) set by governments (European Commission) and national food safety authorities.

Growing concerns over food safety and expanding international trade have led to the development and enforcement of stricter pesticide regulations. In 2014, China's Ministry of Agriculture and Ministry of Health jointly issued a revised national food safety standard, which expanded the number of categories of pesticide residues and total number of MRLs. Together with the Japanese Positive List System and European Union (EU) Directive No 752/2014, these standards are amongst the strictest food safety regulations in the world.

Traditionally, separation technologies such as gas chromatography (GC) and liquid chromatography (LC), coupled with triple quadrupole (QqQ) mass spectrometry (MS), have formed the mainstay of targeted pesticide residue quantitation workflows. The high sensitivity and selectivity offered by these QqQ-based techniques allow analysts to confidently identify and quantify even trace levels of known contaminants, while their robustness ensures fast, reliable, and cost-effective routine analysis.

Yet new pesticides are continually being developed and applied to crops around the world. The growing complexity of global food supply chains means that pesticides approved for use in one country can unexpectedly end up in food consumed in another, where the pesticides are not approved. Other chemicals, previously undetected in food samples and not on target lists, can also enter food chains during product preparation, transport, and storage from an often-surprising range of sources.

As a result, food safety laboratories are not only faced with an increasing number of analytes to screen for—they must be vigilant for new chemicals too. Of course, all of this must be achieved with high turnaround times and at a competitive cost per sample. And as food safety standards continue to evolve, laboratories need to be sure that the technology they use today will still meet their needs five years down the line.

Confident Routine Quantitation

Food safety is an evolving field. Technological advances result in ever lower limits of detection and quantitation, and greater insight into the toxicological effects of the chemicals used in industry and agriculture mean that MRLs are continually being revised. In 2016, for example, the EU announced amendments to regulations governing MRLs for a number of pesticides found in various products, including the organophosphate insecticide chlorpyrifos.

As food safety standards become increasingly strict, what was once the lower end of a permissible pesticide residue level may be the upper end tomorrow. Labs therefore need to be confident the technology they depend on to quantify these analytes is ready for future challenges.

For instance, high-resolution accurate mass (HRAM) Orbitrap MS from Thermo Fisher Scientific offers sensitivity that can help safeguard laboratories against changes in MRLs. Hybrid quadrupole Orbitrap mass analyzer instruments combine quadrupole precursor selection with high-resolution accurate mass detection of product ions. The data is acquired at a resolution that can surpass quadrupole-time-of-flight instruments. This selectivity and mass accuracy help lower and even eliminate interference and permit lower limits of detection and accurate quantification.

Since MRLs vary for different pesticide-commodity combinations, the techniques used to analyze pesticide residues must be able to identify and quantify analytes over a wide dynamic range. EU limits for pesticide residues in beetroot, for example, vary from 30 milligram/kilogram to as little as 0.03 milligram/kilogram depending on the analyte. The Thermo Scientific Q Exactive Focus hybrid quadrupole-Orbitrap mass spectrometer is an option to meet this challenge, enabling quantitation over a wide dynamic range.

Identifying the Unknown

Routine quantitation of analytes against target lists is important in protecting consumers, yet for many food safety labs it's only part of the story. As supply chains become more global and complex, the risk of contamination with previously undetected chemicals becomes greater. In addition, identification of these unexpected analytes can be one of most challenging tasks in pesticide analysis.

While LC-QqQ tandem MS enables highly selective and sensitive quantitation

and identification of hundreds of target pesticides in a single run, this approach requires extensive compound-dependent parameter optimization and can't be easily adapted to screen for untargeted pesticides.

Full scan approaches, on the other hand, are able to screen for a much broader range of analytes, meaning the search is not limited to a pre-defined list of chemical suspects. With the right analytical tools, unexpected analytes can be identified and quantified at the same time as performing routine targeted and quantitative analyses.

However, as full scan approaches produce significantly more data than conventional approaches, it is essential to use data analysis software that can rapidly process results and cross reference against spectral libraries and compound databases to make sense of all this information. These software can quickly and automatically search online compound databases such as ChemSpider and mzCloud, or a lab's own database of analytes, to determine empirical formulae or tentatively identify unknown compounds.

Boosting Laboratory Efficiency

With increasing numbers of residues to identify, labs require robust, reliable, and efficient technologies that enable high productivity. And with budgets a priority for many lab managers, these analyses must also be performed at a very low cost per sample.

One of the benefits of multi-residue screening based on HRAM Orbitrap MS is the ability to analyze multiple components simultaneously. Combining multiple pesticide workflows in a single run can help labs work more efficiently, increasing throughput and boosting productivity. Full scan approaches also allow labs to combine pesticide workflows with other types of analyte workflows, such as toxins and veterinary drugs. This way, laboratories can expand the analytical reach of their food testing workflows while minimizing the time and resources spent preparing samples for separate analyses. Furthermore, as HRAM Orbitrap MS approaches also facilitate retrospective analysis, analytes that are not currently on target lists can be identified at a later date without having to store and re-analyze samples.

In addition to advanced hardware, innovative informatics can also streamline workflows and boost productivity. Many forward-looking laboratories are using integrated method development and data analysis solutions that allow operators to conveniently modify pre-configured methods depending on the matrix or analytes of interest. Used in conjunction with cloud-based spectral library and compound database searching, these integrated software solutions can help minimize the time taken between sample injection and the analyst reaching a conclusion.

Simplifying Residue Extraction

One of the most important stages in pesticide quantitation is residue extraction. While full scan analysis workflows are able to screen large numbers of analytes faster and more efficiently than conventional QqQ techniques, they can only do this if the residues they are analyzing are fully extracted from the food matrix in the first place—and if the analytes are chromatographed and ionized.

In recent years, the widespread adoption of extraction techniques such as QuEChERS (Quick, Easy, Cheap, Effective, Rugged, and Safe) have simplified the preparation of high-moisture food samples and overcome many of the limitations of conventional approaches. Early approaches typically involved the use of multiple, time-consuming procedures, and produced results that were highly matrix dependent. The QuEChERS method, on the other hand, is based on a single acetonitrile extraction step, with an optional dispersive solid-phase extraction clean-up step. And although the method is generic, simple to implement, and amenable to a wide range of food samples, the extracts often contain high concentrations of co-extractives.

The latest separation technology is simplifying sample preparation. Thermo Scientific's TurboFlow inline clean-up technique, for example, is a sample prep approach that eliminates up to two-thirds of the steps required by traditional methods, permitting the injection of complex matrices directly into the instrument. Analytes are separated from the matrix using specialized chromatography columns packed with large particles that retain residues while larger molecules pass through. The residues of interest can then be transferred to an analytical column and subsequently analyzed.

As food supply chains become increasingly global and complex, and residue screening workflows require the screening of ever larger numbers of expected and unexpected analytes, food testing laboratories requires robust solutions that can meet not only today's food safety standards—but tomorrow's unhealthy and unwanted analytes too.

