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The editors and advisory board hope every piece of content in Food Quality & Safety magazine contains at least one (and hopefully more) teaching moments. I define a teaching moment as an “Aha” or “Wow” where a piece of knowledge is conveyed in a way that will be remembered for future reference or the reader will say, “Now there is something that I/we can use in our operations.”

I’m fortunate to have many of these moments over my food career. Going back to sophomore year at Rutgers University, I can thank Dr. Roy Morse. The topic in our food science lab was blanching. Dr. Morse challenged a student to put two 8-ounce bags of spinach into a 303 x 406 can. The student worked like crazy and got about 5 - 6 ounces in the can. Dr. Morse then put the contents of two more bags into a steamer. He covered the steamer and two minutes later, voila—a pound of spinach goes easily into a can. Lesson #1: Blanching reduces volume and removes intracellular air. The blanched spinach also had a bright green color—Lesson #2: Blanching fixes color. Dr. Morse then ran an essay quiz to show that proper blanching inactivates enzymes. Very applied, very visual, and easily remembered.

I can thank Dr. Fergus Clydsdale of the University of Massachusetts for another teaching moment. Dr. Clydsdale did a talk on “Food Facts and Fallacies” while on sabbatical at UC Davis. One of his stories resonated with me for years. He asked students how would they react to the following proposal if they worked for the FDA:

“I have a new business. I am going to create an army of giant six-legged, winged creatures. Each day, I will let them out of the barn and encourage them to eat and eat. When they return in the evening, another giant winged creature will stimulate them to regurgitate on the floor after which the second creature will fan the vomit with its wings to dry the material out. This will lower the water activity and help preserve it. I will then package the material and sell it to the public.”

As he was telling the story, the faces of the audience ranged from grossed out to horrified. Dr. Clydsdale ended by saying, “Well, that is exactly how honey is made.”

I encourage readers to share their teaching moments! Send to Marian Zboraj (mzboraj@uwrf.edu), Dr. Vasavada (purnendu.c.vasavada@uwrf.edu), or myself (rickstier4@aol.com).

Richard Stier
Co-Industry Editor
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WILEY
What's Keeping Diners Away
Thirty-one percent of diners say they would avoid eating at other locations of a chain restaurant if just one location was involved in a foodborne illness outbreak, according to Steritech’s Diners Dish e-book. The e-book includes insights from a survey that tackled consumer preference and behavior in several key revenue-driving areas, including delivery, online reviews and social media, public health and cleanliness, and foodborne illness. It also found that 41% of those surveyed say a restaurant’s health department score factors into their decision on where to dine. The e-book can be downloaded at http://auditbetter.steritech.com/dinersdish.

Sources of Foodborne Illnesses
The Interagency Food Safety Analytics Collaboration (IFSAC) releases a report titled “Foodborne Illness Source Attribution Estimates for 2016 for Salmonella, Escherichia coli O157, Listeria monocytogenes, and Campylobacter Using Multi-Year Outbreak Surveillance Data, United States.” IFSAC analyzed data from just over 1,000 foodborne disease outbreaks that occurred from 1998 through 2016. The implicated foods were divided into 17 categories for the analysis, and the method gives the greatest weight to the most recent five years of outbreak data (2012–2016). Of note in the report: Salmonella illnesses came from a wide variety of foods; E. coli O157 illnesses were most often linked to vegetable row crops (such as leafy greens) and beef; Listeria monocytogenes illnesses were most often linked to dairy products and fruits; and most foodborne Campylobacter outbreaks were associated with unpasteurized milk, which is not widely consumed—these outbreaks likely over-represent dairy as a source of Campylobacter illness. The updated estimates combined with other data might help shape agency priorities and support the development of regulations and performance standards, among other activities.

Long-Time FQ&S Staffer Retires
After working 17 years on Food Quality & Safety, Ken Potuznik, senior account manager, will retire on Dec. 31, 2018, from John Wiley & Sons. During his tenure on the magazine, Potuznik was well-known for his good-natured business savvy. He developed valuable client relationships that helped create innovative media communication programs and was a fixture at all of the major food conferences for nearly two decades, freely sharing his insights about the industry. In addition to John Wiley & Sons, Potuznik’s prolific publishing career included working for Putman Media and Cahners Business Information. The Food Quality & Safety staff sincerely thank him for his dedication to ensuring the continual success of the publication.

Business Briefs
**AVEVA**, a provider in engineering and industrial software, partners with **TOMRA** to embed SCADA technology in sensor-based sorting and packhouse solutions for the fresh produce industry.

The Cold Pressure Council announces its newest membership category for trade partners, which is for retailers and food service companies that sell brand products utilizing HPP to consumers.

**Aurochemicals**, a manufacturer of natural aroma ingredients for the flavor industry, completes new onsite lab at the company’s headquarters in Washingtonville, N.Y.

**BAKERpedia**, a digital Resource for the commercial baking industry, and **AIB International** partner to provide AIB’s Baking Specialist Online Collection on BAKERpedia’s Digital Academy.

**GS1 US** relocates from Lawrenceville, N.J. to a “built-to-suit” office in Ewing, N.J.

**Ocean Mist Farms** selects **Zest Labs** to optimize its freshness management by using Zest Fresh to automate data collection on condition of its produce.

Farm Supervisor Charged with Contaminating Strawberries with Needles
In November, Australia charged farm supervisor My Ut Trinh in a strawberry needle contamination case that sparked a major food scare, according to Reuters. The strawberry industry, worth A$160 million ($116 million), was rocked in September following nearly 200 complaints of sewing needles found in strawberries and other fruits. Police received 186 complaints of fruit contamination, 15 of which proved to be hoaxes. Several major supermarkets withdrew the fruit as shoppers abandoned purchases, forcing some growers to dump fruit amid warnings of widespread bankruptcies. Queensland is reportedly setting aside A$1 million ($722,400) to help farmers make it through the season.
Q3 2018 U.S. Recall Index

According to the newest Recall Index by Stericycle Expert Solutions, undeclared allergens were the top cause of FDA food recalls at 42.6% in Q3 2018, while the leading cause based on recalled units was bacterial contamination at 75%. Overall food recalls decreased by 12% to 129; the lowest quarter since Q1 2016. Recalled USDA pounds of beef, poultry, pork, and other food decreased 58% to 731,462, the second lowest since Q3 2014. And recalled FDA food units decreased 96% to about 8.5 million, with produce comprising the highest food product category at 38.5%. But for the first time since at least 2010, a sickening parasitic contamination triggered recalls in Q3 2018. Eight recalls comprising 6,476 units were caused by *Cyclospora cayetanensis*, a microscopic parasite present in fecal-contaminated food that causes severe intestinal illness. The report can be downloaded at https://www.stericycleexpertsolutions.com/recall-index/.

FDA Updates

The U.S. FDA releases its findings from the initial phase of a 10-year study that is evaluating trends in food preparation practices and employee behaviors that contribute to foodborne illness outbreaks in retail. The "Report on the Occurrence of Foodborne Illness Risk Factors in Fast Food and Full Service Restaurants, 2013-2014" represents the first data collection period, which will conclude in 2023. Data from the 2013-2014 collection will be used as a baseline to assess trends in the occurrence of risk factors during subsequent data collections. Key findings during this period showed there remains a need to gain better control over employee handwashing and proper temperature control of foods that require refrigeration (cold holding of foods). FDA’s National Retail Food Team will continue to work with stakeholders, such as the National Restaurant Association, National Council of Chain Restaurants, restaurant chain companies, and state restaurant associations in addressing food safety behaviors/practices in need of attention.

FDA also releases a final guidance that can be downloaded on its website regarding its mandatory recall authority under FSMA. The final guidance provides questions and answers on FDA’s process, explains what FDA considers when moving forward with a mandatory recall, and more. FDA has issued a mandatory recall order of a food product only once. In April 2018, FDA issued a mandatory recall order for all food products containing powdered kratom manufactured, processed, packed, or held by Triangle Pharmanaturals after several products were found to contain *Salmonella*. In two other instances, FDA started down the path of using its mandatory recall authority until the companies ultimately chose to voluntarily recall their product.
After nearly a year of bureaucratic jockeying, FDA and USDA have agreed to work together to establish a regulatory framework in which the two agencies would jointly oversee the production and marketing of cell-based meat and poultry products.

“Both the USDA and the FDA should jointly oversee the production of cell-cultured food products derived from livestock and poultry,” the agencies announced in mid-November. FDA will oversee cell collection, cell banks, and cell growth and differentiation. USDA oversight will begin from the cell harvest stage, and will continue during the production and labeling of food products. The agencies are “actively refining” the technical details of the framework, and believe they have sufficient statutory authority without the need for additional legislation.

Cell-based meat—also called “clean meat” by supporters and “lab-grown fake meat” by detractors—refers to animal tissue grown or cultured under controlled conditions using muscle or other cells from living animals, such as beef, pork, and poultry. While the process remains costly, supporters say cell-based meat can help fulfill the growing worldwide demand for high-quality protein and be produced in an environmentally friendly and sustainable manner, without the need to raise and slaughter animals.

The regulatory boundaries are somewhat vague. While FDA has purview over most food products, USDA has primary authority over meat, poultry, and most egg products. And FDA, not USDA, is typically involved in labeling disputes.

There are at least two issues of contention: regulatory oversight, namely which government agency or agencies would have jurisdiction over these products and how they should be regulated; and packaging labeling and claims, including what these products can be called.

The U.S. meat industry, including cattle growers, have objected to labeling any such products as “meat,” at least without extensive clarifiers, and maintain that USDA should have primary oversight.

Companies developing cell-based meat, on the other hand, insist there is no difference between muscle tissue obtained from a living animal and the same tissue that is grown in culture. They have favored oversight by FDA because that agency already regulates biotechnology products, which are manufactured in bioreactors using similar techniques, as well as beverages and foods produced by fermentation.

Turf Battles
Until recently, FDA and USDA officials had also supported these delineations. In July 2018, FDA convened a public meeting at its headquarters to explore the potential safety hazards and regulatory challenges in cell-cultured products.

“Our past experience with novel food technologies and our extensive background in cell-culture technologies in the medical products space will help inform our approach to evaluating the safety of these cell-based food products,” said FDA Commissioner Scott Gottlieb, MD, in kicking off the two-day meeting.

It was evident that FDA had not invited anyone from USDA to participate. “I’m both surprised and disappointed,” commented Tiffany Lee, DVM, director of regulatory and scientific affairs at the North American Meat Institute (NAMI). “Primary jurisdiction over the regulation of cell-cultured meat products rests with the United States Department of Agriculture,” she told the gathering during the public comment portion.

But FDA hadn’t been alone in seeking to carve out its turf; Agriculture Secretary Sonny Perdue had been working Capitol Hill to cement USDA’s role as the sole regulator of cell-cultured meat products.
“Obviously there are some gray lines between FDA and USDA on many things,” Perdue told the House agricultural appropriations subcommittee in April 2018. “But meat and poultry has been the sole purview of USDA. We would expect any product that expects to be labeled as meat would come under that same inspection criteria.”

Lawmakers evidently agreed and, with the reported assistance of staffers from USDA’s Food Safety and Inspection Service, inserted language into the final appropriations bill authorizing USDA to be in charge of regulating “products made from cells of amenable species of livestock...or poultry.” The one-sentence directive charged USDA with issuing rules regarding inspections for manufacturing, processing, and preventing adulteration or misbranding of cell-based foods.

**Industry Offers Compromise**

Ironically, a solution to the agency oversight problem appears to have been spurred by industry. Memphis Meats, a developer of cultured meat, and NAMI suggested in a joint Aug. 23, 2018 letter to President Trump that FDA and USDA should both play important roles.

“To ensure the regulatory system protects consumers while fostering innovation, it is imperative that the agencies coordinate and collaborate in their efforts,” wrote Memphis Meats CEO Uma Valeti, MD, and NAMI CEO Barry Carpenter.

Under their proposed framework, FDA would have oversight over pre-market safety evaluations for cell-based meat and poultry products, with USDA providing input. “After pre-market safety has been established with FDA, USDA should regulate cell-based meat and poultry products, as it does with all other meat and poultry products, applying relevant findings from FDA’s safety evaluation to ensure products are safe, wholesome, and properly labeled,” they wrote.

“Such a regulatory framework is not new and plays into the strengths and experience of FDA and USDA,” they noted. They agreed that cell-based meat products “are an ‘and,’ not an ‘or’ solution” to the world’s protein needs. “We support a fair and competitive marketplace that lets consumers decide what food products make sense for them and their families.”

They also agreed to stop the name-calling. “Moving forward we will use the term ‘cell-based meat and poultry’ to describe the products that are the result of animal cell culture,” they wrote. The meat industry took offense at the term “clean meat,” which suggested conventional meat was not. On the other hand, cattle growers and others in the meat industry had disparaged cultured meat, calling it “lab-grown fake meat,” “Frankenmeat,” and other colorful names.

**Sharing the Sandbox**

Subsequently, in October 2018, FDA and USDA convened a joint meeting at USDA headquarters to explore the regulatory framework, potential safety hazards, and labeling and claims issues surrounding animal cell culture technology. More than 600 people attended the two-day meeting, in person and remotely.

“We fully anticipate that both FDA and USDA will have active roles in the regulatory oversight of cell-cultured products,” Dr. Gottlieb said in his opening comments. Speaking with reporters afterwards, Perdue suggested a joint oversight framework might be drafted relatively quickly. “If we can get this done in 2019, I would think that would be probably pretty fast for federal purposes,” he said. “We will be moving posthaste after this meeting to more clearly define that.”

Despite conciliatory comments from the agency heads, many industry and consumer stakeholders held to their previous positions. For example, Kevin Kester, president of the National Cattlemen’s Beef Association, said “lab-grown, fake meat labels should be held to the same standards as other meat labels. Given that the goal of these products is to compete directly with real meat, only USDA oversight can adequately ensure this outcome.”

Jessica Almy, policy director at the Good Food Institute, a nonprofit that supports companies producing “clean and plant-based food products,” said no new regulations were needed. “FDA has a clear and strong precedent to address safety premarket. And FDA can provide a single point of entry for regulation.”

And while NAMI partnered with Memphis Meats in proposing joint FDA/USDA oversight, Mark Dopp, NAMI’s senior vice president, argued that “primary jurisdiction regarding the regulation of cell-based meat products rests with USDA.”

Regulatory clarity is essential, said Eric Schulze, vice president of Memphis Meats. “Without a clear, predictable, and timely framework, this industry cannot succeed. Any delays in moving forward would jeopardize the U.S.’s standing in the world as the leader in protein production and responsible, science-based food innovation.”

Until the federal regulatory landscape is clarified, states may be free to exercise their own oversight authority. In June 2018, Missouri enacted legislation that prohibits “misrepresenting a product as meat that is not derived from harvested production livestock or poultry.” The law applies to existing plant-based meat substitutes and future cell-based meat and poultry products.

The Good Food Institute, Turtle Island Foods (Tofurky brand), and civil liberties and animal rights groups have filed a lawsuit challenging the law’s constitutionality and requested a motion for preliminary injunction. Just as the federal GMO labeling law has pre-empted state-enacted GMO laws, it is likely that federal regulatory decisions will impact state food labeling requirements.

**Funding Moving Forward**

Dozens of companies worldwide are developing alternative protein food products. In addition to Memphis Meats these include Beyond Meat, Amy’s Kitchen, JUST, Inc. (formerly Hampton Creek), Finless Foods, and Morningstar Farms in the U.S.; Cauldron Foods, Quorn Foods, and Vbites Food in the U.K.; Garden Protein International in Canada; Mosa Meat and Meatless B.V. in the Netherlands; SuperMeat and Future Meat Technologies in Israel; and Integriculture in Japan. Numerous small startups, such as San Francisco-based New Age Meats, are also hoping to gain a foothold in this burgeoning industry.

