Volume 27 Number 4 August / September 2020

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Food Quality & Safety (ISSN 1092-7514) is published 6 times a year in Feb/Mar, Apr/May, Jun/July, Aug/Sept, Oct/Nov, Dec/Jan by Wiley Subscription Services, Inc., a Wiley Company, 111 River St., Hoboken, NJ 07030-5774. Periodical postage paid at Hoboken, NJ, and additional mailing offices. Print subscriptions are free for qualified recipients. Annual paid subscriptions are available to European readers at €152, U.K. readers at £123, and rest of the world readers at \$230.

For subscription questions in the U.S., call 844-862-9286. For outside the U.S., call 856-255-5537. Or email customer services at customerservice@d3data.net.

Food Quality & Safety is a proud member of: United Fresh Produce Association APEX, Folio Ozzie, and ASBPE award winner for editorial and graphics excellence.

POSTMASTER: Returns and address changes to Food Quality & Safety magazine, PO Box 986, Levittown PA 19055-0986

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From The Editors

COVID-19 Plus Six Months: Protecting Sensitive Populations

t has now been six months since the novel coronavirus really began to show itself throughout the United States and the rest of the world. Some nations were hard hit early on (see Spain and Italy) whereas case counts in others began to ramp up later.



Ironically, many of the lessons that food safety professionals have been harping on for years have be-

come part of the "Fight COVID-19 Mantra," namely, maintaining personal hygiene and handwashing, working only when healthy, and properly reporting illnesses or injuries to management. The virus has also resulted in an increased emphasis on employee education, another essential element for ensuring the safety and quality of foods and work environments.

Food safety personnel also emphasize the importance of understanding to whom their foods are marketed. One of the five preliminary steps to HACCP is to prepare a product description and to establish a target market, and food processors need to take extra care if their products are aimed at potentially sensitive markets. The acronym YOPI, which stands for young, old, pregnant, and immunocompromised, is used in the food industry to describe the populations who are most susceptible to foodborne pathogens and other potential food safety issues. With COVID-19, we have been rather fortunate with the young; while they have been infected, their mortality rates are low. In fact, according to CDC data, the surges in illness counts in the United States after mid-June have been in large part due to young adults who have acquired mild cases of the virus. So, when it comes to COVID-19, we can replace the "young" in YOPI with people who have pre-existing conditions; the elderly, many of whom have pre-existing conditions such as heart disease, COPD, and diabetes, are the most susceptible.

So, food safety programs designed to protect sensitive populations are essential when it comes to minimizing mortality. But, we must realize, these levels will never be zero. So, let's pray for the biotechnology companies, medical groups, university researchers, and others to come up with a vaccine that will protect us from the virus. But, we must also remember that viruses have a nasty tendency to mutate, so the question is, "Will the vaccine that we develop today be effective when this comes around again?"

Let's hope.

Richard Stier Co-Industry Editor



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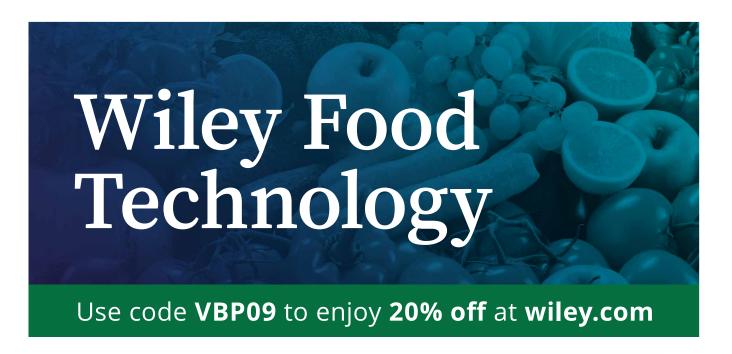
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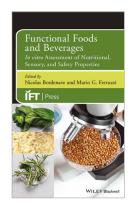
Printed in the United States by Dartmouth Printing, Hanover, NH.