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In The Lab

MEASUREMENT METHODS

Using Rheometers to Enhance Brand Identity of Salad Dressing

Higher value dressings are investing in tests that verify differences in flow behavior

BY **BARRY RIDLEY AND BOB MCGREGOR**

How do food manufacturers of sauces and dressings distinguish their premium brand products? Taste comes first and foremost. Not far behind is the handling property—namely, visual appearance in the bottle and flow behavior when poured on salad. Consumers judge "thickness" and "creaminess" in the supermarket by holding the bottle and moving it gently from one side to another. Perception of how the dressing is likely to pour comes from this simple action. In general, careful application of dressing requires controlled flow from the bottle so that just the right amount comes out. Customer dissatisfaction arises when too much dressing gushes suddenly from the bottle or the squeezing action cannot get sufficient quantity to expel within a short time frame.

Food scientists responsible for formulation of dressings must evaluate flow properties and then set guidelines for QC during manufacturing. Yield stress is one property of interest; this defines how much squeezing force or shaking action is needed to initiate easy flow of salad dressing. Viscosity is essentially "resistance to flow;" it quantifies the physical property that relates to flow rate of salad dressing during pouring. Creep is the property that characterizes how the salad dressing behaves after it deposits on the salad. The point of interest is whether it clings firmly to the coated items or does flow continue causing it to drain off the salad.

All three properties are important, but viscosity alone has been the traditional parameter of interest. In recent years, premium brand manufacturers have also focused on yield stress and creep for the following reasons:

- Visual inspection of salad dressing in the bottle is equivalent to making a judgement on yield stress;
- Ease of use when initiating flow requires a yield stress that can be readily overcome by shaking or squeezing; and
- Adherence to salad components like lettuce and tomato requires minimal creep flow.

Flow Behavior

Figure 1 shows a rheometer with vane spindle used by R&D to characterize the flow behavior of salad dressings. The vane is immersed into a container of salad dressing and rotated at very low speed, perhaps 1 rpm, to determine "yield stress." Figure 2a illustrates the type of data curve that results when plotting stress on the y-axis and strain on the x-axis. The slope of the rising curve is called "modulus" and its value relates to the "stiffness" of the dressing. The steeper the slope, the stiffer the formulation. When the peak value for stress is measured, this correlates with "yield stress" for the dressing. Figure 2b compares two salad dressing formulations for yield stress. The upper curve shows the premium brand that has both higher

Figure 1: Rheometer with Vane Spindle

modulus and yield stress. This stands to reason since dressings with more body are generally preferred by consumers who suspect that "thinner" formulations may be watered down.

Figure 3a shows the data curve that characterizes creep behavior. Low stress is applied to the vane spindle by the rheometer to simulate the action of gravity acting on dressing after it is poured on salad. The data curve shows flow movement of the dressing as a strain value on the y-axis plotted against time on the x-axis. The flatter the strain curve, the less movement of dressing after application to salad. Figure 3b compares the same two dressing formulations. Note that the premium brand has lower creep profile. This makes sense because the non-brand is more likely to not cling as readily to salad.

Viscosity is measured by rotating the spindle at different speeds and recording the value. General observation for dressings is that viscosity reduces as rotational speed increases. This means that there is less resistance to flow the faster the dress-

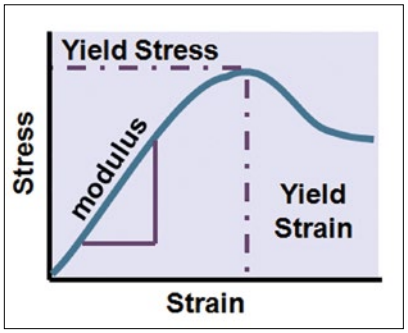

Figure 2a: Illustration of Yield Stress Curve

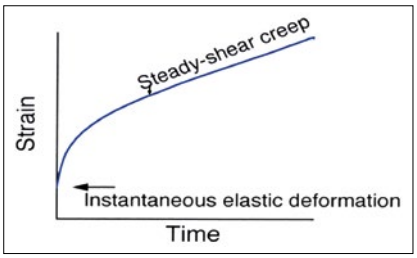

Figure 3a: Illustration of Creep Flow Behavior

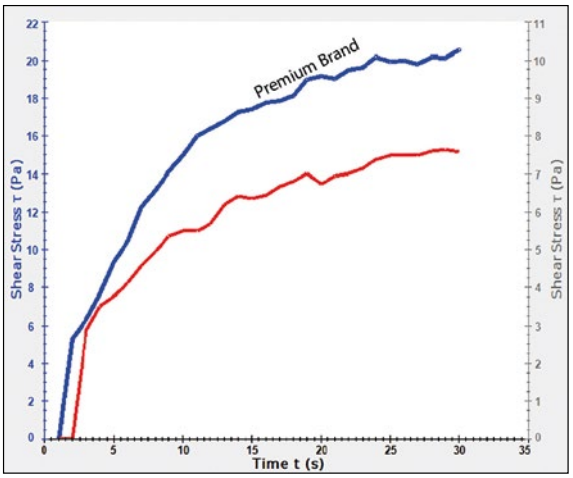

Figure 2b: Comparison of Yield Stress Curve for Two Salad Dressings

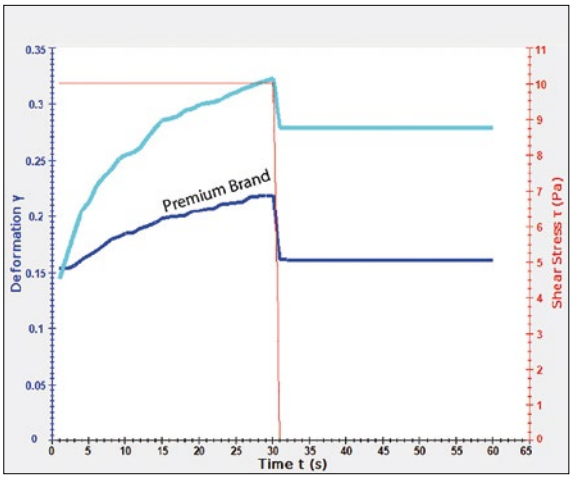

Figure 3b: Comparison of Creep Flow for Two Salad Dressings

ing moves. The graph in Figure 4 shows data for two dressings. The x-axis parameter is "shear rate," which is proportional to rotational speed. Shear rate accounts for the shape of the spindle and the ratio of spindle diameter to container diameter. The curves for both dressings look similar; the premium brand is slightly higher in value than the non-brand.

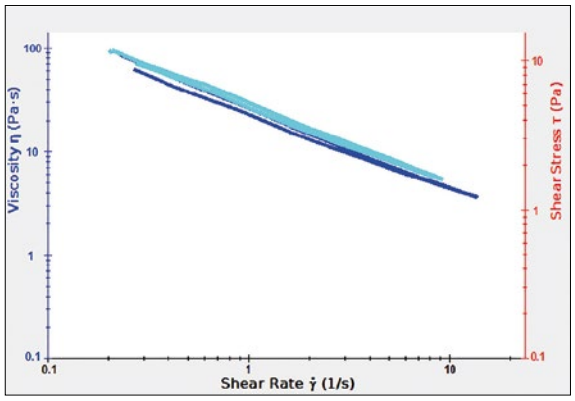

Figure 4: Viscosity Flow Curves for Two Salad Dressings

When the peak value for stress is measured, this correlates with "yield stress" for the dressing.