Memphis Meats has received $17 million in venture capital funding from a group of investors including Cargill, Virgin Group founder Richard Branson, and Microsoft founder Bill Gates. So far, the company has raised at least $22 million, in-

(Continued on p. 49)
On Oct. 5, 2018, in a seemingly ordinary transaction, Eddie and Patti Clinton, retired Wake Co., North Carolina educators/administrators, purchased two 10-pound bags of raw whole fresh shrimp. The original source of the crustaceans was a fisherman who reportedly harvested the shrimp in or near the New River in the southeastern area of the Tarheel State.

Eddie placed the shrimp on ice in a cooler overnight. The next day he scooped the shrimp with his bare hands into smaller bags, then placed them in his freezer. Within about 24 hours, Eddie began experiencing soreness in his legs, shaking, feeling simultaneously hot and cold, loss of appetite, and slurred speech. By October 8, he was on life support at a Raleigh hospital in a medically-induced coma. The next day, doctors determined Eddie was infected with *Vibrio vulnificus*.

Eddie’s heart, liver, and kidneys were affected by the *V. vulnificus*, and his left leg was amputated below the knee on November 6. "The doctors suspect Eddie may have wiped his mouth with his hand or that he had a small cut on his hand when handling the shrimp, but they never found any open wound on him," Patti says. “Every doctor that saw Eddie said they had never seen a case like this before, where a person was infected with *Vibrio* without ingesting it in food.”

According to the CDC, people become infected with vibriosis typically “by eating raw or undercooked shellfish, particularly oysters.” Certain *Vibrio* species can also cause a skin infection when an open wound, which could be a cut or scrape, is exposed to raw seafood, raw seafood juices, or brackish or salt water, CDC says. Brackish water is a mixture of fresh and sea water, often found where rivers meet the sea.

**Vibrio Stats**

CDC estimates that 80,000 people in the U.S. become sick with vibriosis each year, and 100 people die from their infection. About 52,000 of these illnesses are estimated to be the result of eating contaminated food. The most commonly reported *Vibrio* species, *Vibrio parahaemolyticus*, is estimated to cause 45,000 cases of vibriosis each year in the U.S.

When ingested, *Vibrio* bacteria can cause watery diarrhea, often accompanied by abdominal cramping, nausea, vomiting, fever, and chills, CDC says. Usually these symptoms occur within 24 hours of ingestion and last about three days. Severe illness is rare and typically occurs in people with a weakened immune system.

Most people with a mild case of vibriosis recover after about three days with no lasting effects. However, people with a *V. vulnificus* infection can get seriously ill and need intensive care or limb amputation. About one in four people with this type of infection die, sometimes within a day or two of becoming ill, CDC says.

Grateful that he is alive, Patti Clinton says her husband has diabetes, congestive heart failure, and chronic obstructive pulmonary disorder, plus he’s a smoker. “The doctors said most anyone else could have handled those shrimp we purchased with no negative health impacts, but since Eddie is an immuno-compromised senior male, he got life-threatening vibriosis.”

**Postharvest Processing Pearls**

Postharvest processing (PHP) methods can be used to reduce *Vibrio* bacteria, such as *V. vulnificus*, from oysters intended for the raw, half-shell market, most especially those that are harvested from the Gulf of Mexico during warmer months when the organism is most prolific.

With oysters, PHP is any process that has been validated by the National...
Shellfish Sanitation Program, according to Corinne Audemard, PhD, an associate research scientist with the Virginia Institute of Marine Science, College of William & Mary. “PHP aims to reduce the levels of pathogenic hazards to below the appropriate FDA action level or, in the absence of such a level, below the appropriate level as determined by the Interstate Shellfish Sanitation Conference (ISSC),” Dr. Audemard relates.

Four PHP technologies are currently utilized by ISSC-approved firms for PHP: 1.) Individual quick freezing, which involves rapid freezing of half shell oysters on trays, then adding a thin glaze of ice to seal in the natural juices before storing them frozen; 2.) Heat-cool pasteurization, a process whereby live oysters are placed in warm water for a certain time period and then immediately dipped in cold water to stop the cooking process; 3.) High hydrostatic pressure, that subjects oysters to high pressures (35,000 to 40,000 pounds per square inch) for three to five minutes; and 4.) Low-dose gamma irradiation.

High Salinity Relay
A relatively unexplored PHP method called relaying holds promise as an alternative strategy for reducing V. vulnificus levels, Dr. Audemard says.

“High salinity relaying involves transferring oysters from salinity waters, 8 to 15 psu (practical salinity units), to higher salinities, 30 to 35 psu, to achieve a reduction in pathogenic bacteria to less than 30 V. vulnificus per gram in as little as 14 days,” she explains. “High salinity waters appear to negatively affect the survival of V. vulnificus.”

High salinity relay differs from previously approved PHP methods in that it is not a controlled process. “That’s because the procedure typically relies on the exposure of oysters to natural high salinity waters for several weeks,” Dr. Audemard says. “However, high salinity relaying is also used in molluscan shellfish transfer to more controlled environments, such as land-based tanks with similar results.”

In research published in August 2018, Dr. Audemard and several colleagues evaluated high salinity relay as a PHP for reducing V. vulnificus.

Dr. Audemard says the study was based on FDA validation guidelines, which specify, among other things, the initial V. vulnificus density before the process, the number of samples to be analyzed, the analytical methods to be used, and the endpoint concentration criteria to be reached for process validation, 30 per gram (g).

During each of three relay experiments, oysters cultured from three different Chesapeake Bay sites of contrasting salinities (10 to 21 psu) were relaid without acclimation to high salinity waters (31 to 33 psu) for up to 28 days. Overall, nine lots of oysters were relaid with six exhibiting initial V. vulnificus greater than 10,000 per g.

“As recommended by the FDA PHP validation guidelines, these lots reached both the 3.52 log reduction and the less than 30 per g densities requirements for V. vulnificus after 14 to 28 days of relay,” Dr. Audemard relates. “Densities of total and pathogenic V. parahaemolyticus in relayed oysters were significantly lower than densities at the sites of origin, suggesting an additional benefit associated with high salinity relay. This study strongly supports the validation of high salinity relay as an effective PHP method to reduce levels of V. vulnificus in oysters to endpoint levels approved for human consumption.”

Indicator for Pathogenic Vibrios
In 2005, under the leadership of Gary Richards, PhD, a USDA Agricultural Research Service laboratory team in Dover, Del., developed and published a simple and rapid procedure called the colony overlay procedure for peptidases (COPP) assay to quantify total vibrios in oysters and seawater.

Salina Parveen, PhD, a professor in the Food Science and Technology Program at the University of Maryland Eastern Shore, and several collaborators sought to validate the use of the COPP assay. “Regulatory agencies and industry currently use comparable testing of fecal coliform bacteria as an indicator of fecal pollution,” Dr. Parveen relates. “We thought the use of the COPP assay might serve a similar role as an indicator of pathogenic vibrios.”

Dr. Parveen and her colleagues collected oyster and seawater samples from the Delaware Inland Bays and the Maryland Chesapeake Bay and analyzed for total vibrios, as well as pathogenic strains of V. vulnificus and V. parahaemolyticus.

They compared the COPP assay with direct plating and a molecular method that detects total vibrios and pathogenic vibrios. “The results of the study indicate that the COPP assay is a viable alternative to other, more complicated, methods for the detection of V. vulnificus in oysters and seawater,” Dr. Parveen relates, adding that a similar study is in progress for V. parahaemolyticus.

Farm-Raised Oyster Project
Just underway is a three-year study to determine whether an oyster farm’s geographic location, handling practices, and choice of equipment affect Vibrio levels in farm-raised oysters.

William Walton, PhD, associate professor, Auburn University’s School of Fisheries, Aquaculture and Aquatic Sciences, landed a $456,646 USDA NIFA grant in August 2018 to fund the project.

Dr. Walton and his collaborators, FDA microbiologist Jessica Jones, PhD, and Auburn doctoral student Victoria Pruente, are focusing on a management system called off-bottom oyster farming, where oysters are maintained in floating cages or suspended baskets above the ocean floor in food-rich coastal waters.

Once a week, off-bottom farmers raise the baskets out of the water and allow the oysters to air-dry. “This practice prevents barnacles, seaweed, and other undesirable organisms from attaching to and marring the oysters,” Dr. Walton notes.

“Though the air-drying process is crucial to product quality, it is not risk-free,” Pruente interjects. “The frequent handling exposes the oysters to elevated air temperatures and also interrupts filter feeding, and those conditions cause Vibrio levels to rise.”

Once the baskets are lowered back into the ocean, Vibrio levels gradually subside, but questions remain, Dr. Walton points out. “In our trials, we will look at how long after the oysters are submersed the Vibrio levels return to naturally occurring levels,” he says.

New Vibrio Test Kit
On Oct. 1, 2018, Bio-Rad Laboratories, Inc., Hercules, Calif., launched its iQ-Check Vibrio PCR Detection Kit, which provides (Continued on p. 49)
The U.S. imports approximately 19 percent of its total food supply, including 80 percent of seafood, 52 percent of fresh fruits, and 22 percent of fresh vegetables (USDA Economic Research Service, 2013). Although food and beverage comprised the smallest imported product category in 2017, the U.S. imported approximately $115.5 billion of animal and plant foods and $21.8 billion of beverages excluding liquors (USDA Economic Research Service, 2018).

One of the main factors contributing to this sizeable volume in imported foods is the dramatic change in food preferences brought about by an increase of the non-Caucasian population in the U.S. As of November 2016, Pew Research Center estimated baby boomers, those born 1946-1964, comprised approximately 70 million people and were about 28 percent non-white. Generation X, those born 1965-1980, comprised 57 million and was about 40 percent non-white, an almost 43 percent increase in ethnic diversity from the baby boomers. Generation Y/millennials, who were born 1981-1996, numbered 62 million during the same time period. Millennials were about 44 percent non-white. Generation Z, composed of those born after 1996, was estimated at 65 million and was almost 50 percent ethnically diverse.

Every generation has characteristics specific to their population. For example, baby boomers led the demand for fresh and less processed foods, organic, and sustainability—food and beverage trends that we still see today. Generation X depended on nutrition information on food labels to make their choices and were increasingly adventurous with the food they chose. The millennials sought variety in foods, including experimenting with new ethnic foods. The millennials also readily integrated technology in their daily lives, sharing their food experiences with their digital social network, thus broadening the exposure and ultimately the acceptance of ethnic foods. The youngest and fast-growing population who grew up completely in the digital age, Generation Z, preferred authentic, global food experiences that they also electronically shared with their contemporaries and affected the other aspects of their lives. Diversity in foods is becoming the norm and imported foods are projected only to increase in volume.

Imported Foods Called for FSVP
To assure imported foods are of the same level as food produced in the U.S. and are not adulterated or misbranded with respect to allergen labeling, the Foreign Supplier Verification Program (FSVP) was published in the Federal Register on Nov. 27, 2015. FSVP changed the focus on food contamination from reactive to preventive and required importers to conduct risk-based verification activities. This was largely driven by high-profile food outbreaks involving imported food and food ingredients, including the 2009 scandal of imported Chinese melamine-contaminated milk used to prepare infant formula, liquid milk, ice cream, other foods containing dairy products, and animal feed. There were at least three confirmed deaths, approximately 53,000 babies who received treatment, and over 20 companies involved in the scam.

The FSVP importer is defined as the U.S. owner or consignee of an article of food for import into the U.S. If there is no U.S. owner or consignee of the food at the time of entry, the FSVP importer is the U.S. agent or rep of the foreign owner or consignee at the time of entry as confirmed in a signed statement of consent to serve as the importer. Standard FSVP requirements include a hazard analysis of each imported food (or type of food), evaluation of foreign supplier’s performance and the risk posed by the imported food, foreign supplier approval, appropriate...
supplier verification and related activities done by “Qualified Individuals,” corrective action when necessary, and keeping records of the FSVP activities. Although persons with technical backgrounds do not find FSVP requirements difficult to comply with, they describe compliance as a tedious, time-consuming responsibility. Importers, who do not possess the technical knowledge, often feel overwhelmed and intimidated by the required FSVP tasks. Qualified Individuals who may or may not be employees of the importers are allowed to perform FSVP activities.

A very small importer is one whose annual average in food sales, and the U.S. market value of food imported, processed, packed, or held without sale, during the previous three-year period is less than U.S. $1 million in human food or less than U.S. $2.5 million in animal food. The very small importer, small foreign supplier, importers of dietary supplements/components, and importers of certain foods from countries with food safety systems recognized by the U.S. FDA as equivalent to the U.S. are under modified FSVP requirements. These clauses exclude them from having to conduct hazard analyses of the imported food, evaluate the risk of the food, evaluate the foreign supplier’s performance, implement a foreign supplier approval program, or meet certain recordkeeping requirements. There are other requirements of very small importers and their foreign suppliers that cannot be discussed adequately in this column.

There are also foods exempt from FSVP requirements. Exempted foods include those regulated under the FDA seafood and juice HACCP (Hazard Analysis and Critical Control Point) rules and raw materials and ingredients used for those foods; meat, poultry, or egg products under USDA regulation; certain alcoholic beverages and raw materials and ingredients for those beverages; those intended for personal or research use and not for sale or distribution in the U.S.; those manufactured or processed, raised, or grown in the U.S. then exported but not subjected to further manufacturing or processing and returned to the U.S.; foods transshipped through the U.S. but not for sale or distribution in the U.S. then exported; and low-acid canned foods and raw materials and ingredients for such foods but only for microbiological hazards.

Implementation of the FSVP requirements, however, is still proving to be difficult even for importers eligible for modified requirements.

Varying FSVP Enforcement Dates
According to some small food processors, they were advised by U.S. FDA that they will probably not see FSVP enforcement for another two years, i.e., by 2020. Other food processors are stating, however, that they are currently seeing enforcement. The FDA may enter any food facility under its jurisdiction at any time of food manufacture, leaving the food processor uncertain when to expect the FDA investigator—leading to increased anxiety levels brought by the unknown.

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Foreign Supplier Food Safety Plan

Having a working food safety plan may be routine practice in most regions in the U.S., but is still considered novel in other areas including overseas. Some processors have encountered foreign suppliers who prefer not to share their food safety plans because those are considered “proprietary.” There is a misunderstanding about the purpose of a food safety plan. It is not understood or accepted that asking for a food safety plan from suppliers and customers is a standard procedure. The food safety plan demonstrates that the processor has evaluated the risks associated with a food item or ingredient, and if the severity of the risks significantly impacts the safety of the food, at least one preventive control must be identified. The food safety plan also details what corrective actions should be taken when deviations occur, including steps to prevent their recurrence. These actions are verified by various means including records review with management sign-off. These records must be kept as evidence of what the food processor declared as critical in protecting the safety of its food.

To assist very small importers and small foreign suppliers in complying with FSVP, modified requirements grant them exemption from most of the standard requirements, including conducting a hazard analysis of the imported food or ingredient. Without a hazard analysis, there is no working food safety plan. But as is currently occurring in the food industry, these exemptions do not stop a buyer or an auditor from demanding a working food safety plan whether or not it is required.