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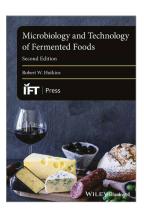
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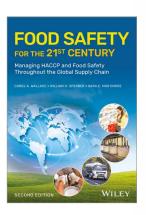




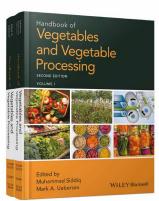
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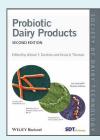


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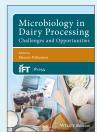


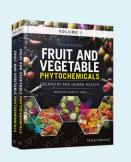
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NEWS & NOTES



For more breaking news, including in-depth coverage of how COVID-19 is impacting the food industry, visit foodqualityandsafety.com.

FDA's "New Era of Smarter Food Safety" to Focus on Technology, Traceability

On July 13, after several months of delays caused by the COVID-19 pandemic, Stephen Hahn, MD, FDA's commissioner, announced the agency's much-anticipated "New Era of Smarter Food Safety Blueprint." The plan, which builds upon foundations set down in FSMA, outlines the next steps in the process to ensure food safety and prevent foodborne illness through the use of science and risk-based standards, says Dr. Hahn.

Frank Yiannas, FDA's Deputy Commissioner for Food Policy and Response, says the blueprint outlines the work the agency plans to undertake over the next decade to modernize its food safety approach and "bend the curve" of foodborne illness.

"At the dawn of a new decade, we are in the midst of a food revolution; foods are being reformulated, new foods and new food production methods are being realized, and the food system continues to evolve," says Yiannas. "To succeed in these modern times, we need more modern approaches."

While the plan places strong emphasis on new technology, Hahn also stresses that the idea is to put in place more effective approaches and processes. The blueprint is centered around four core elements:

- 1. **Tech-enabled traceability.** The plan's first component focuses on new technologies and ways to integrate data streams to help identify outbreaks of foodborne illness and trace the origin of contaminated food to its source "in minutes, or even seconds."
- 2. Smarter tools and approaches for prevention and outbreak response. FDA is looking at ways to use data. "The plans embraced by the blueprint include strengthening our procedures and protocols for conducting the root cause analyses that can identify how a food became contaminated and inform our understanding of how to help prevent that from happening again," says Dr. Hahn.
- 3. New business models and retail modernization. FDA says it will investigate how to adapt its oversight to ensure that the new ways the food industry is inventing to produce and distribute food are safe. It will also work to ensure the safety of novel ingredients and new foods.
- 4. **Food safety culture.** The plan emphasizes the importance of fostering and strengthening food safety culture on farms and in food facilities.

Produce Industry Grapples with COVID-19 Spreading Among Workers BY KAREN APPOLD

Outbreaks of COVID-19 are continuing to emerge at U.S. fruit and vegetable farms and packing plants. "Although the fresh produce industry isn't facing the same depth of challenges that meat packers are facing, they



aren't immune to coronavirus disruptions," says Max Teplitski, PhD, chief science officer at the Produce Marketing Association in Washington D.C. "Even though employers put in place stringent measures to prevent person-to-person transmission of the virus in workplaces, they don't have control over what employees do after leaving a facility's gates."

Dr. Teplitski says the virus has brought an issue to light that the agriculture industry has struggled with for decades: labor issues. "We hear reports of fields left unharvested and of harvested produce not entering the supply chain," he says. "We need to continue to focus on labor issues in agriculture, making sure that the supply chain remains robust and resilient."

Another challenge facing the produce industry is a disruption in demand. "With



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FOOD QUALITY & SAFETY

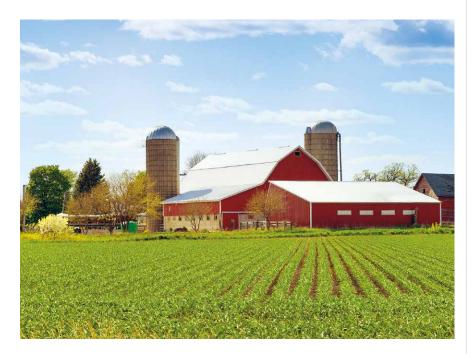
almost 40 percent of fresh fruits and vegetables destined for food service (e.g., restaurants, hotels, and schools), the industry will not fully recover until the demand reaches pre-outbreak levels," Dr. Teplitski says.

To prevent spread of the virus, Dr. Teplitski says individual production facilities have implemented measures to protect workers: They have invested in educating workers to ensure that they practice social distancing and wear face coverings; they take employees' temperatures daily; they have installed plastic shields along conveyor belts; they stagger shifts; they have ramped up sanitation at production facilities; they have implemented multi-lingual education campaigns; and workers get meals and supplies delivered to work sites.