Traditional use of viscosity flow data might have led to the conclusion that the two dressings were relatively similar. Use of yield stress measurements and creep flow data gives a different assessment. The premium brand is more likely to have the rich creamy appearance in the bottle when evaluated in the supermarket. Its flow behavior after pouring allows it to cling to salad.

Manufacturers who strive for the higher value dressings are willing to invest in the tests that verify these differences in flow behavior. QC is now tasked with measuring not only viscosity flow curve, but also yield stress and creep. Advancements in instrumentation make it possible for rheometers to be programmed to perform all three tests at once. This allows the technician to set up the sample as before, run the test with the push of a single button, and automatically record data while tending to other tasks in the lab. Increasing use of rheometers in QC is enabling high-end manufacturers to keep pace with growing consumer demand while producing consistent high-quality dressings.

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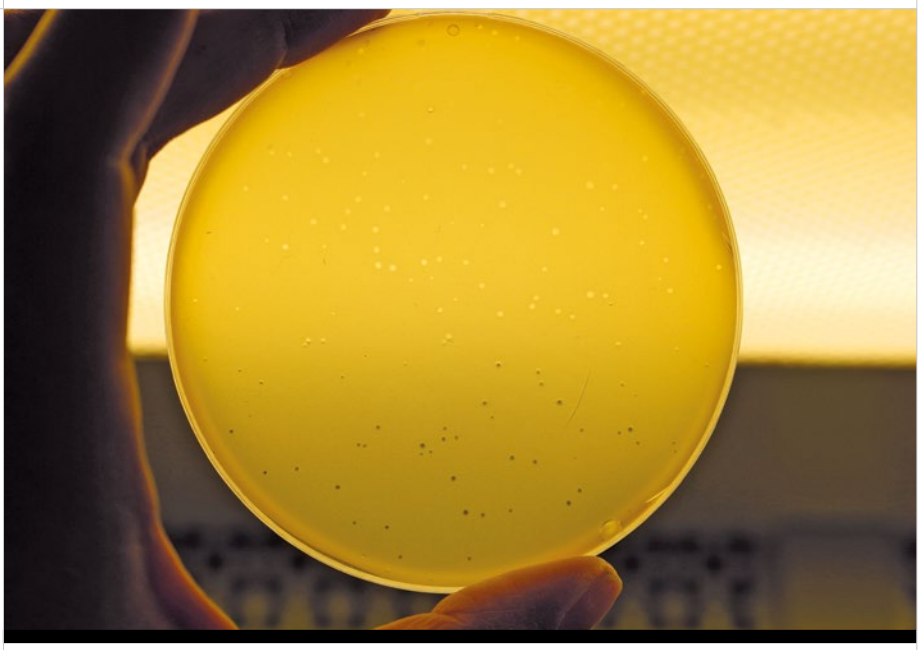


Bacteriophages: The Alternative Antimicrobials

Researching new natural replacements to control foodborne pathogens in fresh vegetables

BY **CLAUDIA NARVAEZ-BRAVO, PHD,** AND **TIM MCALLISTER, PHD**

Bacteriophages (phages) are viruses with specificity to attack and kill bacteria. This curious name originated from English (bacterium) and Greek (phagein "eat"); thus, defined as a virus that eats bacterium. They do not infect plants, animals, or human cells. Phages are abundant in nature and are part of the natural microflora in humans, plants, and animals.

Phages have survived for millions of years, which is an indication of their capacity to overcome bacterial resistance mechanisms. An interesting feature of bacteriophages is that they are very specific to the type of bacteria (host) they infect; for example, to kill *E. coli* O157:H7, particular phages are used that only target *E. coli* O157:H7, and no other *E. coli* or other bacteria present within their environment.

Phages were discovered in 1915 and microbiologists began researching the viral nature of phages as well as their strengths and limitations in the field of medicine. However, soon after the discovery of antibiotics in 1928, the antibiotic golden era began and phage therapy research in the western world was virtually forgotten. During this period, new antibiotics were introduced and millions of metric tons of antibiotics have been employed in human medicine and agriculture. Subsequently, in the late 1930s, antibiotic resistance became a clear problem that has continued to grow to this day.

In the last 60 years, many bacterial pathogens have evolved into multidrug-resistance (resistance against a variety of antibiotics) forms after antibiotic exposure. These bacteria are known as "superbugs." Therefore, the use of antibiotics in humans and in agriculture is adding to the problem of antimicrobial resistance worldwide. Consequently, the public is advocating for a decrease or total elimination of the use of antibiotics as growth promoters and even antibiotic use as a prophylactic in livestock.

The search for new alternatives for antibiotics has pushed bacteriophages to the forefront of research. This research is not only increasing in the field of human medicine, but also there is a growing interest in their potential to be used in agriculture. Bacteriophages are being researched for usage as a biocontrol technology to reduce pathogens on vegetables and ready-to-eat foods throughout the production continuum.

Why Vegetables?

These days, consumers are more aware of human behaviors and habits that can impact the environment, including what they eat, where foods come from, how they are processed, and what preservatives have been added. In this context, minimally processed vegetables are ideal for health-conscious consumers. However, fresh produce is a potential source of foodborne illnesses mainly because many vegetables are consumed fresh (raw) and no steps are employed to effectively eliminate pathogens prior to consumption. A variety of factors can influence the contamination of vegetables with foodborne pathogens. Among these contaminated irrigation water, the use of manure as a fertilizer, contaminated harvesting equipment as well as hygienic practices of workers in the fields, packing houses, and processing plants. The fruit and vegetable industry is very aware of contamination risks, and have dramatically improved food safety procedures in recent years. However, despite all efforts, foodborne outbreaks still occur.

The Shiga-toxigenic *E. coli* serogroups are among the top foodborne pathogens that have been associated with produce outbreaks. These mainly involve seven *E. coli* serogroups (O26, O45, O111, O103, O121, O145, and O157:H7). *Salmonella* and *Listeria monocytogenes* are other important foodborne pathogens that have been linked to fruit and vegetables.

Vegetable contamination with these pathogenic bacteria begins with their attachment to plant tissue. For example, researchers have shown that *E. coli* O157:H7 prefers to attach to cut edges rather than to whole-leaf lettuce, it can attach in a short period of time, and can only be partially removed using chlorinated water washes. However, only a few Shiga-toxigenic *E. coli* cells can cause disease, thus alternative methods to decrease or elimi-

nate these pathogens from fresh produce are needed.