Difficulties in Reviewing

If the FSVP importer can obtain the foreign supplier’s food safety plan, a thorough evaluation of each imported food item (or type of food) is required, unless the imported food is exempt or under modified requirements. If the importer is the U.S. processor or manufacturer, it is already devoting a substantial amount of time developing, monitoring, and maintaining all the elements of a working food safety plan. The FSVP further requires the importer to spend additional time analyzing its foreign supplier’s food safety plan. Some importers have neither the technical background for such analyses nor the time to allot for review. The requirement for the Qualified Individual to read or understand the documents in the language of the foreign supplier further handicaps the U.S. importer. Although the importer understands that its Qualified Individual may perform these FSVP verification activities, some importers are having difficulties searching the already tight employment market then employing another staff member with technical qualifications. Hiring a Qualified Individual as a consultant imposes financial burden to the importer and will most likely not encourage the degree of involvement that is desirable between the importer and its FSVP.

The importer understands there are alternative verification procedures, such as internet searches of publicly available documents describing the foreign supplier’s food safety records. Internet search can be accomplished without significant problems or costs. Sampling and testing of food samples is another FSVP task, but this activity is already costing the food processor tens of thousands of dollars prior to implementing a FSVP. In addition, sampling and testing is not a definitive tool for ensuring food safety and is a major reason for the development of the HACCP system. The preferred FSVP verification activity, an onsite audit, also poses a significant financial cost to the importer.

These are issues that will entail several solutions that cannot be completely discussed in this column.

Customs Brokers—the Forgotten Partners

Importers have a natural close working relationship with their customs brokers. Brokers field questions on the process and the product and try to resolve issues expeditiously. Customs brokers expect their clients (importers) to ask them about FSVP and consider it their responsibility to be familiar with the program, its requirements, and their possible role in alleviating some of the anxiety importers have. Some are asked to be the FSVP importer for products brought into the U.S., a request that brokers reasonably decline. But if a customs broker is located in the U.S. and purchases the food and distributes in the U.S., the broker could become the FSVP importer and is expected to meet FSVP requirements, including a hazard analysis of the purchased food.

The current objective of the customs broker is to at least understand the FSVP issues raised to them and be able to refer importers to the appropriate persons who could assist them. Importers are their customers, and brokers would like to maintain them as satisfied customers.

An issue that brokers have raised is LTL, or less than truckload, of imported products. Although the very small importer may operate under modified FSVP requirements that should assist with the timely compliance to the rule, importers also have to address sanitary transportation issues. LTLs are already occurring in importation and brokers manage them for their importers, but the additional food safety rules increase the cost of operations for both the importer and the broker. Brokers, however, stated they will fully cooperate with their importers in addressing FSVP issues.

It’s recommended that the U.S. FDA continue to include customs brokers in its FSVP update sessions.

What are the Next Steps?

There are modified requirements designed specifically for the very small importer and small foreign supplier. Although FSVP exempts the food from certain FSVP requirements, buyers are continuing to ask for a food safety plan prior to the purchase of the food or food ingredient. This is a reasonable request. Any processor can make people sick, regardless of the company size. When a buyer asks for a food safety plan, the seller produces a food safety plan. Thus, as a trainer, I advocate not depending on exemptions and modified requirements when food safety is concerned. Having a working food safety plan is not only good manufacturing practice but also good business.

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Proposition 65 (Prop 65) is a controversial California health law enacted in 1986 as the Safe Drinking Water and Toxic Enforcement Act. The law—which purports to protect consumers from exposure to substances known to the State of California to cause cancer, birth defects, or reproductive harm—mandates the placement of consumer warnings on products containing any of nearly a thousand different chemicals. In turn, Prop 65 is administered by the Office of Environmental Health Hazard Assessment (OEHHA), part of the California Environmental Protection Agency.

The confusion surrounding compliance with Prop 65 is pervasive and persistent. For starters, neither the regulators, businesses, plaintiff lawyers, or the courts can seem to agree on what products are affected and what warnings are required. In a recent high-profile case involving the sale of coffee, the court ruled that ready-to-drink and ready-to-prepare coffee products must be accompanied by a warning because coffee contains high levels of acrylamide, a chemical known to the state of California to cause cancer and reproductive harm. Following the ruling, OEHHA proposed new coffee regulations that would exempt coffee products from the warning requirements. Meanwhile, after plaintiff lawyers successfully argued that cereal products required warnings because of the presence of acrylamide, a California appeals court overturned the ruling.

In addition to the confusion being sown by the regulators and courts, the federal government is threatening to become involved as well. Recently introduced federal legislation, the Accurate Labels Act (ALA), would demand any food product warning requirements (i.e., those mandated by Prop 65) be subjected to rigorous evidence-based review supported by the best available science. More importantly, ALA would shift the burden of proof from the defendant to the party (government or private plaintiff) bringing any enforcement action.

Revised Warning Requirements
Recent changes to the Prop 65 regulations have also arguably increased the levels of confusion surrounding Prop 65 compliance. Historically, Prop 65 warnings were merely required to notify consumers if a chemical capable of causing cancer or reproductive harm might be present. That began to change in 2016, when OEHHA significantly revised the warning requirements. After a two-year phase-in, the new OEHHA warning revisions went into effect on Aug. 30, 2018. Even though the revisions do not substantively change the purpose of Prop 65, they have nonetheless generated significant confusion regarding how to best comply and are widely expected to lead to an increase in litigation.

Among other things, the new regulations require that any products needing a warning must now identify the specific chemical that may be present in a product. The regulatory changes shift responsibility for warnings further upstream in the supply chain, giving manufacturers the primarily responsibility for providing Prop 65 warnings. Manufacturers can either affix warning labels to their products, or provide written notice to retailers that a product requires a warning, provide the warning materials, and obtain confirmation retailers received the notice.

The revisions also substantially modify the guidance relating to the form and content of the warnings. It should be noted that the precise format of the warnings is not mandated by the law. Rather, the warnings must simply be “clear and reasonable.”

The definition of what it means to be “clear and reasonable,” however, can and does vary greatly between, for instance, a commercial business and a plaintiff’s lawyer. To address this issue, the law gives manufacturers the option to use a form-template “safe harbor warning.” Warnings that meet the safe harbor warn-

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...ing requirements are deemed to be clear and reasonable.

To meet the safe harbor requirements, Prop 65 warnings for food products must: 1) contain the word “WARNING” in all capital letters and in bold print; 2) state whether the product contains a carcinogen, reproductive toxicant, or both; and, 3) reference the Prop 65 warning food website. If the warning is placed on the product label, it must be set off from other surrounding information and enclosed in a box. If the warning is in a language other than English, the warning must be in that language as well. Here is an example of the new warning:

“WARNING: Consuming this product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer and/or (as appropriate) [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food.”

The amended regulations also allow the use of a “short-form” warning. This warning must appear in a size no smaller than the largest font size used for other consumer product information affixed to the product and must be at least 6-point type. A short-form warning label may be used on any size product. Here is an example:

“WARNING: Cancer and Reproductive Harm—For more information, visit www.P65Warnings.ca.gov.”

The warnings must be provided on the food product label (enclosed in a box) or on a product sign, label, or shelf tag at the point of display of the product. The new requirements are applicable to all modes of purchase and distribution, including online/internet and catalog purchases as well as direct-import and drop-ship delivery, and require an understanding of the chemical constituents of all products sold or distributed in the state of California.

Compliance Questions

While the new regulatory changes on their face appear to be relatively straightforward, achieving compliance may remain elusive for many companies. Since there are nearly 1,000 chemicals on the Prop 65 list, how are food companies going to be able to determine which chemicals may (or may not be) present? The problem extends much further up the supply chain, as well, because a food company’s ingredient suppliers may not know either. Some suppliers may not have even heard of Prop 65.

Additionally, some chemicals, like acrylamide, may not be present when the product is sold, but are created when the consumer cooks the product at high temperatures. Under these circumstances, a warning may be required, so food product manufacturers may need to do substantial additional testing.

The placement and type of warnings may create confusion as well. What happens when a product manufacturer chooses not to place the warning on its product, but elects instead to send separate product warnings to their customers instructing them to place the warning on store shelves, and those instructions are not followed? Even if they were followed, since there is no minimum size warning for shelf warnings, who will determine whether the warnings are sufficient. Often, retailers and plaintiff lawyers will disagree.

So, when it comes to Prop 65 compliance, certainty is fleeting. The one thing that is (and will likely remain) certain, however, is Prop 65 is officially a law known by the State of California, and now the rest of the world, to create chaos and confusion. ■

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AUTHORS DISCLAIMER: This article is intended only to offer a broad overview of recent changes to Proposition 65. Businesses should consult with experts or attorneys to evaluate their responsibilities under Prop 65 and protect themselves from any potential claims.

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The carbonated beverage market raises its glass to efforts in overcoming carbon dioxide issues

By Keith Loria
If you’re a player in the carbonated beverage industry, you recognize the saying “No Fizz—No Biz” in regards to the importance of carbon dioxide (CO₂) in all carbonated beverages.

Whether it’s soda, sparkling water, or the more recent popularity of carbonated coffee, tea, or juice, CO₂ is essential for creating those bubbles necessary to ensure a beverage is consistent and safe.

Don Pachuta, PhD, president of Airborne Labs International, Inc., Somerset, N.J., says the quality of CO₂ used in beverage applications was historically often overlooked with minimal testing done. This changed radically, however over the last 20 years.

Interestingly, CO₂ is not only an ingredient in beverages but is also classified by the FDA as a drug among other uses.

“Robust CO₂ quality control not only ensures the desired pleasurable sensory impact of the beverage but also for its freedom from potential ‘health impacting’ harmful effects that can arise from various undesirable impurities in the CO₂,” he says.

Moreover, as more “non-traditional” sources of CO₂ are explored and employed, the issues of CO₂ quality maintenance become more challenging as new potential source-specific impurities must now be carefully studied, and related impurities identified, removed, monitored, and subsequently controlled by appropriate purity standard-setting bodies. These include the Compressed Gas Association (CGA), International Society of Beverage Technologists (ISBT), European Industrial Gases Association (EIGA), FDA, and other governmental or international standard-setting groups.

“It must be understood that all CO₂ quality assurance processes involves a complex, multistep supply-manufacturing-delivery-storage-beverage manufacturing chain, which starts with the composition of the original feed gas source of CO₂ through its final infusion into a beverage product,” Dr. Pachuta says. “For reasonable economics, CO₂ supplies need to be produced and stored relatively local to their end users. The key is that many diverse and new non-traditional types of possible localized CO₂ sources are continually being evaluated for economic, consistent, and sustainable supply reasons.”

Recent reported shortages of beverage-grade CO₂ this last summer in Europe and other areas highlighted the need for a more stable and local CO₂ production picture.

Guidelines in Place

The CGA publishes several industry consensus standards on the production, storage, and transfer of CO₂. CGA published its first CO₂ commodity specification in 1973 and periodically updates it and other CO₂ standards and guidelines to address new uses and feed gas sources. These specifications provide limiting characteristics and identify recommended testing methodologies for the analysis of potential contaminants in liquid, gaseous, and solid CO₂ for various uses.

ISBT has a set of guidelines that establishes production and feed gas considerations, finished product impurity levels, and analytical method recommendations for beverage-grade bulk CO₂.

Larry Hobbs, executive director of ISBT, says the CO₂ guidelines established by the organization’s Beverage Gases committee were created by a group of experts that included members of the beverage industry as well as the suppliers and the producers of CO₂.

“Their work took several years to complete and the result has been to improve the quality and consistency of CO₂ used in the beverage industry,” he says. “As a general practice, suppliers provide

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certificates of analysis upon delivery for ingredients, including
gases such as CO₂ to certify that the material meets the standards
established in the contract with the customer. These are backed
up by a lot of analysis by the shipper as well as whatever internal
sampling and testing programs the customer may have.”

Major gas suppliers like Air Liquide and Aircos (which recently
merged), Linde and Praxair (which recently merged), and Mathe-
son produce and sell CO₂, and all perform quality testing and pe-
riodic third-party testing at approved labs.

The **hose materials** used for
liquid CO₂ transfers has to be **carefully selected** and
tested for plasticizer leaching...

John Willenbrock, technical manager for CGA, says CO₂ is man-
ufactured in accordance with a company’s standard operating
procedures that are developed to meet customer expectations and,
in the U.S., for compliance with the Food Safety Modernization Act
(FSMA) and FDA’s implementing regulations. Interestingly, CO₂
is not only an ingredient in beverages but is also classified by the
FDA as a drug among other uses. That’s why it’s important the
criteria meet the CGA’s standards identified for beverages and also
with CO₂ standards for other intended uses.

The testing of CO₂ has fortunately evolved over the years—
both through more capable onsite production and storage testing
equipment, and relatively simple offsite process. This involves
taking a small, low pressure gasified CO₂ sample that can be in-
ternationally shipped when needed as a “non-hazardous” gas
sample to a qualified CO₂ testing laboratory for a comprehensive
quality analysis.

This offsite sampling requires the use of sample containers
comprised of inert, specially coated (passivated) materials that will
not adsorb the critical impurities of interest such as sulfur agents.

Use of state-of-the-art instruments, both onsite and offsite,
allows for the testing of all critical CO₂ impurities to the very low
(parts per million to parts per billion) levels needed to ensure CO₂
sensory desirability and consumer safety.

**Significance of CO₂ Quality**

Unlike many commodity gases such as nitrogen, oxygen, and
argon that basically come from non-complex “air” as a primary
source, Dr. Pachuta explains commercially produced CO₂ for beve-
erages typically originates as a byproduct or a “waste” product
from more chemically complex sources.

These include natural wells, fermentation of grains and
grasses (corn, molasses, sorghum), combustion of many fuels
including coal, fuel oils, natural gas, plus natural gas based-syn-
thesis of soil fertilizers (ammonia-sources), chemical processes
(neutralization of mineral acids), synthesis of various chemicals
(glycols), and quite recently “anaerobic” digestion of various ve-
getable, animal, and waste stream biomass materials (biogas).

“In all cases, the trick is to accurately determine the identity,
levels and risks of all common types and amounts of potentially
harmful sensory or health-impact impurities that may be present
from a given CO₂ source,” Dr. Pachuta says. “This information is
used to design effective industrial cleanup processes, which can
consistently remove these undesired impurities down to very
low, safe, acceptable levels for use in beverages and other food
applications.”

Due to the physical properties of CO₂ and the strict controls
over the supply chain, the chance of contamination problems
with the CO₂ is pretty low. Containers of CO₂ are under pressure.
Pressurized product flows out of the container, prohibiting the in-
troduction of contaminants into the container as long as there is
product in the container.

“The safety issues are not so much contamination in the
supply chain, but more about safe handling and storage given
the properties of CO₂ itself,” Willenbrock says. “CO₂ is produced,
stored, and transferred under pressure, which virtually elimi-
nates the chance for contamination. In a closed container, such
as a high-pressure cylinder, CO₂’s a liquefied gas under pressure.
If you overfill the cylinder and the temperature change increases,
the pressure can rapidly increase to an extent that the cylinder can
rupture, causing extensive injuries to individuals and equipment.”

Storage of CO₂ in tanks and cylinders in enclosed areas without
adequate ventilation and atmospheric monitoring are concerns.
Even small leaks from equipment could lead to an oxygen deficient
atmosphere in the area, exposing anyone entering to possible as-
phyxiation. Even with what may be considered “sufficient oxygen”
to sustain life, an environment containing high levels of CO₂ can
cause personal harm very quickly.

**Beverage Industry Growth and Innovation**

The beverage packaging and processing industry is
experiencing major growth, according to PMMI’s “2018
Beverage Trends in Packaging and Processing” report.
The North American beverage industry is expected to grow
4.5% to $45.5 billion in the next 10 years. Despite 70% of
respondents believing aluminum cans and bottles are ex-
pected to see the greatest innovation in design, container,
and graphics enhancements, plastic still accounts for 45%
packaging material usage. Ready-to-drink, non-alcoholic
beverages (in glass containers) are expected to grow at
about 46% and wine (in plastic containers) is projected to
increase 100% by 2028.—FQ&S
Recent CO₂ Trends
With an increasing interest in the use of more economic and non-traditional sustainable sources of commercial CO₂, the specific challenges are to design appropriate sampling, analytical methods, test programs, and reasonable purity specification limits that will identify and track the most likely impurity “suspects” present in a feed gas source or produced during the manufacturing process.