"With the costs of personal protective equipment (PPE) skyrocketing, we estimate that produce packing facilities increased what they spend on PPE at least five to 10-fold," Dr. Teplitski says. "This investment in capital, energy, and creativity demonstrates their level of commitment to worker safety."

Defense Production Act

In the spring, President Trump said that he may invoke the Defense Production Act (DPA) to keep produce packing plants open, as he did with meatpacking plants. But Dr. Teplitski doubts that will be necessary. "The produce industry isn't as concentrated and vertically



integrated as the animal protein industry; this relative decentralization offers a degree of resilience," he says. Furthermore, there are many options in the produce aisle in a grocery chain, which ensures that consumers will always see plentiful and affordable fresh fruits and vegetables. "Many vegetables can be planted and grown within a much shorter timeframe (compared with beef or pork, for example), which makes the produce industry better able to respond to disruptions."

Jennifer McEntire, PhD, vice president of food safety and technology at the United Fresh Produce Association in Washington, D.C., also doubts that employing the DPA will be necessary. In the meat industry, federal agencies, as well as state and local health departments, were able to work together to manage individual situations. "I would hope that something similar would happen on the produce side," she says.



Purina Introduces Anti-Allergy Cat Food BY KEITH LORIA

Nestlé Purina Pet Care has <u>launched Pro Plan</u>
<u>LiveClear</u>, the first-ever cat food that reduces
allergens in cat hair and dander. This food
will now allow people who are allergic to cats
to own these pets without having an allergic
reaction.

As many as one in five adults globally are sensitized to cat allergens. Current methods for managing cat allergens often include limiting time or activities with a cat, isolating a cat in the home, or removing a cat from the home altogether.

"Many people think that cat hair is the problem, but it's actually what's on it—the major cat allergen called Fel d 1, which cats produce naturally in their saliva," says Kurt Venator, DVM, PhD, Purina's chief veterinary officer. "When cats eat LiveClear, a protein

sourced from eggs neutralizes the Fel d 1 in their mouths. By reducing the allergen at the source in the saliva, it reduces the allergen that is transferred to the cat's hair and dander when they groom, ultimately reducing the allergen in the environment."

Leslie Brooks, DVM, MPH, a veterinary advisor at betterpet.com, explains that this food has a special protein that recognizes the Fel d 1 allergen in cat saliva and binds it. "By binding it, the protein neutralizes the allergen, making it ineffective, or essentially dead," she tells FQ&S. "It's kind of like how our bodies fight off a virus. An antibody (the protein) recognizes the virus (the antigen) as bad, and binds to it, neutralizing it. People with cat allergies can now have fewer symptoms while being around these cats that eat this food."

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Washington Report



How Sweet It Is

Industry group petitions FDA to amend labeling rules for low- and no-calorie sweeteners

BY AMANDA MCCOROUODALE

ueled by revised dietary guidelines and new FDA labeling regulation, supermarkets are suddenly teeming with sugar substitutes in packaged foods. In response, the Sugar Association filed a citizen petition in June asking FDA to update labels of low- and no-calorie sweeteners on food packages to increase accuracy and transparency.

The petition makes four specific requests:

- 1. Add the term "sweetener" in parentheses after the names of all non-nutritive sweeteners in the ingredient list.
- 2. Indicate the type and quantity of nonnutritive sweeteners prominently on children's products.

- 3. Market labels as no/low/reduced sugar to include the disclosure, "sweetened with [name of sweetener(s)]" under such claims.
- 4. Disclose on labels the potential gastrointestinal side effects from the consumption of sugar alcohols and some sugar substitutes in foods at the lowest observed effect levels.

The petition follows FDA's first major change to food label regulation in 27 years. In January, FDA <u>began requiring</u> that manufacturers with \$10 million or more of annual food sales list the amount and percent daily value for added sugars on nutrition and supplement facts labels. "Sugars" on the label has also been changed to "Total Sugars" to help consumers understand

that "Added Sugars" is a subset of "Total Sugars."

"Consuming too much added sugars can make it difficult to meet nutrient needs while staying within calorie limits," says a spokesperson for the agency. "The FDA recognizes that added sugars can be a part of a healthy dietary pattern. But, if consumed in excess, it becomes more difficult to also eat foods with enough dietary fiber and essential vitamins and minerals and still stay within calorie limits." Specifically, the Dietary Guidelines for Americans 2015-2020 recommends limiting calories from added sugars to less than 10% of total calories per day.