How It Works

Bacteriophages possess attributes to control foodborne pathogens in a unique fashion by infecting bacterial cells, destroying the bacteria, and producing more phages that can repeat the cycle. They also have a history of safe usage and have proven to be effective in reducing *Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes* in foods. With a research project funded by Ontario Ministry of Agriculture, Food and Rural Affairs, our research team was particularly interested in phages that will reduce Shiga-toxigenic *E. coli* on fresh lettuce. We tested eight phages. These phages originated from beef cattle manure as the targeted seven pathogenic *E. coli* serotypes are often found in cattle manure. This is because phages flourish where their targeted bacterial thrive. The phages we used in our laboratory were isolated and purified and then we multiplied the phages to thousands. All eight phages were finally pooled together to produce a phage cocktail. To evaluate the effectiveness of the phage cocktail, we first checked if the phages would be effective in killing bacteria at a refrigerated temperature of (2 degrees Celsius), since this is the temperature used to store fresh vegetables. Then we proceeded to spike lettuce with a cocktail containing all seven *E. coli* bacteria to simulate contamination.

Our results indicate that STEC bacteriophage mixtures can control some of the six Shiga-toxigenic *E. coli* on lettuce. The phage cocktail is very effective on lettuce against *E. coli* O157:H7, O145, and O26, serogroups that are frequently associated with foodborne outbreaks in produce. This phage intervention has the potential to be adopted by industry in order to decrease the foodborne risks associated with fresh produce. A very interesting finding was that these particular phages are more effective at refrigerated temperatures. It is normally reported that bacteriophages are more effective at 25 and 37 degrees Celsius—it has been pointed out as a disadvantage for phages to be used in refrigerated food. Another disadvantage is that phages could potentially carry virulence or antibiotic resistance genes. Therefore, it is necessary to assure that phages intended for use in foods are not carrying undesirable genes through whole genome sequencing. This is the process used to determine the complete DNA sequence (all of the genes) of an organism's genome.

Another issue is the development of resistance; however, this problem can be overcome when multiple phages are used in a mixture, as it overwhelms the bacteria with multiple phage attacks. This intervention can be used during lettuce washing and/or packaging steps without altering the flavor, color, or aroma of fresh produce.

Dr. Narvaez-Bravo is the assistant professor at the University of Manitoba, Food Science Department. She has more than 10 years of experience working on research within the area of microbiology and food safety. Reach her at Claudia.narvaezbravo@ad.umanitoba.ca. **Dr. McAllister** is principal research scientist with Agriculture and Agri-Food Canada, Lethbridge Research Centre, Lethbridge, Alberta, and has been with the organization for the past 25 years. Reach him at Tim.mcallister@agr.gc.a

Manufacturing & Distribution

TRACKING & TRACEABILITY

Mass Serialization of Food Packages

Mass algorithmic and cloud-based serialization can perform at high speeds when dealing with volumes in the billions by linking coded packages to data through algorithms

BY **THOMAS KÖRMENDI**

Every automobile sold in the U.S. bears a unique serial number that enables the car's seller and buyer to track the vehicle's history, authenticate ownership, and manage safety recalls. Today's food consumers have similar interests in transparency about the products they buy and the ability of the food producer to take responsibility for the product across the entire value chain.

It's one thing, however, to serialize on an economically feasible basis the fewer than 20 million new cars sold in the U.S. each year at an average price exceeding $30,000. It's another thing to do so on thousands of food products, many of which sell billions of individual units or packages at a price of a few dollars or less. The good news is that modern information technologies make mass serialization of food packages not only possible at very low, cost but able to be done in ways that establish transparency across the value chain and facilitate two-way communication between brand owners and consumers.

The potential benefits of serialization are tremendous for consumers and industry alike, enabling firms to tackle a series of food safety and consumer protection challenges, such as instant track and trace, targeted product recalls, and real-time authentication, while opening up fresh opportunities for direct consumer engagement on subjects ranging from environmental sustainability and animal welfare to customer loyalty rewards and other marketing possibilities.

While the technological capability exists, dialogue is needed among food companies, technology providers, consumers, and food safety experts to devise applications tailored to particular value chain traceability and transparency needs and that thereby maximize both the consumer and commercial benefits of new information technologies.

Evolving Consumer Drivers

The search for mass serialization solutions stems from the food industry's need to meet changing consumer expectations.

In 2016, Deloitte published a study in collaboration with the Food Marketing Institute and the Grocery Manufacturers Association revealing that the drivers of consumer choice are shifting. Historically, purchasing decisions have been made largely on the basis of traditional drivers, namely taste, price, and convenience. However, a set of evolving drivers has become increasingly influential, encompassing health and wellness, safety, social impact, experience, and transparency. Over half of the 5,000 U.S. consumers Deloitte surveyed said that they now weigh these evolving value drivers more heavily than traditional ones, a trend that spans product categories, region, age, and income and seems set to continue.

Further, research conducted by The Centre for Food Integrity in 2016 revealed the high levels of concern regarding food safety among consumers, with two in three American consumers identifying this as a key area of concern. The research also showed that only 40 percent of consumers feel they have the information they need

about where food comes from, how it is produced, and its safety credentials.

In sum, consumers are demanding more information about the foods they purchase and stronger assurances that products meet today's higher expectations for safety, wellness, and sustainability.

Industry Needs

The food industry has long sought efficient solutions to full value chain traceability, from sources of ingredients and raw materials through finished product manufacturing and all the way to the consumer. This serves the internal needs of the company's food safety management system with respect to such factors as supplier management, oversight of cold chain management, and the efficient conduct of rapid, targeted recalls. These needs remain unmet in many sectors of the food system, but now with heightened consumer expectations about transparency and the speed with which safety issues are addressed there must be a shift.

The food industry is also seeking ways to meet the interest of today's consumer in much greater transparency and connectivity with those who are producing and marketing their food. Companies need to cater to the next generation of consumers—Gen Z—who are "born digital," and to target and share information with consumers in real time in order to build consumer confidence and nurture brand loyalty.

However, in an industry known for tight margins, ensuring traceability and transparency without compromising on competitiveness is essential. Technological solutions must support mass volumes at low cost and high speed, enabling communication between actors in real time while ensuring adaptability and minimal implementation burden.

A Potential Solution

Mass algorithmic and cloud-based serialization offers a potential solution to food manufacturers. Originally developed and applied to solve the problem of pharmaceutical counterfeiting, mass algorithmic and cloud-based serialization can now be adapted to meet food industry and consumer needs. Simply put, it is a unique, package-level ID that can be scanned using mobile phones. With a simple scan, it can link both value chain participants and consumers with the brand owner and create an interactive highway of information among these stakeholders.

The technology is able to perform at high speeds even when dealing with volumes in the many billions by linking coded packages to data through algorithms rather than a central database of codes. This enables firms to scale easily, operating at volumes of billions and billions of products without slowing down the relay of information and incurring large data processing costs.

Meanwhile, high-volume manufacture of food products is maintained through the pre-serialization of packaging and labels by the packaging and label manufacturer. A unique code is integrated into the product packaging or label and then is simply activated later at the direction of the brand owner via the cloud. This means there is no additional time required during the food production phase, and serialization can thus take place without slowing down operations by a second. Even better for keeping processes simple and streamlined, the ID can simply overlay existing codes or labels displayed on the packaging to provide the added functionality.