Dr. Pachuta says the next step is developing appropriate and routine onsite monitoring and periodic testing programs to assure a CO₂ producer can effectively remove these source-based impurities from all CO₂ loads destined for beverage and other food uses (dry ice for food preservation).

Uschi Mannl, a manager at Austria-based V&F Analyse- und Messtechnik GmbH, says transport and time in storage could impact the actual gas composition of beverages and no true CO₂ assessment can be done. This is why V&F created the CO₂ Sense mass spectrometer, which can offer continuous real-time monitoring and detects inorganic and organic impurities.

“The rising demand for pure carbon dioxide and the shortage experienced during the summer months of 2018 has opened the door for new feed gas sources for carbon dioxide,” she says.

“Depending on the gas source, the degree of contamination may vary, rendering the CO₂ non-viable for its use in food and beverage if contamination levels are exceeding industry prescribed limits.”

The Regulatory Landscape
Many international societies of gas quality governance groups—for example, ISBT, CGA, and EIGA—have responded to the changes in CO₂ source-based manufacturing and new applications that occurred the last two decades and continue to evolve.

“Associated upgrades of CO₂ quality standards were primarily spearheaded and driven by several major beverage manufacturers in the late 1990s who themselves were most severely impacted by major, expensive recalls and brand name damage caused by the unrecognized use of poor quality CO₂,” Dr. Pachuta says. “To date, however, food-grade purity regulating bodies have not in our opinion significantly upgraded their traditional purity specifications in response to the many new types and levels of impurities that can come from non-traditional commercial CO₂ sources.”

Richard Craig, technical director at CGA, says since FSMA came into play, the facilities that manufacture CO₂ for beverage or food need to do so in accordance to the Code of Federal Regulations Title 21, Part 117, which is the Good Manufacturing Practices for foods, including ingredients.

“We are a regulated industry and we take compliance with regulation very seriously,” he says.

Airborne Labs International recommends taking a second look at these medical and food-grade CO₂ specification issues. For instance, liquid CO₂ is a strong solvent and can leach various plasticizers from transfer hoses that feed storage tanks at restaurants and bars. The hose materials used for liquid CO₂ transfers has to be carefully selected and tested for plasticizer leaching, which sometimes is not done.

“Even though filters are many times used, the quality of CO₂ stored in special tanks used in most fast food restaurants and bars are not regularly checked for the slow buildup of many, potentially harmful, non-volatile impurities that can accumulate with time,” Dr. Pachuta says. “New, non-traditional, home-based personal ‘carbonated beverage’ manufacturing applications do not require the use of beverage quality-tested CO₂ cartridges. This can pose a potential risk that has not been adequately studied or monitored to date.”

Retaining Quality Control
Industry insiders agree that all carbonated beverage manufacturers, including fountain operators, should become familiar with the educational guidelines available from various organizations such as the ISBT.

“We recommend that, when possible, ISBT Purity Grade CO₂ be used for their carbonated beverage products. ISBT CO₂ purity is higher than food-grade purity levels, but both are acceptable,” Dr. Pachuta comments. “Users of mini-bulk tanks or large storage tanks with only gas phase CO₂ removal should periodically test their liquid CO₂ for any slow buildup of non-volatile residues.”

Additionally, all CO₂ manufacturers should routinely monitor and test their CO₂ feed gas sources for any changes in composition as well as routinely monitor the quality of their CO₂ throughout the in-process, cleanup, bulk storage, and truck or rail car-filling steps.

Regional CO₂ storage and trans-fill depots also need to have some basic and low-cost CO₂ purity monitoring systems available that can quickly catch any incoming off-quality CO₂ “bad apple” loads in order to prevent any major CO₂ quality upsets.

Dr. Pachuta emphasizes that ISBT-recommended onsite monitoring analyzer methods be employed for routine CO₂ testing and ISO-17025 accredited gas testing laboratories be used for periodic CO₂ feed gas, in-process, and final product CO₂ purity testing. He also suggests that beverage manufacturers and fountain operations periodically audit the quality practices of their CO₂ suppliers for consistency and require them to periodically verify their CO₂ quality by an independent ISO-certified laboratory.

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CIP: Are You Cleaning Enough or Too Much?

How harnessing data and the UV spectrum can help clean-in-place operations highlight issues and predict potential areas of failure before they occur

BY HEIN TIMMERMAN

Cleanliness is fundamental in any food processing facility. When any incidence of contamination can prompt product recall, factory closure, and ultimately reputational damage and potential litigation, maintaining food safety in your operations is paramount. A clean-in-place (CIP) system is the first line of defense, helping to drive operational efficiency, ensure that processing equipment is clean, and protect your bottom line.

However, in a sector that demands robust hygiene, traditional CIP systems have evolved while remaining defined by outdated metrics that are overly reliant on historical statistical parameters. If you measure standard factors, such as the flow in the system, conductivity, and temperature, they will show you that the cleaning cycle has fulfilled these parameters. Crucially, this will not, however, indicate the level of clean that the system has achieved.

Where cleaning is based on historical averages, CIP cycle times are in many cases too long, which in turn negatively impacts product safety and operational efficiency. The traditional cleaning sequence is based on historical and empirical sampling without gathering any automated data. Fortunately, new CIP technology exists to reduce over cleaning, preserve resources, and ensure accurate insights.

Microscopic Risks
Pathogenic microorganisms such as Listeria, Salmonella, and E. coli pose a significant risk to the food and beverage processing industry. These bacteria, can build up on processing equipment. This can create the potential for cross-contamination and result in serious problems for manufacturers. Knowledge of common problem microorganisms and the risks they pose is crucial to avoid a food safety breach.

In 2016, Listeria was discovered at the Jeni’s Splendid Ice Creams manufacturing facility in Columbus, Ohio. Further analysis revealed it was the same strain of Listeria found the year before at both the Columbus facility and in a finished product sample of ice cream. According to a warning letter from the FDA, the “sanitation procedures have historically been inadequate to control, reduce, or eliminate this pathogenic organism” at the facility.

After the initial 2015 discovery, the company halted production, recalled all products, and embarked on a thorough cleaning, sanitizing, and reconfiguring of its production kitchen that reportedly cost $200,000. Jeni’s was also forced to destroy 265 tons of ice cream—worth more than $2.5 million. The importance of sanitary maintenance cannot be overstated.

How CIP Can Help
CIP systems are often implemented in food manufacturing operations to effectively clean assembled equipment, pipework, and other hard-to-reach areas where the survival of pathogens and other bacteria is more likely. Because CIP is conducted without disassembling equipment, it cuts down on labor such as manual scrubbing, reassembly, and final sanitizing steps. Less easy to quantify is the peace of mind that an effective CIP system provides to industry professionals regarding their facility’s level of sanitation.

Implementing a CIP system into an operation bolsters sanitation processes to improve product safety, making it an invaluable component of a business. As the food and beverage processing industry moves to place a greater value on sanitary design, CIP serves as a vital component of... (Continued on p. 28)
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quality assurance. Particularly in larger production facilities, the automation of a CIP system is invaluable to reduce cleaning time and labor costs.

The Vicious Cycle of Over Cleaning
Retroactive correction is commonplace. For example, in a plant where overconsumption prevails due to a “better safe than sorry” approach, identifying contamination often leads to a determination to build a more robust program. The process becomes exponentially longer, and the concentration of cleaning chemicals soars to increase safety margins. As a result, as revealed by Diversey data, the majority of CIP systems are over cleaning by up to 50 percent, even though this over cleaning is carried out with the best of intentions.

CIP is a fully automated process that takes place within a closed system. Since the process can’t be seen, factory automation provides a food-safe solution. However, according to CIP benchmark data based on Diversey experience, an estimated 75 percent of CIP systems run unvalidated—which means they aren’t fine-tuned and optimized. If a CIP process is not underpinned by a painstaking analysis of all the elements involved, the result will be long cleaning cycles with exaggerated times and chemical concentrations. Without effective parameter data to prove the efficacy of actions, it can be difficult to break free of this vicious cycle.

Assessing whether cleaning is occurring enough—or perhaps too much—is a challenge many processing facilities face. Every factory has many data parameters available to inform their conclusions, but it is often scattered across multiple systems and can be difficult to interpret. The lack of a system providing real-time monitoring of cleanliness contributes to the current difficulties of achieving any absolute certainty of hygiene standards.

Harnessing Light and Data
The ideal CIP technology will rigorously challenge an existing system and add new elements that highlight whether traditional parameters have become exaggerated. Applying new technology based on a meticulously defined algorithm and appropriate software—analyzing data from an entire process from start to finish, multiple times—will bring a fresh perspective to an operation. Improvements from this new scientific and statistical methodology can optimize and significantly shorten CIP processes without compromising food safety.

Food processors need an approach that integrates new technology with some traditional elements, such as temperature monitors and timers to control automation. However, the new technology should reveal the details of what really happens with the chemicals. With clearly defined predetermined parameters, professionals can seamlessly weave artificial cleaning intelligence into a traditional process.

Advanced CIP technology is now available to harness the power of light to monitor data. For example, Diversey’s CIPTEC technology uses the UV and infrared light spectrum to monitor CIP systems in real time. A spectrophotometer measures light traveling through the liquids inside the CIP system, measuring the volume of soil and the cleaning chemical level in the final rinse stage to accurately determine how effectively soils were removed. Utilizing this information, along with the conductivity, flow, and temperature during the wash, statistical data analysis methods calculate the optimal regime to eliminate over washing.

Reaping the Benefits of CIP
A collaborative, consultative approach to CIP ensures that if a failure occurs, it will get flagged immediately through a proactive alarm system of feedback. Issues are typically identified within the first month of checking a factory’s data. Once on track with automatic data analysis, a medium to large processing plant can expect a significant ROI in just a few months.

The CIP process for hygiene translates chemistry, resource management, and data analysis into safety and product quality. Continuous remote monitoring helps reduce wash times and enables your business to achieve more efficient and sustainable operations, which is crucial in an industry defined by tight margins and intense competition. With a 24/7 monitored process, including predictive analytics, advanced CIP technologies are delivering the future of hygiene to an industry that has held on to traditional methods for reducing food safety risks for too long.

The OpX Leadership Network recently released “CIP for CPGs” guidelines that outlines generic definitions, equipment considerations, and best practices for CIP that can be leveraged across multiple process lines. The CIP for CPGs checklist, for a system to truly be cleanable in place it must abide by the following five rules.

1. The unit operations and equipment components used in the system have been designed for CIP and verified to clean in place by 3-A-SSI, EHEDG, or an acceptable alternative method.

2. Installation of the system must maintain its CIP integrity. This includes not only the materials and craftsmanship but also the proper fluid dynamics for the CIP solution supply and return to the process equipment.

3. The process piping and equipment must be able to receive the prescribed flow, temperature, time, chemical concentration, and pressure of cleaning solution required by the manufacturer or process design engineer. Often the process lines are not capable of delivering the CIP flow required by the equipment and additional design considerations are necessary.

4. Once a CIP process has been validated, proper change control procedures should be in place to maintain an accurate record of the critical process parameters (e.g., time, temp, flow, pressure, and conductivity/concentration). Routine visual inspection, chemical residual verification on final rinses, and microbial verification ensure system performance is consistently achieving proper cleaning.

5. A preventative maintenance and instrument calibration program must be in place to ensure the equipment and process are maintained as designed. Periodic inspection of in-line filters and magnetic traps is required to mitigate potential threats from foreign materials.

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A host of audio and video webinars are available on demand at www.foodqualityandsafety.com/webcast/

TAKE YOUR PICK!
Ensuring the Integrity of a Food Safety Program

Process validation is critical in providing evidence that a particular production process is capable of consistently delivering quality product | BY JON KIMBLE

Validation. It’s not a word that piques most people’s interest when they first hear it. But if your occupation involves any food safety responsibilities you probably know validation is one of the most important things you do. Proper validation helps ensure the integrity of your company’s food safety programs. It’s one of the most common areas where non-conformities occur in food safety audits, and if not done properly can potentially lead to a recall, consumer illness, or death.

Initial validation of food safety systems and its controls verifies that each program works effectively. Revalidation acts as a secondary check on systems. During this process, employees and systems can be redirected if issues arise before they become serious concerns. Validation protects the company, its employees, customers, and consumers. Additionally, proper validation is an important part of developing a food safety culture—ensuring what we are doing is effective rather than just going through the motions because we think it’s what we’re supposed to do.

Learning from Recalls

The industry can learn a lot from companies that experienced recalls and regulatory action. One of the most well-known and widely-discussed cases of “what not to do” is the Peanut Corp. of America outbreak and recall in 2008-2009. The company made some bad choices, such as reportedly shipping product known to contain Salmonella, and having a facility ridden with pest activity, holes in the roof, and other food safety issues. One key mistake was not validating its programs. The company used its roaster as a control for biological hazards, and yet had not conducted any validation to establish suitable process parameters to achieve a 5-log reduction of the target pathogen species. It’s also fairly obvious the company didn’t validate the effectiveness of its pest control and maintenance programs. If Peanut Corp. of America had process validation in place, it would have seen the gaps in its system and reacted accordingly.

In another example, Death Wish Coffee recalled its products in 2017. The company determined that although nobody had gotten ill at the time of the recall, there was a possibility of botulism from its nitrogen-infused product. The risk was due to the product’s formulation and lack of a process for eliminating the risk of Clostridium botulinum growth.

These instances show that any one company can have a real impact on the entire food industry. In 1996, Odwalla was involved in a recall caused by improper validation. The company sold products containing apple juice that wasn’t pasteurized and had E. coli 0157:H7. More than 65 individuals became ill from the products and one child passed away. As a result, the FDA interjected itself into industry practices and shortly thereafter created regulations requiring all juice be pasteurized through a valid system.

There are other relevant outbreaks and recalls in the industry in which processes were not validated and consumers suffered the repercussions. Suffice it to say, the importance of validation in a food safety program cannot be overstated.

FDA’s View on Validation

The FDA applies validation in a relatively limited way for the food industry. According to the Food Safety Modernization Act’s Preventive Control Qualified Individual (PCQI) course, of the four kinds of preventive controls, only process preventive controls are required to be validated. In the PCQI training, Lead Trainers also discuss how a company may, in some cases, validate an allergen preventive control. In this instance, think of a clean-in-place (CIP) system, where process parameters such as time, temperature, fluid flow rate, and chemical concentration can be consistently managed, allowing the process parameters to be validated as effective.

FDA defines validation as:

“Validation means obtaining and evaluating scientific and technical evidence...
that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.”

In cases where validation is required, the FDA intends for the approach to be as rigorous as possible. Gathering any relevant data, regulatory guidance, and additional resources ensure that processes and the food safety plan as a whole are valid.

Let’s use metal detection as a simple example, since it’s a common control and would typically be considered a process preventive control (it’s often designated as a critical control point). Some companies have their detector checked by a qualified third party, which is often referred to as “calibration,” and based on those results they will consider it validated. But what’s missing? They didn’t conduct a thorough yearly review of consumer complaints. They didn’t examine their internal process data, looking for trends in equipment performance. They didn’t review finished product inspection results, if those are available, for any indicators of a potential problem. These are all valid pieces of information needed in a proper validation to ensure the device is working correctly. In other words, when it comes to validation (effectiveness), things aren’t always as simple as they may appear, and we really need to dig below the surface to be as detailed and comprehensive as possible, focusing on avoiding “worse-case” outcomes.