Truth in Numbers

However, the Sugar Association, which represents 142,000 sugar beet and cane growers, processors, and refiners in the U.S., says that lower sugar doesn't always equate to lower calories per serving. Sideby-side comparisons of peanut butter, for example, show that the "No Sugar Added" versions contain 30 more calories per serving. In other cases where the listed calories are lower—in the low-sugar version of oatmeal, for example—the serving size has actually been decreased.

"There's now this labeling gap," says Courtney Gaine, PhD, RD, president and CEO of the Sugar Association. "We know one of the goals of the FDA for having added sugars on the label was to prompt manufacturers to reformulate and reduce the added sugars in foods. But, since the FDA announced this new labeling regulation in 2014, we started seeing labels making reduced sugar claims that are really misleading."

The Question of Safety

Consumers also have a right to know what they are replacing sugar with, says Dr. Gaine, pointing out that, over the last four years, the use of sugar substitutes has tripled, if not quadrupled. "What was once primarily used in diet soft drinks is now ubiquitously found throughout the food

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supply," says Dr. Gaine. "Our consumer research showed that, given a list of food additives, consumers could correctly identify sweetening ingredients only 37% of the time."

To date, FDA has approved six high-intensity sweeteners: saccharin, aspartame, acesulfame potassium, sucralose, neotame, and, advantame. Additional high-intensity sweeteners siraitia grosvenorii fruit extracts and steviol glycosides are also permitted for use under FDA's GRAS (generally recognized as safe) status.

The threshold of safety for these sweeteners has been studied extensively, says Kris Sollid, senior director of nutrition communications at the International Food Information Council Foundation, by scientific and regulatory authorities around the world, including the Joint FAO/WHO Expert Committee on Food Additives, FDA, the European Food Safety Authority, and others. "There is an acceptable daily intake (ADI) amount that has been established for each of these that has a safety factor of more than 100 times. The amount of these sweeteners used in individual products is also very low because they are so much more intense in terms of their sweetness, compared to sugar."

While consumers with phenylketonuria (PKU), a rare genetic disorder, may have difficulty metabolizing phenylalanine, a component of aspartame, regulatory agencies consider high-intensity sweeteners safe for the general population to consume.

What was once primarily used in diet soft drinks is now ubiquitously found throughout the food supply.

-courtney gaine, PhD, RD, president and CEO of the Sugar Association

"Adding a parenthetical after every listing of a sweetener on the ingredient list is repetitive and does not provide a public health benefit," says Robert Rankin, president of the <u>Calorie Control Council</u>, which represents manufacturers and suppliers of low- and reduced-calorie foods and bever-

ages. "Low and no-calorie sweeteners are an effective tool for reducing sugar and calorie content in foods. Requiring that sweeteners be called out on the front of pack calls into question these extensive safety reviews, diverts attention from the sugar reduction and other benefits they provide, and implies there is some underlying concern."

Meanwhile, there's a new category of sweeteners such as allulose, a monosaccharide found in raisins and figs that is not metabolized in the same way as sugar. FDA recently issued a statement that it will allow allulose to be excluded from the total and added sugars declarations on the Nutrition Facts and Supplement Facts labels but still be counted as four calories per gram.

Wary Consumers

Today's consumer is more and more likely to prefer clean-label foods with easy-to-comprehend ingredients. A 2018 market insights <u>survey by Innova</u> found that three out of five consumers say they would rather just reduce sugar consumption instead of increase their consumption of artificial sweeteners. With consumers' desire for transparency, certain manufacturers have already begun adding sweetener identifiers in their ingredient list voluntarily. "We thought this was a great idea and wanted to see it as the new standard," says Dr. Gaine.

In addition, in November 2019, the American Academy of Pediatrics <u>published a statement</u> saying that the long-term safety of non-nutritive sweeteners in childhood has not been assessed in humans; the organization recommended that FDA require food labels in the U.S. to list type and quantity of any non-nutritive sweeteners per serving.