A Multi-Purpose Vehicle

With a low-cost, cloud-based serialization solution in place for traceability and transparency, brand owners can use it in any number of ways. For example, the technology can be used to identify hold ups and inefficiencies in the supply chain by recording the time products spend in warehouse and transit. At the same time, unique product identities best position manufacturers to identify and pre-empt any potential issues in real time, for example when shipments go astray or are over-exposed to conditions such as heat that may compromise the quality or the safety of the product. When problems with a product are identified, the company can scan items to trace back to the point of failure and identify products from the exact batch to recall them, minimizing the recall. Through the same channel—the same code—consumers can authenticate the products before purchase by scanning the code using a smartphone.

All in all, the ability to trace back to source the trigger for a product recall through serialization of raw materials and ingredients can deliver benefits from public health to supplier management. When problems occur reactions will be quicker, damage minimized, and lessons learned.

Critical is the fact that a unique product ID and the availability of information in real time makes track and trace instantaneous. This minimizes the operational costs, both in terms of time and resources spent identifying the source of any particular problem and the amount of product that ultimately needs to be recalled. It also means minimal reputational cost, with the company able to respond and communicate quickly with stakeholders across the value chain.

The brand can make further use of this same technology if customers choose to register and share their personal information, perhaps incentivized with promotions. In that case, the brand would be able to derive critical consumer insight to inform their research and future product development function, incentivize consumers to repurchase the product through individually-tailored promotions, and build confidence in the quality and safety of the product through transparency regarding its ingredients and production, thus nurturing brand loyalty and trust.

Transparency Transformed

Giving a product its own digital DNA opens an interactive highway containing the information and data required by the manufacturer and commercial value chain participants. It makes all relevant value chain information instantly available to brand owners and other value chain participants according to the permissions determined by the brand owner. These permissions can also be altered over time, retaining flexibility and adaptability for industry to respond to changing operational considerations and consumer preferences alike.

With a growing number of drivers, both traditional and evolving, weighing on consumer behavior, the value of being able to share relevant product informational in real time is rising. The opportunities opened up by enabling two-way communication and engagement between consumers and industry are also becoming increasingly apparent, whether as a means

(Continued on p. 54)

Food Service & Retail

CLEANING & SANITIZING

Avoiding Restaurant Restroom Disasters

Many customers rank a clean restroom as a strong indicator of a clean kitchen | BY **FABIO VITALI**

Customers expect a restaurant to provide a delightful dining experience, from the food to the service to the restrooms. The level of cleanliness in a restaurant's restroom speaks volumes about the entire business, especially if it's a disaster zone. According to a recent survey by retail consulting firm King-Casey, 78 percent of restaurant-goers rank a clean restroom as a strong indicator of a clean kitchen, and vice versa. Additionally, over 94 percent of the surveyed group felt that restroom cleanliness is more important today than ever before.

Modern-day customers are more aware of what they eat and where they eat, often checking online reviews before trying out a new restaurant. They're also equipped with smartphones and social media, which means a quick snapshot of a messy restroom could easily go viral, harming a restaurant's reputation in the process. It's crucial for restaurant owners to take sanitation seriously in order to avoid potential catastrophes. One of the best ways to ensure a restaurant restroom exceeds customer expectations is to take a walk in the customer's shoes.

Expectation vs. Reality

Customers expect public restrooms to provide high-quality essentials, like toilet paper and paper towels, at all times. They also want clean floors and tidy stalls, streak-free mirrors, and unclogged sinks and toilets. Updated fixtures like touchless faucets and soap dispensers are an added bonus, showing that the business cares about its customers.

Unfortunately, the reality is that these expectations aren't always met in restaurants. It only takes one messy customer or forgetful employee to turn a picture-perfect restroom into a disaster zone. According to a survey by Zogby International, more than 80 percent of consumers would avoid eating at a restaurant with a dirty restroom again. If trash bins overflow with waste or a clogged toilet causes unpleasant odors, customers will take notice and it could negatively impact their experience. But a messy facility doesn't just turn away current customers; negative online reviews and social media sites that encourage sharing, like Facebook, Snapchat, and Instagram, can also discourage potential customers from ever entering an establishment.

Many of today's customers expect a sustainable, locally sourced menu, as well as environmentally-friendly features throughout a restaurant. Failing to incorporate green strategies, like low-flush toilets and biodegradable toilet paper, eliminates the opportunity for a restaurant to build its brand and customer loyalty, as well as reduce its operational costs.

Clean Restroom Components

Restrooms are an extension of the restaurant, so it's important for managers to listen to customers and incorporate their needs and wants into a restroom. A study by Deb Group found that 75 percent of people prefer paper towels to hot air dryers. Paper towels can dry hands quicker and more thoroughly than air dryers, and they also keep customers safe from dangerous restroom germs. In fact, a recent study in

> The level of cleanliness in a restaurant's restroom speaks volumes about the entire business, especially if it's a disaster zone.

the Journal of Applied Microbiology found that jet dryers spread germs 1,300 times more than paper towels.

King-Casey's study showed customers appreciate soft and absorbent toilet paper, opposed to thin or waxy paper. Managers should look for paper products that are high-quality and feature dissolvable and biodegradable technology to keep drains free of expensive clogs. Purchasing high-quality toilet paper is a better long-term investment because customers will need to use less paper. This will result in environmental and cost savings, while keeping stall floors free of torn and shredded low-quality paper.

Guests also value automated soap dispensers, faucets, and paper towel dispensers since they limit germ transmission and unnecessary waste. Restaurants may also want to consider installing touchless trash receptacles and entrance doors that have foot pedals or open automatically via sensors.

Maintenance Tips

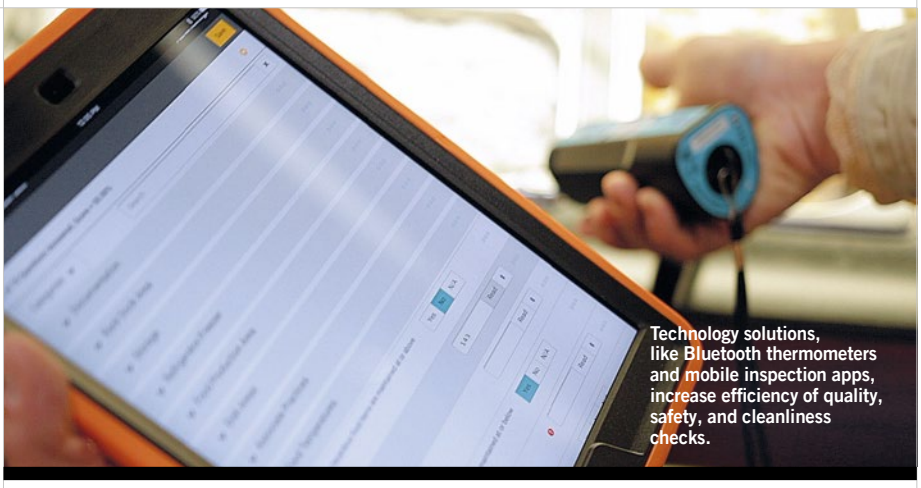
Establishing regular maintenance routines helps keep restroom disasters from happening or going unnoticed by staff. Restaurant managers can utilize the following tips to maintain a sparkling restroom image.