**GFSI’s Broader View**

Global Food Safety Initiative (GFSI) programs, which are HACCP (Hazard Analysis and Critical Control Points)-based but also contain additional requirements, take a similar view of validation as the FDA but are typically much broader. The schemes often require companies to have a documented process for validation of the things FDA would look for. For example, validation of the food safety plan, critical control points, changes to food safety programs, CIP systems, shelf life, rework activities, and product cooking instructions.

Notably, under the Safe Quality Food (SQF) standards, all elements of the program are required to be validated, as a whole. Any of the GFSI programs require this, in spirit, but the SQF requirements make it a bit more rigorous.

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**Help with Equipment Validation**

Many industries have established experts who are referred to as “process authorities” and assist companies with validation of certain critical processes. This is typically limited to processes intended to control pathogens, such as canning processes and pasteurization. There aren’t always official recognition processes for these individuals, but some industries and trade associations may be able to make recommendations.

In absence of this option, there are other ways to get help. The FDA has a Technical Assistance Network (referred to as TAN) on its website, where visitors can ask questions about how to validate their processes, or who might help do so. University extension agents can be contacted at universities such as UC Davis, Cornell, and Kansas State that may facilitate connections to an expert.

**The Role of Internal Audits**

Internal audits are a great tool. As with any program, they can be done well or they can be approached with a “check the box” mentality—simply getting them done to satisfy the requirements of certification. If done properly, an internal audit can also function as validation of a program; killing two birds with one stone.

An internal audit completed to simply meet the requirements of certification might include one visit to the production floor, watching the activity for a few moments, and reviewing a few records. This might be considered an internal audit, but so much more can be done to validate.

An internal audit should include:

- Assessment of the procedure for any needed changes and to ensure it meets regulatory and certification requirements;
- Observation of the operation on the production floor, on all shifts;
- Completion of staff interviews to confirm their understanding;
- Review of training records to verify staff are suitably trained per program requirements;
- Review of through sampling of records of the program, looking for any relevant trends or issues that have arisen;
- Evaluation of customer or consumer complaints that looks for anything relevant to the program; and
- Consideration of any other processes potentially affected by this one, and review those programs as well if relevant.

A thorough internal audit, like described above, is a great way to validate a program—thereby ensuring a high level of confidence on the controls’ effectiveness.

**Actionable Takeaways**

Get the whole food safety team involved, and others if relevant. Validation isn’t something one person can do on their own, it takes a comprehensive approach that only a team can provide.

Validate the program as a whole when it’s first created, then at least annually thereafter or on any significant changes.

In order to validate a plan as a whole, review all programs first. Then take a look at everything together and judge if the program is working as designed.

Validating controls means reviewing any potential hazards in the ingredients or raw materials, finished products, and processes. Follow the HACCP approach:

- Identify any potential hazards—do this thoroughly, using relevant resources;
- Evaluate significance of each hazard—determine what sort of control is required;
- Identify the right control—evaluate what is currently in place to confirm it’s the appropriate control;
- Set up critical parameters for each control, and implement programs for monitoring, corrective actions, and verification; and
- Reference FDA's guidance on Preventive Controls, particularly Appendix 1.

In addition, create a schedule for all verification and validation activities for the year, and issue assignments to responsible parties (activities should be saved on employees’ calendars). This needs to be a team approach. If another meeting or activity takes precedent, make sure the event is rescheduled, not ignored.

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For more information on internal auditing techniques and developing programs, check out Safe Food Academy’s web-based training at [https://safefoodalliance.com/learning/](https://safefoodalliance.com/learning/).
There has been a lot of research on the health benefits of consuming tea, especially the five main types that are produced from the leaves of the *Camellia sinensis* plant (white, black, green, oolong, and Pu-erh). Pu-erh tea is a fermented-tea that is produced from broad-leaved variety, *Camellia sinensis var. Assamica*. The tea shrub only grows in the southwest Yunnan province of China. To produce the tea, the leaves are stacked, dampened, and fermented during a 60- to 180-day process. Bacteria such as *Actinoplanes* and *Streptomyces* are added during the process, and these bacteria are responsible for the tea’s distinct, earthy flavor. Pu-erh has increased in popularity in many parts of the world in recent years, leading to an increase in production to meet the growing demand.

High value, specialty food products such as Pu-erh tea, which are characterized by origin and are produced in limited quantities, are more likely to be adulterated with lower-cost ingredients for financial gain. While teas can be differentiated by profiling the type and concentration of bioactive compounds such as flavonoids, phenolic acids, alkaloids, and polyamines, these compounds are known to be affected by oxidative processing. Increasingly, the trace element composition of foodstuffs is being used for authentication studies. Since the minerals and nutrients present in plants may be representative of the composition of the surrounding soil, plants grown in the same area tend to have their own characteristic elemental fingerprint.

Fast, Multi-Element Analysis

The fast, sensitive, multi-element capabilities of inductively coupled plasma-mass spectrometry (ICP-MS) make it an ideal tool for elemental fingerprinting. Instruments fitted with a collision/reaction cell that can operate in collision mode using an inert gas such as helium are especially useful for food authentication studies. Through multiple collisions with helium gas atoms, the relative transmission of larger, polyatomic ions is reduced compared to the smaller, monatomic analyte ions that they overlap. This allows the interferences to be resolved by kinetic energy discrimination. The approach lowers the detection limits and accuracy for many elements, providing large, high-quality datasets.

Triple quadrupole ICP-MS (also referred to as ICP-QQQ) offers greater flexibility than single quadrupole ICP-MS for applications that require greater sensitivity and accuracy for some specific elements. In addition to the helium collision mode, ICP-QQQ allows the controlled use of reaction cell gases to lower detection limits for elements that suffer from isobaric or doubly-charged ions.

Building a Model for Specialty Tea

Twenty-four Chinese tea samples including Pu-erh (12 samples), gunpowder green (seven), breakfast (two), green (two), and oolong (one) were obtained directly from a U.S. import merchant. Four teas from Egypt (Moroccan mint variety) were also analyzed in this study. Each tea was sampled at least two times (different lots or boxes), and each sample was prepared in triplicate using microwave-digestion.

The tea samples were measured using an 8800 ICP-QQQ from Agilent Technologies. All elements that were determined above the detection limit are given in Table 1. As indicated by the calibration correlation coefficient, excellent linearity was achieved for both major elements and trace elements. Instrument setup, operation, data acquisition, and data processing were performed using the instrument’s ICP-MS MassHunter software. Mass Profiler Professional (MMP) chemometric software was used for statistical analysis of the dataset. All software was from Agilent Technologies.

Pattern Recognition Software

The multi-element data batch file (30 tea samples, 29 elements, 3 replicates) was imported into MMP chemometric software for statistical analysis using supervised discriminant analysis, spe-
(Faiyum and Sikkim). Clear separation of each group is also achieved within the different Chinese regions. These results indicate that the elemental composition of teas is influenced by where the tea leaves are grown. Along the first dimension, explaining 70 percent of the total variance ratio, macro elements like Na, Mg, and Ca, micro elements like Sr, Zr, and Mo, as well as trace elements, including the rare earth elements La and Ce, were found to be higher in the Faiyum teas. Meanwhile, Mn, Ni, Zn, Rb, and Re were higher in the other teas, leading to the clear separation between the different regions.

A similar clear separation is shown in Figure 2, where teas were classified by type. Moroccan mint teas clearly separate from the other teas, along the first dimension, explaining 68 percent of the total variance ratio. Further, green teas (i.e., simply green, green, and gunpowder green) were located closer to each other, with the gunpowder green teas being closer towards the black and fermented teas (i.e., Chinese breakfast, oolong, and Pu-erh).

Discriminating elements along the first dimension include the macro elements Mg, Na, Ca, and Fe, micro elements like Sr, Mo, and Hf, and rare earth elements like Ce, Pr, Nd, Sm, Eu, and Gd. All of these elements were higher in the Moroccan mint teas, while Mn, Ni, Cd, and Re showed higher levels in the green, black, and fermented teas.

Along the second dimension, where green teas separate from black and fermented teas, levels of Rb, Mn, W, Re, and Ti were higher in the black and fermented teas.

In Summary

Once a model has been established based on a full range of samples, elemental profiling can identify the geographical origin of specialty foods and beverages.

In this study, multiple elements were determined in digests of 29 tea samples using ICP-MS to demonstrate the capability of multi-elemental profiling for authentication purposes. The teas, which were sourced from a reliable importer, included different varieties of tea, teas grown in different growing regions of southern China, and teas from Egypt.

The methodology could be run on a single quadrupole ICP-MS. However, the use of a triple quadrupole ICP-MS provides better detection limits and accuracy for some analytes that are prone to complex interferences in certain matrices.

Easy-to-use MPP chemometric techniques were applied to process the large dataset and to visualize the differences between samples. An exploratory analysis with discriminant analysis as a supervised multivariate analysis showed a clear separation of teas by region and by type.

Looking Forward

Future studies will aim to strengthen the model with additional data from the analysis of more teas from different geographical origins, as well as tea mixtures. A market basket study on all commercially available Pu-erh teas can then be carried out. The method has the potential to quickly check the authentication of tea on a routine basis.

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**Roundup of New Rapid Testing Tools**

Industry stakeholders explain the latest technology breaking ground for food producers | BY LINDA L. LEAKE, MS

The world is awash with new rapid testing technology that is enhancing food quality and safety knowledge for the global food industry.

**Identifying Listeria Patterns**

In July 2018, Rheonix Inc., Ithaca, N.Y., launched its Listeria PatternAlert assay, which the company calls a breakthrough method for rapidly identifying molecular patterns from *Listeria* strains.

“The method is designed to assist food producers in identifying harborage sites for persistent *Listeria* and in tracing back sources of contamination,” says Brooke Schwartz, MBA, vice president for strategy and marketing, Rheonix.

“We are supporting this technology because of the potential value that it would have for our clients,” says Timothy Freier, PhD, vice president of scientific affairs and microbiology for Médecins NutriSciences, Chicago, Ill., Rheonix’s beta testing partner for the Listeria PatternAlert assay. “The ability to have *Listeria* tracking information within hours of a presumptive positive result would greatly enhance environmental contamination investigations, allowing manufacturers to find and fix issues before their product is impacted, saving costs and benefiting public health.”

Current strain typing methods take up to two weeks to complete and require an isolate in pure culture, Schwartz points out. “The Listeria PatternAlert assay, which is performed using the fully automated Rheonix Encompass Optimum workstation, enables users to detect molecular patterns in just six hours directly from a positive enriched sample, without the need for an isolate,” she relates. “Each result can be matched against a user’s specific PatternAlert database to identify their pattern matches across locations and time.

“This method provides users with a rapid, cost-effective tool to aid in identifying, tracking, and addressing recurring *Listeria,*” she adds.

According to Morgan Wallace, PhD, scientific director for applied markets, Rheonix, the Listeria PatternAlert assay detects the presence or absence of independently occurring genetic targets that can sort *Listeria* into thousands of potential patterns. “Each pattern generated by the assay encompasses a group of strains and may include multiple species of *Listeria,*” he explains. “Our approach is to provide information directly from enriched samples that can help users identify recurring strains or populations. The discriminatory power of the PatternAlert assay was carefully calibrated to enable users to make informed decisions based on molecular patterns, without the assay providing a strain level characterization equivalent to whole genome sequencing (WGS) or pulsed-field gel electrophoresis.”

The assay, in combination with the PatternAlert analytical software, addresses the questions:

- Where and when have I seen this pattern before?
- Do I have a potential harborage site?
- Am I seeing the same pattern over time or across facilities?

In some situations, the PatternAlert assay and WGS can be effectively used in combination, Dr. Wallace adds. “In a traceback situation, for example, many isolates might need to be sequenced to determine whether the outbreak strain is present,” he elaborates. “The isolates or positive enrichments can first be quickly screened for likely matches with the PatternAlert assay; only those with relevant patterns would go on to be sequenced.”

**Three Tests in One**

Thermo Fisher Scientific, Basingstoke, England, introduced its RapidFinder *Salmonella* Multiplex PCR (polymerase chain reaction) Workflow in December 2017. The technology is specifically designed to test raw, ready-to-eat, and ready-to-reheat poultry, as well as production environment samples and primary production samples, according to Cheryl Mooney, the firm’s global marketing and communications manager for food protection.

“What is particularly noteworthy is that with RapidFinder, laboratories performing tests for poultry producers can simultaneously screen samples for *Salmonella* (S.) species, S. Typhimurium (S. *enterica* subspecies 1 sporov Typhimurium), and S. Enteritidis (S. *enterica* serotype Enteritidis),” Mooney says. “We believe this is the first independently validated PCR assay of its kind. RapidFinder features simple sample preparation and provides combined *Salmonella* species and serovar..."
Fat in 30 Seconds

Soon after the ORACLE rapid fat analyzer was introduced by CEM Corp., Mathews, N.C., in October 2016, the instrument was named one of the top new products at Pittcon 2017 by Instrument Business Outlook. Then it captured an IFT17 Food Expo Innovation Award in a field of some 40 entries.

“The ORACLE is the first instrument that requires absolutely no method development for fat only analysis,” says Ian Olmsted, product manager of CEM’s Process Control Division. “ORACLE can analyze fat in any food sample with reference chemistry accuracy, without any prior knowledge of the sample matrix or composition. The instrument can analyze any sample containing from 0.05 percent to 100.00 percent fat with an exceptionally accurate and precise fat result in 30 seconds. It functions with newly developed nuclear magnetic resonance technology that completely isolates protons in fat from all other proton sources in food matrices, such as carbohydrates and proteins.”

Droplet Digital Enhancements

In early 2019, Bio-Rad Laboratories, Hercules, Calif., plans to make its QX200 Droplet Digital PCR System commercially available. This new dd-Check STEC (Shiga toxin-producing E. coli) solution combines the company’s Droplet Digital PCR (ddPCR) technology and iQ-Check STEC real-time PCR assay.

“Employing the co-localization benefit of ddPCR, dd-Check STEC will reduce the number of false positive samples to quickly confirm the linkage of Shiga toxin (stx) and intimin (eae),” says Mike Clark, MS, international PCR group manager of Bio-Rad’s Food Science Division.

“ddPCR technology is a method for performing digital PCR within several thousand water-oil emulsion droplets,” Clark relates. “The key to ddPCR is sample partitioning. In traditional PCR, a single measurement is performed on a single sample. In ddPCR, a single sample is partitioned into thousands of nano-sized droplets, allowing thousands of independent, single amplification events within that sample.”

With a PCR reaction taking place in individual droplets, this technology brings several advantages to food safety testing. “These benefits include absolute quantification without the need for running a standard curve, greater tolerance to PCR inhibitors, and one-step unambiguous identification/confirmation of genomes bearing dependent markers (co-localization of markers),” Clark points out.

Co-localization ddPCR can detect true enterohemorrhagic E. coli (EHEC) positive samples in a variety of food matrices, Clark says. “Food matrices confirmed positive for EHEC, a highly pathogenic subset of STEC, results when two virulence factors, stx and eae, are present together within one E. coli bacterium,” he elaborates. “The ddPCR technology makes it possible to detect both virulence markers in a single bacterium by observing the percent linkage of two markers (stx and eae), making it possible to discriminate bacterium containing both markers from multiple bacteria each carrying a single marker.”

NCBI Gene ID Tools

At the National Center for Biotechnology Information (NCBI), Bethesda, Md., involvement with rapid testing methods is limited to tools and databases used for rapid analysis of WGS data, according to Michael Feldgarden, PhD, an NCBI staff scientist.