And while sugar alcohols are also deemed safe, studies have found they may have some undesirable side effects. For example, the Academy of Nutrition and Dietetics advises that consuming more than 50 g/day of the sugar alcohol sorbitol or more than 20g/day of mannitol may cause unwanted gastrointestinal effects. "We are consumers and parents ourselves," says Dr. Gaine. "Suddenly, there are sugar substitutes in so many of the juice and snacks we are feeding our kids."

Dr. Gaine says that, ultimately, the Sugar Association's petition is not about

safety but about transparency. "We want to emphasize that this is a campaign for presenting accurate information on food labels," she says. She believes there's a lot of consumer support for this issue, citing research that 73 percent of parents think it's important to know the amount of sugar substitutes in their children's food and 66 percent of consumers say it's important for

Requiring that sweeteners be called out on the front of pack calls into question extensive safety reviews [and] diverts attention from the sugar reduction and other benefits they provide.

-ROBERT RANKIN, president of the <u>Calorie Control Council</u>

sugar substitutes to be clearly identified as sweeteners on food labels.

Meanwhile, the petition is garnering support from consumer groups. "As the citizens' petition points out, consumers may want to follow FDA's advice and reduce their consumption of added sugars, but don't realize that they may be unknowingly increasing their ingestion of novel sweeteners, sugar alcohols, and artificial substances," writes Sally Greenberg, executive director of the National Consumers League, in a recent letter to the FDA. "By taking the enforcement actions set out in the petition, FDA can ensure that its addition of 'added sugars' to the Nutrition Facts label does not have the unintended result of permitting food and beverage manufacturers to deceive well-meaning consumers who are trying to make healthy food purchasing decisions as they shop for their families."

FDA says it will respond to the Sugar Association within 180 days of the petition's filing, and that such petitions typically require a significant amount of discussion within the agency by a multidisciplinary group of experts.

McCorquodale is a freelance writer based in New York. Reach her at amandamccorq@gmail.com.

LAURENT RENAULT- STOCK, ADOBE, COM

Market Initiatives



Beefed Up

Efforts to promote quality and safety in beef abound, from farm—and ranch—to fork | BY LINDA L. LEAKE, MS

umans have been eating beef since prehistoric times. Early cave art dated back 38,000 years depicts what some anthropologists think is the hunt for aurochs (now-extinct bovines that survived in Poland until 1627). The domestication of cattle occurred around 10,000 years ago, and, subsequently, beef consumption likely took off.

Fast forward to today. Beef is still a big deal. Even though, in 2020, chicken is the most consumed meat in the United States at 95.4 pounds per capita, beef ranks second at 57.7 pounds, according to Statista.

Beef is produced in all 50 states. The leading states for beef cows that have calved are Texas, Oklahoma, Missouri, Nebraska, and South Dakota, according to the <u>National Cattlemen's Beef Association</u> (NCBA). Additionally, the top states with cattle on feed are Nebraska, Texas, Kansas, Iowa, and Colorado, NCBA says.

Initiated in 1898, and with offices in Denver and Washington, D.C., the NCBA is a marketing organization and trade association for America's one million cattle farmers and ranchers, according to Josh White, NCBA's executive director of producer education.

As of 2020, there were 31,316,700 head of beef cows in the U.S. and just under 11.75 million head of cattle at U.S. feedlots with 1,000-plus head capacity; as of 2019, 27.155 billion pounds of beef by carcass weight were produced in the U.S., according to

data from the USDA National Agricultural Statistics Service (NASS).

In 2018, USDA reported that the U.S. exported 3.2 billion pounds of beef by carcass weight, representing 11.7 percent of total production, valued at \$7.7 billion. That year, the top importers of U.S. beef by carcass weight were:

- 1. Japan (885 million pounds valued at\$1.844 billion);
- 2. South Korea (638 million pounds valued at \$1.692 billion);
- 3. Mexico (449 million pounds valued at \$869 million); and
- 4. Canada (300 million pounds valued at \$793 million).

The retail equivalent value of U.S. beef produced in 2018 was \$106.7 million, as per the USDA Economic Research Service.

New Consumer Education Campaign

In October 2019, the NCBA initiated efforts to educate consumers about its <u>Beef</u> <u>Quality Assurance</u> (BQA) program. The

program's goal is to help consumers feel confident about the way in which U.S. beef is raised, White says.