- ***Use a cleaning log.*** Employees should keep track of when and how often restrooms get cleaned via a cleaning log. This ensures people are held accountable and regularly maintain restrooms. Restrooms should be checked multiple times a day, and especially during busy hours.
- ***Clean from top-to-bottom.*** Along with a cleaning log, managers should provide a list of duties that employees must perform while cleaning restrooms. A step-by-step guide reminds workers to focus on smaller, yet critical, areas that are often overlooked, like light switches and soap dispensers.
- ***Use a cleaning cart.*** Restaurants should have a cleaning cart dedicated to restroom use, with supplies such as disinfectants, plungers, scrubbers, towels, and mops. Having an all-in-one cart helps employees stay organized and gives them everything they'll need to properly clean. It also reduces the opportunity for cross-contamination in critical areas like the kitchen and dining room.
- ***Stock up on products.*** A restroom can't function properly unless necessary products and essentials are available at all times. Employees should ensure that restrooms have enough toilet paper, paper towels, and soap products, and that storage closets are stocked with extra inventory that is easily accessible.

Achieving Restroom Success

While great meals and customer service help restaurants achieve success, a clean restroom also plays a key role. Restrooms, when properly maintained, communicate that restaurants care about food safety, customer and employee satisfaction, and their reputation. Don't flush away the opportunity to grow your restaurant into a respected business by only focusing on select front-of-house areas, like your dining area. Design, maintain, and stock your restrooms accordingly and you can strengthen customer loyalty and the bottom line.

Vitali is vice president AFH marketing and sales for Sofidel America.



Technology solutions, like Bluetooth thermometers and mobile inspection apps, increase efficiency of quality, safety, and cleanliness checks.

Improving Processes with Inspection Data

How to manage data in food service for better operations in all business locations

BY **SUE CANIGLIA**

The promised world of big data has certainly come to fruition. IBM estimates that every day, 2.5 quintillion bytes of data is created—so much that 90 percent of the data in the world today has been created in the last two years alone. In the everyday lives of food service and food safety, there's a veritable data deluge as information is monitored in order to be successful.

Generated from a variety of sources—including sensors wisely placed throughout the farm-to-fork global supply chains, customer experience input gathered from social media sources, point-of-sale figures, and your own quality measurement results—this data is necessary to ensure the safety of your customers and the longevity of your business.

When adding in the necessity of government health and safety regulations, there's a lot to think about. There is no shortage of regulations driving industries to meet higher standards. Whether you are driven by regulations tied to the Hazard Analysis and Critical Control Points (i.e. HACCP), the Food Safety Modernization Act, Country of Origin Labeling requirements, or even proactive participation in the Produce Traceability Initiative, you're probably generating more and more data to manage. And frankly, it can get overwhelming.

How do you keep up with corporate and government standards and deal with the growing mountain of data generated? How do you turn that data into actionable insights more powerful than those previously available? And how do you drive continuous improvement in quality, safety, and cleanliness scores across the organization without further overwhelming you and your team? The answer lies in defining your end goals and choosing technology solutions that facilitate continuous improvement. I've been working with the world's biggest brands for more than a decade and have seen how quality management software help those brands grow and maintain a positive brand reputation.

Quality Measurements

The foundation of continuous improvement relies on data that tells a story. From regulations to food temperatures, it's important to only collect data that matters and eliminate obsolete questions. To do this, start by looking at what your competitors are tracking; if similar operations are finding success using a certain practice, you will likely have a similar experience in your operation.

From my experience with top food service brands, I found award-winning food safety programs share a best practice—a robust quality, safety, and cleanliness (QSC) program that includes these key parameters:

- Adherence to standard operating manual requirements;
- Having permits and certifications complete and on-hand;
- Food storage, protection, handling, and temperature;
- Food labeling (calories and allergens);
- Staff hygiene, handwashing, clothing, gloves, and footwear;
- Facility maintenance and overall condition;
- Cleaning chemicals and cleaning materials;
- Pest control; and
- Cautionary signage and devices.

The list of recommended conditions to monitor is long, and there are numerous contributing factors for each area. The key to a successful QSC program is determining what's important for your business. Starting with goals—an increase in unit sales of a specific food item, utility cost savings, 3 percent profitability increase—will help identify the areas that need a closer look.

It then may be the case that all your locations or suppliers consistently meet your standards nearly every time their results are monitored. If this is true, you may be ready to move on to monitoring next-level standards that don't just let you stay in compliance, but set your operation apart from the competition. It could also be the case that you are kicking off new quality and safety programs and simply need to start with the basics. Regardless, it pays to take the time to determine critical items to measure, the nice items to monitor, and the unnecessary details to leave behind.

Insights that Matter Most

After determining what's critical for your operation today, create a checklist of specific quality, safety, and cleanliness elements to monitor throughout your suppliers and locations. Be sure to think carefully about the insights you'd like to glean from the results you'll monitor.

The following are some examples of insightful takeaways based on the information you may choose to monitor.

Food safety. If temperature monitoring devices consistently show that your restaurant locations are adhering to requirements, but just barely, it may be a wise choice to calibrate approved equipment in every location in such a way that ensures temperatures are well within safe parameters all the time.

A cross-contamination issue identified early is a great insight to use when developing employee training programs, or when redesigning kitchens or other food prep areas.

Food waste. Looking at how food is being prepared or consumed across all locations can help optimize everything from order size and frequency to how much of a certain item is needed for the lunch rush, which helps reduce food waste and increase profitability.

Building condition. When a dangerous situation is identified in a single location, you'll be well positioned to see it as a red flag and preemptively address the issue in every location before customers or employees are harmed.

Consumer response. If consumer-impacting signage gets a great response in one area of the country, it may indicate that region is a good candidate for a targeted campaign that further drives in-store sales and increases profitability.

Security. A system or building security infraction identified in one location is likely an organization-wide security risk, and you'll be glad a quality management software was used to see trends and correct the issues before a larger problem has a chance to propagate.

Corporate goals. Marketing departments love introducing new ideas that affect your locations and/or suppliers. Prepare for new program implementations by gathering the impact insights needed well in advance of marketing program launches.

There is never a shortage of corporate goals to save money while driving revenue and profitability. Why not think through the information needed to gather this year to achieve goals next year? The insights proactively gathered give an inside edge to meet the requirements your corporation sets for you, quickly setting you apart from your peers and competitors.

If you're a corporate franchisor, you can also gather information on franchisee consistency to ensure they are carrying out contractual obligations from their franchise agreements.

Putting Technology in Place

Most companies quickly outgrow tracking these details with a manual pen-and-paper process. After reaching more than 10 locations, it's time to think about getting a technology solution for data collection. As your business grows, it's imperative to gather quality measurement data digitally. If paper and pen, spreadsheets, or other antiquated checklist apps are used at any stage of the process, that can equate to hours wasted transcribing data from paper and pen to spreadsheets and emails. The time-consuming transcription process also increases the chance for errors, and slows down the time to remediation—if corrective action happens at all—once the form hits an inbox or file cabinet.