“We don’t have wet labs at NCBI, but instead collaborate with labs at public health agencies, such as the FDA, CDC, and USDA to analyze their whole genome sequencing data in real time,” Dr. Feldgarden points out. “Our tools are used by these collaborators to facilitate investigation of foodborne disease outbreaks and to track antimicrobial resistance genes.”

The NCBI Pathogen Detection pipeline has data on over 280,000 bacterial isolates, including the four major foodborne bacterial pathogens—Campylobacter, E. coli, Listeria, and Salmonella—as well as 18 other pathogens. “Within 24 hours of sequence data submission, the pipeline can identify closely related isolates, describe how they are related to each other, and provide different visualizations of these relationships and data in NCBI’s Isolate Browser,” Dr. Feldgarden says.

In 2018, for several of the foodborne pathogens, NCBI has added the capacity to identify a preliminary set of isolates related to a particular isolate within 60 minutes of the sequence data being uploaded to NCBI, Dr. Feldgarden relates. “These tools provide a provisional set of isolates for our partner agencies and programs to investigate, helping them to focus their resources more effectively and determine cases for a full epidemiological analysis,” he explains.

Ringing the Bell with Smartphones

Many smartphone-based approaches to food testing have been developed by scientists and start-up companies. “So far, we can distinguish smartphone-based spectrometers or food scanners for rapid non-invasive analysis of food products for macro-components (proteins, fat, carbs, moisture) and smartphone-based biorecognition assays for low levels of certain food contaminants,” says Michel Nielen, PhD, an analytical chemistry professor at RIKILT Wageningen University & Research, the Netherlands. Dr. Nielen is the coordinator of FoodSmartphone, a technology funded by the European Union’s (EU) Horizon 2020 research program under the Marie Skłodowska-Curie grant for on-site testing.

“The primary challenge for food scanners is the robustness of the associated... (Continued on p. 46)
Dusts produced when manufacturing and processing food products create significant challenges. Dust particles often become airborne, which can threaten employee health and cause combustible dust incidents. Food dust particles vary in size, and some are so fine they are not visible to the naked eye. Common food dust hazards include cereal ingredients, spices, feed and raw grain agricultural products, egg shell dust, flour, corn starch, sugar, and flavoring additives.

Manufacturers must comply with Occupational Safety and Health Administration (OSHA) regulations to protect their employees from exposure to airborne dusts, as well as National Fire Protection Association (NFPA) standards to provide a safe working environment. In addition, food processors must follow regulations from the USDA and FDA, which has begun implementing the Food Safety Modernization Act (FSMA).

Manufacturers need to control the dusts generated in food and beverage facilities that can:

- Cause serious harm to human health and negatively impact the environment;
- Cross-contaminate and proliferate the spread of pathogens and allergens; and
- Become combustible and cause devastating explosions that harm workers, damage machinery, and destroy buildings and corporate reputations.

Cross-Contamination
Traveling dust in a food processing plant can result in allergen exposure or a pathogen outbreak from the spread of microorganisms. Preventing cross-contamination requires effectively cleaning equipment and processing suites—collecting and removing all contaminants before they become widely dispersed. Collecting, controlling, and filtering pathogens and allergens minimize the spread of harmful contaminants and keep them from returning to the processing environment.

Controlling Exposure to Dust
The best way to reduce hazardous dust exposure and cross-contamination is to install dust collection systems with high-efficiency primary and secondary cartridge-style filters. Primary filter media should be selected for each application based on the dust particle size, flow characteristics, quantity, and distribution. If the primary filtration system does not use a HEPA filter, it is recommended that a secondary HEPA filter be used downstream. Secondary filters prevent hazardous dusts from discharging to the atmosphere and can be configured to prevent return air ducting contamination and the associated costs of cleaning hazardous dust leakage.

A wide, uniformly pleated filter allows the collected dust to release from the filter, keeping the resistance lower through the filter for a longer time. When pleats of the filter media are tightly packed, the reverse-pulse cleaning system of the dust collector will not eject the dust that has settled in between the pleats; tightly packed pleats increase the resistance of the air through the filters and diminishes airflow.

Don’t Let the Dust Settle
Tips on how dust collectors help mitigate combustible hazards and prevent cross-contamination

BY DAVID STEIL
There are two basic categories of media commonly used in pleated cartridge filters. The choice is usually driven by dust type, operating temperatures, and level of moisture in the process.

1. Nonwoven cellulosic blend media is the most economical choice for dry dust collection applications at operating temperatures up to 160 degrees Fahrenheit (71 degrees Celsius).

2. Synthetic polyester media or polyester-silicon blend is a lightweight, washable media that can handle dry applications with maximum operating temperatures ranging from 180 degrees Fahrenheit (82 degrees Celsius) up to 265 degrees Fahrenheit (129 degrees Celsius). These filters are washable and can recover from a moisture excursion, but they are not intended for wet applications.

Standard and nanotechnology filter media treated with a flame retardant are recommended for applications considered a fire risk. Conductive or antistatic filters may be used where conveyed dusts generate static charges that require dissipation. Cartridge filters with antistatic media can also be used in explosive dust applications, making it possible to conform to NFPA requirements and lessen the risk of ignition sources due to static electricity charges.

High-efficiency dust collection systems also use self-cleaning mechanisms that regularly pulse dust off the filters, allowing units to run longer between filter change-outs. When a layer of nanofibers is applied on top of the base filter media, it promotes surface loading of fine dust and prevents the dust from penetrating deeply into the filter’s base media. This translates into better dust release during cleaning cycles and lower pressure drop readings through the life of the filter.

**Combustible Dust Explosions**

A dust explosion occurs when a confined and concentrated combustible dust cloud meets an ignition source. Many solid food and beverage ingredients produce explosive dusts including sugar, starch, flour, spices, tea, grain, and proteins. Good housekeeping and installing a well-designed dust collection system can prevent airborne dust from building up in the work environment, on electrical equipment, and on other areas where dust can accumulate, such as false ceilings. These measures help negate the risk of a primary or secondary explosion. The primary explosion is the first point where an explosion occurs and is usually an isolated incident. A secondary explosion occurs when the primary explosion pressure disturbs the dust collected in the areas mentioned above, creating a far more extensive and potentially deadly explosion.

**Relevant NFPA Standards**

In trying to sort through the list of combustible dust standards, a good starting point is **NFPA 652**, the Standard on the Fundamentals of Combustible Dust. This covers the requirements for managing combustible dust fires and explosions across industries, processes, and dust types. The owner or operator of any facility where combustible dust exists is responsible for conducting a dust hazard analysis to identify hazards, create a plan for managing hazards, and provide training for anyone affected by hazards.

NFPA 654, the Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, is an all-encompassing standard on how to design a safe dust collection system.

NFPA 61, the Standard for the Prevention of Fires and Dust Explosions in Agricultural and Food Processing Facilities, covers facilities engaged in dry agricultural bulk materials or manufacturing and handling starch.

NFPA 68, the Standard on Explosion Protection by Deflagration Venting, focuses on explosion venting on devices and systems that vent combustion gases and pressures resulting from a deflagration within an enclosure.

NFPA 69, the Standard on Explosion Prevention Systems, covers explosion protection of dust collectors when venting is not possible.

**Traveling dust in a food processing plant can result in allergen exposure or a pathogen outbreak from the spread of microorganisms.**

Designed to install over a standard explosion vent, a flameless vent extinguishes the flame front exiting the vented area, not allowing it to exit the device.

(Continued on p. 38)
Mitigating Combustible Dust

In food manufacturing, it is critical to know the explosive potential of the dusts, gases, and dust/gas mixtures emitted during processing. NFPA states that a hazard analysis is needed to assess the risks and determine the required level of fire and explosion protection from combustible dust. The analysis can be conducted internally or by an independent consultant, but either way the authority having jurisdiction will ultimately review and approve the findings.

The first step in a hazard analysis is determining whether a facility’s dust is explosive. NFPA classifies dusts according to their explosibility, that is, their Kst values. Kst is the normalized maximum rate of explosion pressure rise, measured in bar m/s. (See Combustible Dust Properties list, p. 37.)

A bar is a metric unit of pressure, which is slightly less than the average atmospheric pressure on Earth at sea level.

NFPA Class ST1 dusts are rated below 200 Kst, Class ST2 dusts range from 200 to 300 Kst, and Class ST3 dusts are rated above 300 Kst. As a rule of thumb, when dusts approach 600 Kst, they are so explosive that wet collection methods are recommended. However, any dust above 0 Kst is considered to be explosive, and the majority of dusts fall into this category. If OSHA determines that even a very low Kst dust is present in a facility with no explosion protection in place, a citation will result, per OSHA’s NEP policy.

In addition to Kst, it is important to know other combustible dust properties such as Pmax (the maximum explosion pressure of a dust cloud, measured in bar) and Pred (the maximum pressure developed in a vented enclosure during a vented deflagration). These can be determined using ASTM E1226-10, Standard Test Method for Explosibility of Dust Clouds.

A dust collection equipment supplier will need the Kst and Pmax values to correctly size explosion venting or suppression systems. Failure to provide this information will increase costs, since the supplier will have to use worst-case estimates of the Kst and Pmax values or may even refuse to provide the equipment.

Dust Collectors and Explosion Protection

Combustible dust explosions are a risk in many areas of a food processing plant, but one of the most common locations is the dust collection system itself. There are many types of devices and systems used to comply with NFPA standards for the explosion protection of dust collection systems, but they fall into two general categories: passive and active.

Passive devices include the following.

Explosion venting. Designed to be the “weak” link of the dust collector vessel, an explosion vent opens when predetermined pressures are reached inside the collector, allowing the excess pressure and flame front to exit to a safe area. It minimizes damage to the collector and prevents it from blowing up in the event of a deflagration, thereby reducing the safety hazard.

Flameless venting. Designed to install over a standard explosion vent, a flameless vent extinguishes the flame front exiting the vented area, not allowing it to exit the device. This allows conventional venting to be accomplished indoors where it could otherwise endanger personnel and/or ignite secondary explosions. A safe area around the flameless vent still needs to be established due to the release of pressure and dust/gases.

Passive float valve. Designed to be installed in the outlet ducting of a dust collection system, this valve utilizes a mechanical barrier to isolate pressure and flame fronts caused by the explosion from propagating further through the ducting. The mechanical barrier reacts within milliseconds and is closed by the pressure of the explosion.

Backdraft damper. A mechanical backdraft damper is positioned in the inlet ducting. It utilizes a mechanical barrier that is held open by the process air and is slammed shut by the pressure forces of the explosion. When closed, this barrier isolates pressure and flame fronts from being able to propagate further up the process stream.

Flame front diverters. These devices divert the flame front to atmosphere and away from downstream piping. Typically, these devices are used between two different vessels equipped with their own explosion protection systems. The flame front diverter is used to eliminate “flame jet ignition” between the two vessels that could overpower the protection systems installed.

Active devices include the following.

Chemical isolation. This system creates a chemical barrier that suppresses the explosion within the ducting, eliminates the propagation of flame, and minimizes pressure increase within connected process equipment.

Chemical suppression. This system detects an explosion hazard within milliseconds and releases a chemical agent to extinguish the flame before an explosion can occur.

Fast-acting valve. This valve creates a mechanical barrier within the ducting that effectively isolates pressure and flame fronts from either direction, preventing them from propagating further through the process.

Summary

Effectively controlling the dusts generated in food manufacturing facilities is an essential, life-saving legal obligation. Dust can cause serious harm to employee health, reduce product quality, and cause devastating explosions that can hurt or kill workers and bring irreparable damage to a food processing operation. A high-efficiency dust collector designed specifically for your facility is an accepted and proven engineering control that will filter hazardous contaminants to make indoor environments safer.

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When it comes to food quality control, humidity and temperature are often primary concerns. Left unchecked, moisture can plague a facility with spoilage and mold as well as pose fall risks to workers—challenges that are exacerbated when temperature levels are irregular.

Managing these risks often begins by managing your facility’s indoor air quality. Establishing consistent air quality throughout the various sectors of a structure—from its cold storage to its packaging areas—is paramount to create a steady indoor climate that will support optimal product and employee safety.

**What’s Indoor Air Quality?**
Indoor air quality typically refers to the air quality within and around buildings and structures. With proper circulation, a majority of air quality concerns can be eliminated—and HVLS (high-volume, low-speed) fans are particularly adept in this area due to their ability to move large volumes of air with minimal energy.

By consistently providing large-scale airflow, HVLS fans accompanied by HVAC systems are critical tools in regulating a facility’s temperature and humidity while preventing stagnant air and a dust-riddled environment. The fans’ high air turns can also eliminate toxic airborne chemicals at a more rapid pace.

**Moisture Management**
Moisture is a daily concern in many food processing, packaging, and manufacturing environments. With frequent washdowns and products that may contain moisture, managing humidity can feel like an uphill battle. Condensation can easily form on the floor in between two different climate-controlled environments, presenting a significant safety hazard.

By increasing a facility’s air circulation and adjusting HVLS fans to an adequate, steady speed, condensation evaporates much more quickly—reducing slips, trips, and falls as well as pollutants and bacteria associated with unchecked moisture.

For example, Hunter Industrial worked with an award-winning beverage distributor in central Florida whose loading area often experienced condensation buildup on its concrete floors. The team would scrub the moisture from the floors, but its efforts only provided a temporary fix.

“Due to the condensation on the floors, our employees were constantly at risk of a safety hazard,” says the distributor’s operations manager. “When our team would operate forklifts, they would need to exercise extra caution because of the machines’ tendency to slip on the damp floors. I had a couple small exhaust fans in the facility, but their air movement was only within a few feet of the fans, which doesn’t help to dry the floors at all.”

After installing two 24-foot Hunter Industrial HVLS fans, the operations manager noticed an immediate difference with the fans operating at just half-speed. There was no longer condensation buildup and employees were able to operate forklifts and execute daily tasks more efficiently.

In another instance, a microbrewery in Tennessee saw a need for better airflow and a proper cooling mechanism in its facility, particularly during the hot summer months. While it had ventilation fans installed on the apex of its roof, there was no way to move the air throughout the 12,000 square foot building. Because of the large amounts of water used in the facility, moisture control was a primary issue; the warehouse floor was consistently wet with stagnant moisture, but installing a 16-foot HVLS fan from Hunter Industrial remedied the issue.

**Temperature Regulation**
In addition to moisture management, most food manufacturing facilities require set temperatures specific to cold storage, dry storage, packaging areas, and more to maintain optimal product safety and quality. In buildings that are expansive and/or have multiple sectors, maintaining these temperature requirements can be a challenge at best.

With the ability for speeds to be programmed systematically or to fit the tailored needs of a specific space, HVLS fans can be efficient solutions in regulating room temperatures—optimizing the operation of HVAC systems and increasing far-reaching indoor air flow to previously underserviced areas.

For manufacturing and warehouse spaces that have lofted ceilings, HVLS...
installations can be particularly useful in de-stratifying an environment. To break this down, when heat is introduced into a space, it forms temperature levels, or strata. The warmest air rises to the ceiling while the coolest air remains at the floor level. HVLS fans can level out these variations, de-stratifying the air so that the desired space achieves a consistent, sustainable air temperature—ultimately stabilizing HVAC costs and helping ensure required temperatures are maintained.

HVLS Fans vs. Conventional Options

Not all fans are created equal. Some of the key differences between HVLS fans versus traditional high-speed fan options are the reduced noise, reduction in energy consumption, and ergonomic safety.