Launched approximately 30 years ago, the BQA program trains cattle farmers and ranchers on best practices and management techniques to ensure that their animals and the environment are cared for within a standard set of guidelines, he says. BQA's curriculum includes cattle handling, health, nutrition, and transportation. The program's goal is the production of safe, quality beef under humane conditions. "Today, more than 85 percent of beef produced in the U.S. comes from a farmer or rancher who has been BOA certified, and more than 80 percent of U.S. beef is grading the highest available USDA quality grades of Prime or Choice, which we attribute in large part to the BQA program," he says.

Until last October, BQA had never been a consumer-facing program. "Through market research, we found that consumers respond favorably to knowing there is a set of animal care standards that are consistently followed throughout the beef industry," White says.

The foundation of the BQA campaign is a 30-second video highlighting how U.S. farmers and ranchers raise cattle under BQA guidelines. The video is available to consumers on BeefftsWhatsForDinner.com, where clicking on "Raising Beef" leads to the new BQA section.

"The website and video demonstrate the ongoing commitment of cattle farmers and ranchers to caring for their animals and providing the safest and highest quality beef possible," White says.

Carcass Interventions: Validation Issues

One of the most important issues currently influencing beef quality and safety is the validation of carcass interventions to minimize pathogen contamination in abattoirs, according to Alex Castillo, PhD, an associate professor of meat science at Texas A&M University (TAMU) in College Station. "In my interactions with beef processing stakeholders, I have discerned that validation is often confused with other verification activities," he says.

Validation involves two major components, Dr. Castillo adds. The first step is to provide scientific proof that the antimicrobial intervention (a lethality process, for example) will achieve its intended purpose of preventing, reducing, and/or eliminating the hazard in the food processing operation. The second step is to ensure that the process will consistently meet the critical limits of the parameters that would impact the efficacy of the antimicrobial treatment.



Of the various alternatives designed to validate a pathogen control protocol, conducting in-house experiments is best, Dr. Castillo advises. "Carcasses should be inoculated with a USDA Food Safety Inspection Service (FSIS) inspector-approved harmless <u>surrogate organism</u> that represents pathogens," he advises. "Then, trials should be run using the plant's established decontamination processes."

As an alternative to in-plant experiments, Dr. Castillo recommends reviewing a peer-reviewed document that represents the process in question to procure details about the efficacy of the procedure, notably the log reduction of the pathogens. "The International Commission on Microbiological Specifications for Foods and Codex Alimentarius are two excellent resources for validation guidelines," he says.

STEC-Reduction Studies

Dr. Castillo has supervised a number of research projects at TAMU evaluating the efficacy of different antimicrobial interventions. In the most recent study, his team used either conventional spray or handheld electrostatic spray to apply treatments for reducing Shiga toxin-producing *Escherichia coli* (STEC) on fresh beef surfaces.

In <u>results</u> published in 2019, Dr. Castillo's team found no advantage in the use of electrostatic spray to reduce STEC on cold beef. The greatest reductions in STEC were

achieved by lactic acid with conventional spray. Lauric arginate ester was the second-best antimicrobial agent at reducing STEC. Lactic acid reduced pH on the beef surface significantly. "The significance of these findings for beef processing is that beef slaughter establishments do not need to invest in new equipment to enhance the effectiveness of their carcass interventions, and that lactic acid, an antimicrobial already being used frequently, is one of the most effective FSIS-approved compounds available," Dr. Castillo says.

Aerosol Pathogen Transport

Sanitation continues to be a significant food quality and safety concern in U.S. beef processing plants, Dr. Castillo points out.

Under the sanitation umbrella, in another <u>study</u> published in 2019, Dr. Castillo led a TAMU team that combined bioaerosol concentration measurements with computational fluid dynamics modeling to track and verify bioaerosol transport in beef slaughterhouses.

Aerosolized bacteria have been recognized as a threat to human health and the shelf life of food, Dr. Castillo says. "In beef processing facilities, the majority of harmful bacteria are introduced by the cattle, and these bacteria are later aerosolized during the hectic operations in the kill floor area," he adds. "But, then, heating, ventilation, and air conditioning (HVAC) systems can transport these microorganisms throughout the plant if it is not adequately designed. Our study detected significant bioaerosol concentrations, STEC, and *Salmonella* in the plants we sampled."