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NEW PRODUCTS

Biological Hygiene Indicator

In a ready-to-use spray bottle, Indicon Gel provides a visual indication of the presence of biofilm on a wide variety of surfaces that may contain harmful microorganisms, such as *Listeria, E. coli,* or *Salmonella*. When the product encounters biofilm, Indicon Gel rapidly produces white micro-bubbles/foam within 2 minutes, providing a quick visual indicator of potential harborage niches that swabs cannot reach. **Sterilex, 443-541-8800, www.sterilex.com.**

Verification of Milk Pasteurization

The ZymoSnap ALP is an alkaline phosphatase testing system designed to verify pasteurization efficiency in short shelf-life dairy products within just 5 minutes. It has been specifically developed to offer definitive and repeatable results, even at low levels (25-100 mU/L). Featuring an all-in-one design and requiring only minimal equipment, the system can be used without specialist knowledge or testing facilities. It allows users to meet their sustainability objectives by being a 100% recyclable test device. The Zymo Snap ALP has been independently validated by Campden BRI. **Hygiena, 888-494-4362, www.hygiena.com.**

Pathogen Detection System

The CERTUS System for rapid pathogen detection and environmental monitoring is a bio-contained, in-house solution for small- and mid-sized food processing plants to prevent environmental *Listeria*. It simplifies environmental testing and monitoring by eliminating media preparation, sample preparation, courier expense, and risk of opening an enriched sample in the plant. Users with minimal training can simply swab a surface, add media to the Bio-Lock Detection Tube, and insert the tube into the CERTUS Detection Unit to start getting results during the enrichment cycle. There is no need for centrifuges, incubators, pipettes, stomachers, bags, or other ancillary items and steps. **CERTUS, 872-810-4123, www.certusfoodsafety.com.**

ICP-OES

The Avio 500 Inductively Coupled Plasma Optical Emission Spectrometer (ICP-OES) is designed for all analytical labs running high throughput multi-elemental inorganic analyses for various sample matrices. It features simultaneous background correction for faster sample-to-sample time. Flat Plate plasma technology generates a matrix-tolerant plasma using only half the argon consumed by other ICP systems. Dual View optical system technology optimizes axial and radial plasma viewing, measuring high and low concentrations in the same run, regardless of wavelength. And Universal Data Acquisition enables simultaneous acquisition of all available wavelengths, helping to reduce or potentially eliminate the need to re-run samples. **PerkinElmer, Inc., www.perkinelmer.com.**

Real-Time In-Transit Monitoring

FlashLink real-time monitoring system combines the FlashLink Real-Time In-Transit Logger with a 24/7 cloud service. The logger records temperature, humidity, shock, light, and location and sends data via GSM cellular network to a web account. Up-to-the-minute information is accessed with a standard web browser using a PC or any Internet-ready device. **DeltaTrak, 800-962-6776, www.deltatrak.com.**

Listeria Test with No Enrichment

Listeria Right Now test system can detect all species of *Listeria*, including the pathogenic *L. monocytogenes*, in under 60 minutes through their ribosomal RNA (rRNA). The process starts with taking an environmental sample to capture any *Listeria* present. The entire swab sample is placed in a tube that contains a lysis buffer that breaks up any bacteria present, and releases its rRNA. If *Listeria* is in the sample, the test's reagents will amplify thousands of copies of its rRNA—and make the *Listeria* easily detectable. The system has been validated by NSF International to detect low levels of *Listeria* in environmental samples. **Neogen Corp., 800-234-5333, www.neogen.com.**

Software for Direct-from-Sample Food Analysis

LiveID Software is used for near-instantaneous, direct-from-sample measurement and classification of food products, including meat and crops, by Waters' quadrupole, time-of-flight (QTof) mass spectrometers. The new software enables Waters Xevo G2-XS QTof or SYNAPT G2-Si Mass Spectrometers equipped with an iKnife Sampling device, Rapid Evaporative Ionization Mass Spectrometry ion source, and MassLynx Mass Spectrometry Software to help laboratories detect food fraud. **Waters Corp., 508-478-2000, www.waters.com.**

Transmission Fixture

MicroNIR Transmission Fixture is used for the transmission analysis of liquids and/or thin filters and films. It is one of several new fit-for-purpose sampling accessories for the MicroNIR spectrometer. The MicroNIR spectrometer coupled with MicroNIR Transmission Fixture allows companies to perform rapid quality tests of various products, such as dairy products, beverages, and edible oils. Companies are able to monitor nutritional levels (fat, protein, lactose, sugar, etc.) of beverages in real time with the analysis taking only a couple seconds. The speed of the analysis subsequently allows for customers to realize potential production efficiencies while maintaining optimum product quality. The fixture features an integrated tungsten lamp and can accommodate industry standard cuvettes with 0.5-10 mm path lengths. It also features a filter slot for the transmission of thin films and filters that are up to 3 mm thick. **Viavi Solutions, 844-468 4284, www.viavisolutions.com.**

Bioprocess Control Station

The BioFlo 120 bench scale fermentor/bioreactor system for research and development is capable of microbial fermentation as well as mammalian cell culture applications with a single platform. It features a range of glass and BioBLU Single-Use Vessel options (250 mL-40 L). Universal connections for digital Mettler Toledo ISM and analog sensors allows users to monitor a variety of critical process parameters. The embedded software offers real-time local process control through an integrated touchscreen. **Eppendorf, www.eppendorf.com.**

In Other News

Bureau Veritas and **Schutter Group** introduce a rapid aflatoxin pre-shipment inspection and quality control process for agricultural industry to mitigate the risk of toxin exposure through on-site quick detection tests.

LexaGene Holdings' technology for its automated pathogen detection instrument has been successfully de-risked through a series of tests that looked at each of the instrument's critical functions. Tests were conducted by Boston Engineering.

Roka Bioscience receives AOAC Certification for 18-hour sample enrichment using Actero ELITE *Listeria* Enrichment Media and the Atlas *Listeria* Environmental Assay.

Neogen's new NeoSeek genomic services enable food companies to accurately identify all bacteria in a sample in a single genomic test.

Alchemy Systems launches 140-course training library built for the dairy industry via www.alchemysystems.com/dairy-solutions.

3M Food Safety's Molecular Detection Assay 2—*E. coli* O157 (including H7) test receives an NF Validation certificate from AFNOR Certification.

InfinityQS International upholds its certification to ISO 9001:2015 and ISO 27001:2013 standards.

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The Cannatourism ...

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out the food production activities. This is particularly important when handling a federally-controlled hallucinogenic substance that can have different interactions and tolerances for different people.

Aside from having a comprehensive knowledge of cannabis concentrate and extracts and working with infusions to produce an intoxicating meal, following ordinary food safety guidelines is imperative. Individuals interested in pursuing this kind of business model must: understand and implement food safety requirements, follow standard food safety protocols for the preparation and transfer of food, create and implement defensible best practices for caterers operating at a host's home, and understand social-host liability for guests that over-consume cannabis-infused edibles and available insurance options.