The design of an HVLS ceiling fan allows for a safer working environment, eliminating trip hazards from electrical cords found with high-speed fans—a key factor considering many facility and plant managers identify cords as one of the top workplace hazards. However, with many models of HVLS fans, the overall direct interaction between an employee and a fan is virtually eliminated. This feature is compounded by the maintenance-free aspect of those HVLS fans with direct drive motors, which also eliminate the risk of oil leaks posed by traditional gearbox motors. This particular characteristic has been one of the most beneficial.

For instance, Hunter Industrial replaced a food distributor’s HVLS fan after its gearbox motor leaked oil onto its products. The distributor attached a makeshift drip pan underneath the fan to catch leaking oil, which posed a risk of contaminants in the facility, so a replacement was clearly needed. After installing industrial fans with direct drive motors, the distributor had no further maintenance problems.

Investing in a Solution

Considering all these factors, HVLS fans are emerging as a comprehensive solution to improve energy savings, cost savings, workforce health, and product quality and safety conditions. The importance of a facility’s air circulation and air management cannot be underestimated. Investments in the right HVLS solution can make radical transformations in realizing quality assurance standards, while boosting worker productivity and your bottom line.

Chastain is senior vice president and general manager at Hunter Industrial. Reach him at jchastain@hunterfan.com.
Safety is a concern in any part of a facility, but there is one area that typically worries managers the most: loading docks. In today’s fast-paced environment, the loading and unloading of semi-trailers can pose risks for everyone from forklift operators and dock attendants to service technicians and bystanders. In fact, roughly 34,900 people are seriously injured and 85 killed every year in forklift-related incidents in the U.S., according to OSHA.

Unfortunately, there is no one-size-fits-all solution since no two facilities—or no two dock stations—are exactly the same. However, the lynchpin in any dock safety system is the vehicle restraint.

Old-Fashion Wheel Chocks
One of the most common loading dock accidents happens when drivers mistakenly drive away while a forklift is still inside the trailer, which is called early separation. Another common problem is “trailer creep,” which occurs when trailers (particularly those with air-ride suspension) gradually move away from the dock due to the ongoing impact and momentum of forklifts traveling in and around them.

In both cases, the first step in accident prevention is to secure the trailer to the dock using a locking device on either the trailer’s rear impact guard (RIG) or rear wheel. Many loading docks still use old-fashion wheel chocks in front of trailer tires as a means of restraint. However, multiple problems can come with this including: insufficient pullout resistance, chock slippage, and the time and safety concerns related to placing them by hand on the busy drive approach. Additionally, chocks have no embedded communication system to let the truck driver, lift driver, or dock personnel know they are in place.

RIG-Based Restraints
RIG-based manual or automatic restraints can use a vertical barrier or a full rotating hook to lock onto the trailer’s RIG. They help prevent all types of trailer separation, including early departure, trailer creep, trailer tip-over (from landing gear collapse), or trailer up-ending. Most also incorporate full-time communication systems that indicate when they are properly engaged and it is safe to load and unload.

The most basic type of RIG-based system is a vertical barrier restraint. Vertical barrier restraints provide solid, dependable upward pressure to RIGs, helping to address the most common trailer separation accidents. They can be wall-mounted, ground-stored, or use a recessed design that stores beneath the dock leveler pit.

Rotating hook restraints are generally considered the industry-leading standard for vehicle restraints. As their name implies, they employ a rotating hook that swings up and around the RIG, utilizing the energy of the backing trailer.

Unfortunately, conventional RIG-based restraints do not work in all situations. For example, docks that handle a large volume of trailers with hydraulic gates (such as retail, beverage, and grocery industries) typically cannot use them as those gates block access to the RIG. Likewise, facilities that regularly handle trailers with damaged RIGs or RIG obstructions (such as axle-wide splash guards) cannot use them, nor can dock facilities in foreign countries where RIGs are not standardized or required. International shipping container (intermodal) chassis traffic is another consideration, since these chassis also commonly have RIG obstructions.

Fortunately, there are RIG-based restraints that can alleviate this problem. These models incorporate a “shadow hook” to form a secondary point of engagement on the RIG, helping to secure the chassis to the dock and providing an additional layer of safety when dealing with rear-impact guard obstructions. When these restraints are activated, their hook attempts to wrap around the rear-impact guard. If the hook comes in contact with a rear-impact guard obstruction, the shadow hook pivots to secure the trailer in place. If the trailer moves, the shadow hook locks in the safety stop, which prevents a wide variety of trailer separation accidents.

Securing Safety at the Loading Docks
Choosing the correct vehicle restraint depends on the trailer and loading dock application | BY CHAD DILLAVOU

Vehicle restraints can help prevent trailer/dock separation accidents.
matic re-fire if tampered with and can interface directly with security systems. Some restraints can be interlocked with levelers, doors, and barriers in dock control systems, as well as use sensor-based light communications/safety systems that trigger audio and visual warnings when they sense a trailer backing in.

**Wheel-Based Restraints**

Wheel-based restraints are another option, as they engage the wheel of a trailer and secure the vehicle in place. They offer much needed flexibility at facilities with multiple docks that are set up to service virtually any trailer at any time—including those with lift gates and potentially missing or damaged RIGs. Like RIG-based restraints, they eliminate dangers associated with early departure and trailer separation and provide full-time communication using lights and audible alarms.

The most common wheel-based restraint mounts to the surface of the drive approach directly in front of the dock opening. It engages one of the trailer’s rear tires with a barrier that locks in place and prevents the vehicle from moving forward when parked at the dock. The restraint protects against different types of trailer separation including early departure, trailer creep, and dock walk. Automatic or manually-operated devices are available.

Although automatic units are generally considered the safest and most productive option, there are now many manual wheel-based restraints that deliver safety benefits (and pricing) similar to those of RIG-based restraints. One design utilizes a steel barrier that is positioned along a frame assembly in front of the trailer’s tire. The barrier securely locks into place and doesn’t require adjustments. This is generally the best option.

**Importance of Communication**

A key aspect to consider with any type of restraint is its communications system.

Leading RIG- and wheel-based restraints feature systems that automatically and clearly communicate the status of the restraint so that both the lift truck operator and truck driver know when they can safely perform their duties. These communication systems detect when a restraint is safely and properly engaged, triggering red or green LED lights inside to indicate it’s safe for the lift truck operator to begin unloading or loading. They also trigger LED lights outside the dock that signal when loading or unloading is completed and it is safe for driver to pull away.

Some restraints can be equipped with advanced systems. Recent technology utilizes lights around the corners of the dock doors, providing clear communication of the restraint status directly in the forklift driver’s line of sight—free of any visual obstructions from stacked pallets or other equipment. It also offers lights at the rear of the leveler to confirm the status of the re-

(Continued on p. 49)
Sanitary Design Lowers Foreign Material Risks
A simple approach to assessing risks and creating control measures for foreign materials as they pertain to equipment design | By James T. Davis

In recent years, foreign material present in food products have comprised a large root cause of recalls. Plastic, metal, wood, and other extraneous items are commonly found, as reported in various regulatory agency published incident reports. While the source of the foreign material contamination often varies across each product category, and may often be unknown, incident investigations have pointed towards process inputs and materials, equipment, and tools as contributing factors. As with all factors, the design and maintenance of processing equipment has become more heavily scrutinized as a means to mitigate associated risk.

The prevention of food product contamination resulting from foreign material associated with equipment begins with a basic understanding of sanitary design. Once this foundation is established, methodologies to assess and quantify risk to the product can be determined. Control measures, including redesign, can subsequently be implemented to address any identified high-risk concerns.

Counting on Sanitary Design
Sanitary design is often defined as the process by which equipment and facilities are designed or reconfigured to enable effective cleaning, inspection, and preventative maintenance in an effort to reduce risk in three critical areas: physical, biological, and chemical. Food manufacturers need to develop sanitary design programs that seek to reduce overall risk associated with the three risk types. Internal programs and standards based on historical manufacturing risk and recommendations from industry associations provide the foundation for effective food safety control associated with equipment design. Several food industry organizations publish sanitary design recommendations for reduction in adverse food safety incidents. Examples of these include the North American Meat Institute (NAMI), 3-A Sanitary Standards Inc., and the European Hygienic Engineering Design Group.

Examples of basic elements of sanitary design programs that seek to address common equipment design risks include:

- Wear points and friction zones;
- Material selection and compatibility;
- Locations of critical components;
- Surface finishes and welding; and
- Ease of inspection and maintenance.

Wear points and friction zones on equipment are critical areas where foreign material contamination may arise. Design programs seek to identify and reduce the prevalence of these areas during operations. Common cases include plastic on plastic (conveyor belts with support or diversion guides), metal on plastic (wire belts with plastic guides), and metal on metal (grinding knives and plates). Many sources of wear and friction stem from improper setup, inadequate maintenance, or misalignment. Careful consideration should also be placed on how food product may induce additional wear on equipment components—for instance, grinding frozen meat—and how the specific equipment operates over the course of a production timeframe. A best practice recommendation is to catalog points of wear and friction on equipment to allow for further analysis and preventative measures.

Selecting the proper equipment materials and understanding compatibility with all aspects of the manufacturing process is also a key point to consider. Typical industry guidance as noted from the NAMI sanitary design checklist includes:

- Metals should be stainless steel and appropriate for the process;
- Composites, plastics, and synthetics are made of metal detectable materials (compliant to CFR 21 175-177) and limited in use in product zones;
- Coated, plated, or painted surfaces are not utilized in product zones;
- Exposed fibers are not utilized; and
- Selected materials are compatible with each other.

Improper metals (uncoated aluminum, carbon steel, etc.) likely to become corroded during the chemical sanitation process pose a risk through flaking and premature failure. Considerations must also be taken for anticipated temperatures, process characteristics, and production runtime when selecting components.

The placement of components utilized in the construction of processing equipment is of high concern and should be thoroughly reviewed. Component failure or breakage is often attributed to foreign material incidents. Items that pose a risk of breakage, falling off, or failure should not be located in the product zone. Examples of items that should be mounted (Continued on p. 44)
outside of product zones include, but are not limited to, electrical items (switches, e-stops, sensors, panels, conduit, cables, etc.), mechanical items (motors, gearboxes, drives, bearings, etc.), identification items (name tags, plates, labels, etc.), and fasteners.

An additional aspect of design is the inspection of surface roughness/finish and welding. Rough surface textures increase friction on components in contact with each other and are more prone to excessive wear. Welding poses much of the same risk if burrs, improper polishing, and poor technique are present.

Often overlooked is the level of clearance in and around equipment, particularly in the product zones. Full access to equipment while performing preventative maintenance tasks to ensure proper function is important to eliminate premature failure or breakage. Providing adequate distance allows employees to inspect equipment throughout production operations for integrity, alignment, and setup.

Process Characteristics
Understanding overall foreign material risk requires both an analysis of the process environment and of the equipment itself. Characteristics of the process environment to consider when determining foreign material risk include, but are not limited to, product exposure status or zones, location of equipment on the production line, detection methods throughout the production line, and frequency of equipment inspection.

The concept of zones is of particular importance as it pertains to exposure of the product to components in the equipment. Product zones where direct contamination can occur are inherently higher risk than non-product zones on equipment or facility infrastructure. Risk management efforts are thus first focused on higher risk product zones.

The location of a selected piece of equipment within the production line also determines the level of risk associated with the process. The amount or volume of product that could potentially be affected if a foreign material incident occurs should be taken into consideration. Upstream grinding operations that feed numerous lines are higher risk than a single line where product is already formed or packaged, see Table 1.

The type and quantity of detection methods present throughout the production line can impact overall risk. Methods such as X-ray are able to detect a wider scope of materials than a simple metal detector or visual inspection and would lower total process risk. Having multiple devices, such as X-rays, spread out over the process would also lower risk.

Similar analysis could be applied to the frequency of equipment inspections performed during operations. Equipment that is continuously inspected for integrity present lower process risk than those items only inspected prior to startup.

Equipment Design Characteristics
As when assessing risks associated with certain process characteristics, a similar structure can be used when analyzing sanitary design for foreign material. Examples pertaining to metal selection in a chemically cleaned environment are demonstrated in Table 2.

Other sanitary design specifications as defined by various industry organizations can also be placed on a spectrum of risk for further analysis.

Table 1

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<tr>
<th>Process Risk Factor</th>
<th>Risk Rating (1-10)</th>
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<tbody>
<tr>
<td>Location of equipment</td>
<td>4</td>
</tr>
<tr>
<td>Detection methods and type</td>
<td>6</td>
</tr>
<tr>
<td>Frequency of inspection</td>
<td>3</td>
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</table>

Average 4.5

Table 2

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<tr>
<th>Material</th>
<th>Risk</th>
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<tbody>
<tr>
<td>316 SS</td>
<td>Lower Risk</td>
</tr>
<tr>
<td>304 SS</td>
<td>Lower Risk</td>
</tr>
<tr>
<td>303 SS</td>
<td>Lower Risk</td>
</tr>
<tr>
<td>Aluminum</td>
<td>Lower Risk</td>
</tr>
<tr>
<td>Mild Steel</td>
<td>Higher Risk</td>
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</table>

Table 3

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<th>Process Risk Factor</th>
<th>Risk Rating (1-10)</th>
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</thead>
<tbody>
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<td>Product exposure status or zones</td>
<td>5</td>
</tr>
<tr>
<td>Location of equipment</td>
<td>4</td>
</tr>
<tr>
<td>Detection methods and type</td>
<td>6</td>
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<tr>
<td>Frequency of inspection</td>
<td>3</td>
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</tbody>
</table>

Average 4.5

Table 4

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<th>Risk Level</th>
<th>Description</th>
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<tbody>
<tr>
<td>Low Risk</td>
<td>1 – 8</td>
</tr>
<tr>
<td>Moderate</td>
<td>9 - 13</td>
</tr>
<tr>
<td>High Risk</td>
<td>14 - 20</td>
</tr>
</tbody>
</table>

Acceptable as designed Requires preventative action (i.e., increased inspection, maintenance interval, etc.) Requires redesign

Quantifying Overall Foreign Material Risk
Once an assessment of all the various risk factors has been undertaken, numerically quantifying given risk can be helpful to determine priority of corrective actions and preventative measures.

A simple method to numerical rank risk is using a 1-10 scale, where a high-risk item or characteristic would be assigned a number 10 and lower risk items or characteristics would be assigned a lower number.

The example process risk factors described earlier could then be assigned a number in a table, after which the average of process risk can be computed, see Table 3.

Adding the process risk rating with the assigned sanitary design risk rating would give a total overall sum of risk.

A spectrum of risk can then be established for actions needed, see Table 4.

Equipment and associated components can pose a risk for foreign material through various physical means. Understanding sanitary design factors allows for the ability to assess and quantify risk and subsequent actions needed to bring the system into appropriate control.

Davis is corporate sanitation manager at OSI Group, LLC. Reach him at Jadavis@osigroup.com.
Did You Know?

BPA Has Been Studied to Death, So Enough Already

With a landmark study declaring bisphenol A as safe, can the food industry utilize this compound in packaging and containers without criticism?

BY JOSH BLOOM, PHD

Of all the phony scares the American Council on Science and Health wrestled with during its 40-year history, no chemical scare has been as resilient as bisphenol A, otherwise known as BPA.

So it should come as no surprise even after the U.S. FDA’s unambiguous statement on February 23 from Deputy Commissioner Stephen Ostroff, MD, about the results of the two-year CLARITY-BPA Core Study that there are still holdouts calling for even more studies.

According to FDA’s statement: “One area that has been of significant consumer interest is the use of Bisphenol A (BPA) in food packaging. BPA is authorized for use in polycarbonate plastics and epoxy resins in certain food and beverage can linings. Given this interest, the FDA has routinely considered and evaluated the scientific evidence surrounding the use of BPA and continues to conclude that BPA is safe for the currently authorized uses in food containers and packaging.”

It is impossible to prove anything is completely safe, but at some point, you have to stop trying to concoct more far-fetched experiments and accept the best possible evidence. There is now plenty of evidence.

Chemicals Everywhere

BPA is one of two chemicals that react to form polycarbonate plastic polymers, which have properties ideal for lining food containers, especially metal cans. Polycarbonate plastics are ubiquitous and very small quantities of BPA, which has been used for 60 years, can leach from the plastic into the food.

It’s not surprising that minuscule quantities of BPA (specifically, its metabolites) can be found in the urine of virtually everyone. But this is not due to the world being flooded with more BPA. It’s because of technology, or the power of modern analytical instrumentation. Concentrations of common chemicals, which used to be measured in parts per million can now be measured in parts per quadrillion range—a billion times less.

Chemicals that have been in our environment, food, and bodies all along can now be detected. As silly as it sounds, these chemicals have become scary simply because we know they’re present.

But this should not be entirely surprising; activist groups, most of which have little or no expertise in chemistry or toxicology, equate the presence of a chemical with harm from that chemical—a violation of the basic tenets of toxicology since it ignores dose or exposure.

Getting “CLARITY”

The CLARITY-BPA was conducted by FDA senior scientists at the agency’s National Center for Toxicological Research. Studies in rodents were conducted at multiple doses of BPA. These doses were selected to mimic levels ranging from those far below to far higher than expected to be found in humans. A number of endpoints were selected in advance, including growth and weight of the rodents, and development of tumors.

With the exception of “minimal effects” on the development of tumors, nothing was found to suggest there was any cause for concern. These minimal effects can probably be dismissed outright because of the animal model chosen for the study—the Sprague-Dawley rat is known for spontaneous generation of tumors, regardless of whether the rats are exposed to a given test chemical. The “effect” noted was the increase in the occurrence of mammary gland tumors at one of the five doses, in one of the five groups, which is far from compelling.

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Although these findings must still be subjected to peer review, Dr. Ostroff’s conclusion will almost certainly stand: “Overall, the study found ‘minimal effects’ for the BPA-dosed groups of rodents.”

**Unfounded Fears**

Scientifically, it should come as no surprise nothing was found. The knock on BPA is it bears a structural similarity to the estrogen hormones and therefore acts as an “endocrine disruptor”—a term that is scientifically questionable.

Although structural similarity is subjective, receptor-binding affinity is not. Estradiol, the most important of the estrogens, binds about 12,000 times more tightly to estrogen receptors than to BPA. Thus, if BPA is an endocrine disruptor, it is a mighty poor one. This is the primary reason BPA scares are unfounded.

But there is another.

As the name implies, BPA is a member of a class of organic compounds called phenols—molecules that have a hydroxyl group attached to a benzene ring. Phenols are known to be notoriously difficult to work with for medicinal chemists, given they are tasked with discovering new drugs. Although an experimental phenol-containing drug may work very well in a “test tube,” the story in a living animal or human is quite different.

The reason phenols are poor candidates is the same reason BPA does not remain in our bodies. Phenols are known to rapidly undergo a particular type of metabolism called conjugation, in which the hydroxyl group is coupled to one of a small number of ubiquitous, highly water-soluble biomolecules. The resulting conjugate then becomes water-soluble and is excreted in the urine.

Conjugation is a very important mechanism for eliminating multiple chemicals, either natural or synthetic, that are exposed to our bodies. This is why when BPA is measured in studies it’s almost always sampled from urine.

As is the case with many other phenols, BPA is rapidly conjugated and eliminated; it does not accumulate in our bodies. That it’s found in urine simply means our livers are doing exactly what they are supposed to do. If it were not found in urine, it’s conceivable it could accumulate in the body and do harm.

It is more than a little ironic that the so-called “BPA Scare Industry” is making troubling claims, when, in fact, detection of BPA in urine is an indicator it is not doing harm.

The FDA has spoken. Science has spoken. Enough.

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**Roundup of New ...**

(Continued from p. 35)

Mathematical models needed to convert the rather nonspecific spectral fingerprint into a simplified, but still reliable, conclusion with respect to food composition,” Dr. Nielen says. “A major trend in food scanners is in the extension of the spectral range. Initially these handheld devices were mainly based on near infrared (NIR) spectroscopy, but recently a prototype hyperspectral food scanner has been developed in the EU program PharmaFOOD that effectively combines NIR, UV, visible, and photography data.”

Dr. Nielen is quick to point out that there is an urgent need for industry professionals and regulators to have more efficient and effective monitoring schemes in the food chain. “Current approaches are costly, time consuming, and cannot prevent the thousands of food safety alerts and major food fraud cases and crises each year,” he laments.

The main challenges for smartphone-based biorecognition assays, Dr. Nielen says, are in the speed of the biorecognition, simplification of sample handling and purification protocols, robustness and ease-of-use, and remote and/or built-in quality control. “Within FoodSmartphone, we accelerated the biorecognition of allergens to less than 30 seconds and will simplify assay steps by exploiting 3D-printed microfluidic approaches.”

**Handheld Food Analyzer**

New on the scene is the FoodScanner, a portable device that offers food sensing and analysis, courtesy of Spectral Engines Limited, Helsinki, Finland.

According to Janne Suhonen, Spectral’s chief commercial officer, the FoodScanner concept utilizes the world’s smallest true NIR spectroscopy sensing module, advanced algorithms, and a cloud-based library to measure the fat, protein, carbohydrates, and total energy content of foods below 5 percent detection limits. The technology also detects allergens like egg and milk.

“A comprehensive spectrum library has been built by measuring 10,000 different food products,” Suhonen notes. “There are 14 different food and beverage categories. New food products can be easily added to the library.”

Measurements with the FoodScanner occur in four steps. “A user makes a Bluetooth connection between our NIRONE wireless scanner and a mobile phone, then selects the desired food category to be measured,” Suhonen explains. “The sample is scanned, which takes roughly one second. Data is sent to a cloud where intelligent algorithms calculate the food nutrition facts and return those results to the user in one and a half to two seconds.”

The basic software can be further developed for different applications, such as detecting adulterated foods by creating libraries in collaboration with big food manufacturers, Suhonen adds.

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NEW PRODUCTS

Vibrio Real-Time PCR Detection Kit
The iQ-Check Vibrio Real-Time PCR Detection Kit detects the three main Vibrio species that cause vibriosis: V. cholerae, V. parahaemolyticus, and V. vulnificus. The process uses the Vibrio Enrichment Broth that promotes the growth of Vibrio while inhibiting associated competitive flora. The broth shortens culture times from 18 to eight hours, and the entire detection process can be completed within 11 hours. The kit reduces false positives by using Bio-Rad’s Free DNA Removal Solution that eliminates free DNA from the sample and provides specialized probes and primers to help prevent nonspecific DNA amplification. A synthetic DNA internal control is included in the reaction mix to validate any possible negative results. Bio-Rad Laboratories, Inc., 800-424-6723, www.bio-rad.com.

DfE-Certified Disinfectant
SureTouch is a ready-to-use, one-step cleaner disinfectant and deodorizer that is powered by Accelerated Hydrogen Peroxide technology. The product has been certified under EPA’s Design for the Environment (DfE) labeling program, which recognizes least-hazardous classes of EPA’s acute toxicity category hierarchy. Highly compatible with a wide variety of hard, non-porous surfaces, the SureTouch disinfectant is effective against key bacteria and viruses including MRSA, VRE, influenza, and norovirus. The product disinfects in five minutes and can be used as a 30-second sanitizer on non-food contact surfaces. Additionally, the active ingredients break down to oxygen and water after use, and it is non-irritating to eyes and skin. Diversey, www.diversey.com.

Alkaline Food Plant Detergent
DairyClean DESTROYER is a non-foaming, heavy-duty, alkaline food plant detergent for in-place or recirculation cleaning of tough food processing soils. The company says it is proven at dairy and juice plants as a heavy-duty CIP cleaner in separators, evaporators, and other equipment where heavy burn on deposits is likely. Acting both chemically and physically, it saponifies and emulsifies oils and fats, disperses proteinaceous soils, breaks down carbohydrates, and can penetrate cooked on food residues. Good wetting and rinsing characteristics with little or no foaming permit fast cleaning at high recirculation velocities. Acceptable for use in food and beverage plants as an A2 compound for use only in soak tanks or with steam or mechanical cleaning devices in all departments. Madison Chemical Co., Inc., 812-273-6000, www.madchem.com.

Compact Titrators
According to the company, HI931 and HI932 titrators feature a 50% smaller footprint, allowing for easy integration into a lab space. Gutters and wells are built into the titrator design to protect important connections and safeguard internal electronics from spills. Titrators feature a 40,000-step dosing pump that is capable of dosing extremely small volumes of titrant so a precise endpoint is achieved. This new generation of titrators produces customizable analysis reports so the required data for each application is stored for added traceability. In addition, important Good Laboratory Practice information is recorded. Hanna Instruments, 800-426-6287, www.hannainst.com.

Enterprise Labeling Solution
The TEKLYNX CENTRAL 5.0 enterprise label management software offers manufacturers of all sizes a centralized solution that encompasses label design, security and traceability, and print automation to support next-generation digital labeling transformation. True reprint feature shows end users the exact data that was originally printed and allows them to reprint a label with the original expiration dates, pack dates, counters, and other vital information. Includes access to the 2018 version of CODESOFT label design, SENTINEL print automation, and LABEL ARCHIVE label storage and traceability software. TEKLYNX International, 888-629-4444, www.teklynx.com.

Microbial Reduction Technology
The Microbial Reduction Process uses controlled pressure steam sterilization with a validated 5-log reduction kill step to naturally eliminate pathogens while preserving the organoleptic properties—color, texture, and taste—of ingredients. The chemical-free application transforms raw agricultural commodities into ready-to-eat ingredients with increased product stability. The process is ideal for higher risk ingredients like chia and pumpkin seeds. Terra Ingredients, LLC, 855-497-3308, www.terraingredients.com.

In Other News

The CERTUS System for accurate and rapid pathogen detection achieves AOAC Performance Tested certification (101802).

Clear Labs, the automated NGS platform purpose-built for food safety testing, raises $21M in its latest round of funding to expand commercial operations and build new features for the company’s flagship product.

AOAC issues its Performance Tested Methods Certificate to Hygiena’s UltraSnap Surface ATP Test for identifying the possible presence of microbial contamination.
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Government Turf War ... (Continued from p. 13)

Including funding from Tyson New Ventures LLC, a $150-million venture capital fund.

Not surprisingly, given the overlap in cell-culture technology, biotech companies are showing an interest in cell-based food research and production. M Ventures, the corporate VC arm of pharmaceutical giant Merck, for example, has provided part of an initial €7.5 million ($8.5 million) investment into Mosa Meat. Merck has expertise in cell media, which currently comprises 80 percent of the cost of cultured meat. Mosa Meat plans to construct a pilot production plant by 2021, which is also when Memphis Meats expects to launch its first commercial products in the U.S. ■

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Vibrio Vigilance (Continued from p. 15)

Qualitative detection of the three main Vibrio species that cause vibriosis—V. cholerae, V. parahaemolyticus, and V. vulnificus, according to Frédéric Pastori, the company’s international product manager.

With its main targeted matrices being seafood, including fish and shellfish, the kit is a multiplex test based on gene amplification and detection by real-time polymerase chain reaction, Pastori says. “This kit uses Bio-Rad’s Vibrio Enrichment Broth that promotes the growth of Vibrio while inhibiting associated competitive flora,” he relates. “The broth shortens culture from 18 hours to eight hours incubation time, and the entire detection process can be completed within 11 hours.” ■

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Securing Safety ... (Continued from p. 42)

Strait to the forklift operator where he/she is most at risk—inside of the trailer.

The leading shadow hook restraints go a step further, incorporating sensors, audio, and visual safety alarms, as well as a real-time trailer presence monitor, which provides a camera view of the exterior vehicle restraint on the internal control panel. Additionally, these vehicle restraints can be programmed via integrated control systems to interlock with overhead doors and dock levelers so they operate in a safe sequential order.

It Depends on the Application

Food facilities often have an array of different trucks and vehicles that require their loading docks. Each dock position needs to address the unique challenges that every type of vehicle brings.

While automatic vehicle restraints with rotating hooks generally are the best option, specialized trucks or operations requiring wheel-based restraints might be necessary in some instances. Facility managers need to consider vehicle restraints that offer the greatest efficiency and the highest degree of safety. And no, antiquated wheel chocks are never the right answer. ■

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ARTICLE: Approach to Select Lactobacillus Isolates as Protective Cultures for Food Fermentations

Food waste reduction can be achieved by applying protective cultures to avoid spoilage of fermented food products. In this study, researchers present an approach to screen large numbers of strains for potential use as protective cultures in food. A phenotypic screening of 504 Lactobacillus strains for 27 food-relevant growth conditions revealed variations and physiological limits for the genus. Previously, the strains were tested for their antibacterial activity in a high-throughput assay. Here, the activity of 22 positive strains from that screening was assessed in more detail, mainly against *Listeria, Enterococcus, Rhodotorula,* and *Candida* species. The proteinaceous nature of the inhibiting substances was confirmed by protease digestion. *Journal of Food Safety, Volume 38, Issue 5, October 2018, e12483.*

ARTICLE: Chlorate and Other Oxychlorine Contaminants Within the Dairy Supply Chain

The presence of chlorate in milk and dairy products can arise from using chlorinated water and chlorinated detergents for cleaning and sanitization of process equipment at both farm and food processor level. Chlorate and other oxychlorine species have been associated with inhibition of iodine uptake in humans and the formation of methemoglobin—with infants and young children being a high-risk demographic. This comprehensive review of chlorate and chlorine derivatives in dairy highlights areas of concern relative to the origin and/or introduction of chlorate within the dairy supply chain. This review also discusses the associated health concerns, regulations, and chemical behavior of chlorate and chlorine-derived by-products, and provides a summary of mechanisms for their detection and removal. *Comprehensive Reviews in Food Science and Food Safety, Volume 17, Issue 6, November 2018, Pages 1595-1612.*

ARTICLE: Natural Preservatives for Extending the Shelf-Life of Seafood

Quality loss in seafood occurs immediately after death, during processing and storage, and is associated with enzymatic, microbiological, and chemical reactions. To maintain the quality, several synthetic additives (preservatives) are promising for preventing the changes in texture and color, development of unpleasant flavor and rancid odor, and loss of nutrients of seafood during storage at low temperature. However, the use of these preservatives has been linked to potential health hazards. As a result, natural preservatives with antioxidant and antimicrobial properties are showing promise as safe alternatives in seafood processing, with the sole purpose of extending shelf life. Natural preservatives commonly used include plants extracts, chitosan and chitooligosaccharide, bacteriocins, bioactive peptides, and essential oils. This review provides updated information about the production, mode of action, applications, and limitations of these natural preservatives in seafood preservation. *Comprehensive Reviews in Food Science and Food Safety, Volume 17, Issue 6, November 2018, Pages 1561-1575.*

ARTICLE: Sensory Quality Defects in Chicken Seasoning During Storage

Chicken seasoning is a widely consumed palatable seasoning made with chicken meat. Quality, and especially sensory quality, may determine the consumer choice of food. The same bag of chicken seasoning will be stored by consumers over a long period of time when it is in use, so it is particularly important to be able to assess its sensory quality. However, the sensory quality defects of chicken seasoning during storage remain unknown. This study evaluated flavor changes in seasoning during storage using sensory evaluation and gas chromatography-mass spectrometry. *Journal of Science of Food and Agriculture, Volume 98, Issue 15, December 2018, Pages 5807-5815.*
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