Finally, consumption options at public restaurants will have a different regulatory structure with other legal considerations. A public-use, on-premises licensing structure is feasible, once the public consumption problem is resolved, that could be the future of legalized cannabis in the U.S. It is critical to understand the legal issues involved in the commercialization of cannabis-infused food products from a regulatory, safety, and liability perspective.

Cetel and **Wiand** are attorneys with GrayRobinson's Alcohol Beverage, Medical Marijuana, and Food Law Departments, a group of lawyers and government consultants with extensive experience in all aspects of the commercialization of heavily-regulated products. Reach them at jason.cetel@gray-robinson.com and anna.wiand@gray-robinson.com.

Mitigating the Risk ...

(Continued from p. 37)

requirements of GFSI-recognized certification programs.

Training is Best Line of Defense

Food fraud prevention must be an important aspect of every food safety and quality management system. All employees should be aware of the potential for food fraud and be empowered and encouraged to report any concerns of potential food fraud incidents. Food processors should provide relevant personnel with appropriate education related to recognizing and reducing food fraud risks.

This education may include Preventive Controls Qualified Individual training seminars for those responsible for conducting the FDA-required hazard analysis; specialized training for QA and receiving personnel responsible for verification of product specifications and COAs at time of receipt; and general awareness training for all employees.

Chilton, VP professional services at Alchemy Systems, has over 30 years of experience in the food industry, specializing in food safety, quality assurance, and plant management. Reach him at Jeff.chilton@alchemysystems.com. **Dr. Everstine,** scientific liaison at USP, joined the organization in 2015 to advance the development of food fraud mitigation tools and resources.

Mass Serialization of ...

(Continued from p. 47)

to meet transparency requirements, undertake consumer research, or utilize the same platform as a channel for marketing promotions. Critically, building confidence through transparency becomes much easier as brands can let consumers know directly in real time whether a product has been recalled, or just as importantly if it has not.

Full Value Chain Transparency

Low cost, cloud-based mass serialization for the food industry makes possible full value chain traceability and transparency and two-way communication between brand owners and consumers. This potentially transformative technology will best serve the food industry and its consumers if there is active dialogue among all participants in the value chain to further define consumer and industry needs and optimal applications. By engaging suppliers, manufacturers, retailers, technology providers and, importantly, the consumers whose expectations and needs drive the industry, the dream of full value chain traceability and transparency can be turned into a practical reality.

Körmendi, current CEO of Kezzler, was previously employed at Relacom (a Swedish technology services company), Tetra Pak, and Procter & Gamble Nordic. Reach him at t.kormendi@kezzler.com.

Improving Processes ...

(Continued from p. 51)

Another reason top brands harness technology for QSC programs is the built-in ability to quickly delve into the data, identifying insights in minutes not months. It's these insights that will drive corrective actions, helping you move from a reactive model of dealing with problems to a proactive model that addresses issues before the conditions impact your customer experience.

Using the latest quality management systems available can also securely share your operations manuals with locations and suppliers, and receive compliance documentation and signatures from contacts at the intervals needed to stay compliant.

Lay a foundation for future success by identifying the technology needed for QSC measurements today.

It's not easy to track all the information across dozens, hundreds, or thousands of locations. But with the right technology in place, you'll be able to mine company data for the insights needed to drive the corrective actions most important to your organization.

Caniglia is a senior product manager at RizePoint. Reach her at sue.caniglia@rizepoint.com.

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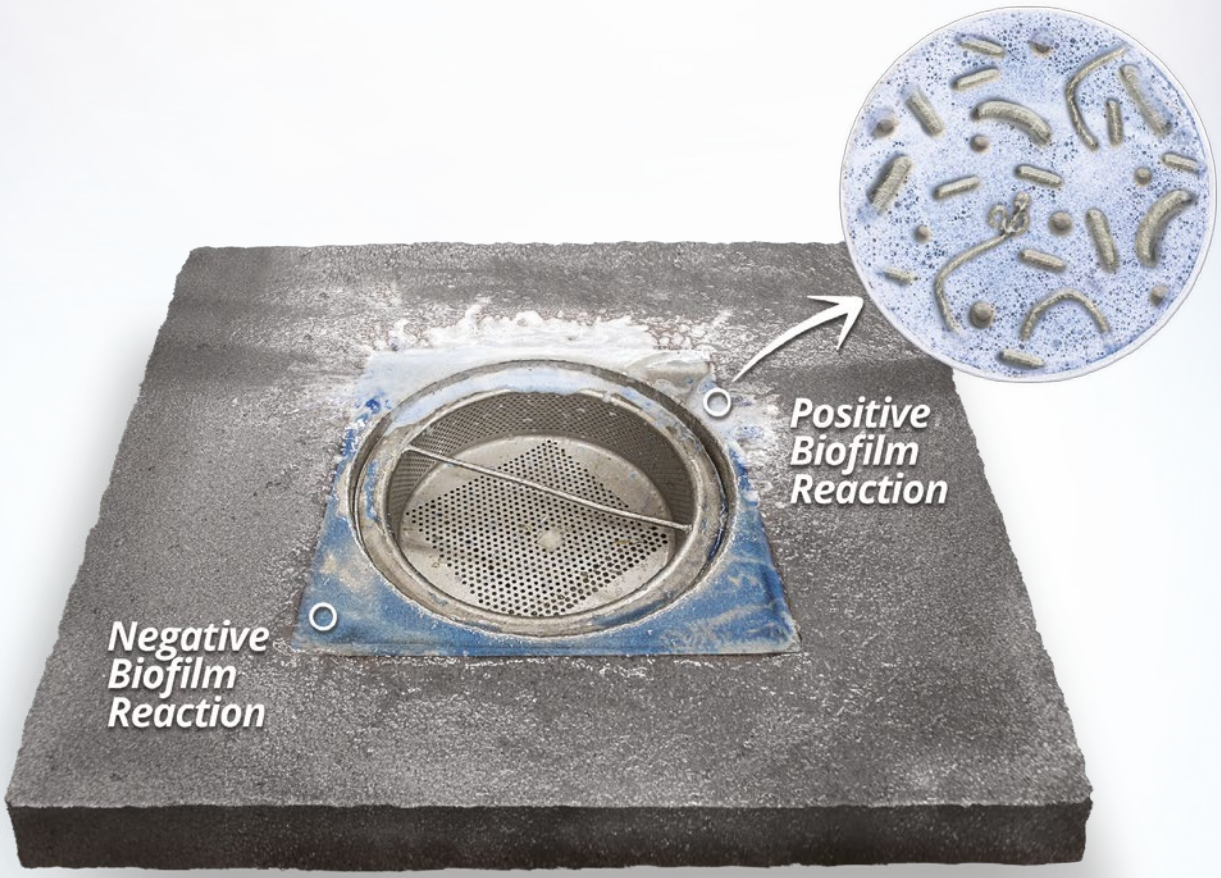

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