"The microbiomes at the kill floor showed a high relative concentration of Enterobacteriaceae, potentially including STEC," Dr. Castillo reports. "Salmonella was detected in the kill floor and de-hiding area samples. And, in some instances, the same pathogen was detected in the chiller room. Bioaerosol pathogen counts increased with each subsequent day of our study, indicating that pathogens can remain suspended in the plant's air even after cleaning and sanitizing processing surfaces. Our results indicate bioaerosols were transported from the kill floor toward chiller containing final food product."

The take home message, Dr. Castillo says, is that airflow created from inade-

(Continued on p. 14)

MARKET INITIATIVES



to targeting producers' needs across the spectrum of societal needs."

The Supply Chain During the Pandemic

Meanwhile, Dr. Belk believes the major issue currently affecting the U.S. beef industry is the supply chain problem caused by the COVID-19 pandemic. Thirty packing plants handle 90 percent of the fed beef processing volume in the U.S., he says, adding that, when plants are shut down or not processing at their capacity, mar-

(Continued from p. 13)

quately designed and laid out HVAC systems can have a significant effect on the spread of bioaerosols. "We determined that, depending on plant size and layout, sanitation can be improved with new, improved displacement ventilation designs," he adds.

Addressing Biosecurity-Related Health Threats

In 2019, Colorado State University (CSU) in Fort Collins spearheaded the launch of the Coalition for Epi Response, Engagement and Science (CERES), an entity designed to protect and defend the U.S. agricultural industry, including beef, against global health threats, according to Keith Belk, PhD, CSU's department head of animal sciences.

CSU's CERES collaborators include the University of California at Davis, Texas A&M University, Kansas State University, Iowa State University, the University of Nebraska, and the University of Nebraska Medical Center. The consortium partners are currently funding CERES internally, but its efforts are expected to be supported ultimately by the 2018 Farm Bill, which included funding to bolster the National Biodefense Strategy, Dr. Belk says.

Top Importers of U.S. Beef (2018)

Japan (885 million lbs.) South Korea (638 million lbs.) Mexico (449 million lbs.) Canada (300 million lbs.)

Source: USDA

Under the leadership of Alan Rudolph, PhD, CSU's vice president for research, CERES is aligned around three thematic pillars, Dr. Belk says. "Diagnostics and surveillance will focus on rapid detection of high-consequence threats," he adds. "The countermeasures and manufacturing component supports agile countermeasures and production of treatments and vaccines to thwart regional and national outbreaks. This pillar will also strive to prevent such outbreaks. Outreach and engagement entail work with urban and rural communities and stakeholders to affect the adoption of better biosecurity practices and innovation."

Beef is, perhaps, the least prepared of any of the food animal species to deal with intentional or accidental infection by contagious livestock or human diseases and pathogens, says Dr. Belk. "This is partly because the beef supply chain is segmented, and cattle grow outdoors on range and in feedlot environments," he adds.

Additionally, he says that the CERES projects will engage private companies. "Including a variety of stakeholders is intended to take competition out of finding solutions for shared food industry and societal problems," he says. "We are committed to working together in a multidisciplinary way to develop sustainable livestock systems."

To that end, CERES has just recently launched a program called the Sustainable Livestock Systems Collaborative to further engage with the livestock industry, Dr. Belk says. "Hiring a director and multidisciplinary faculty is in the works to address modern problems faced by livestock producers," he says. "We are committed

During the COVID-19 crisis, beef carcass weights have, at times, exceeded their typical average by 40 pounds or more as a consequence of reduced packing capacity.

ket-ready cattle are held back, which leads to heavier carcass weights. During the COVID-19 crisis, beef carcass weights have, at times, exceeded their typical average by 40 pounds or more as a consequence of reduced packing capacity, he says, adding that "heavier carcasses mean more waste, so carcasses also are sold at reduced prices due to yield considerations."

Dr. Belk says that he especially fears the ramifications of the supply chain disruption at the cow/calf level. "If the bottom falls out for feeder cattle demand, producers will be looking for ways to cut calf pre-conditioning costs, including feed, vaccinations, and parasite control," he says. "In the long term, this could result in meat quality issues."

Diminished large abattoir capacity associated with the pandemic has resulted in many small processing plants in Colorado and other states increasing production, Dr. Belk says. "We are seeing a huge demand for small FSIS-inspected plants," he adds. "A number of small plants in Colorado and Kansas are booked through 2021."

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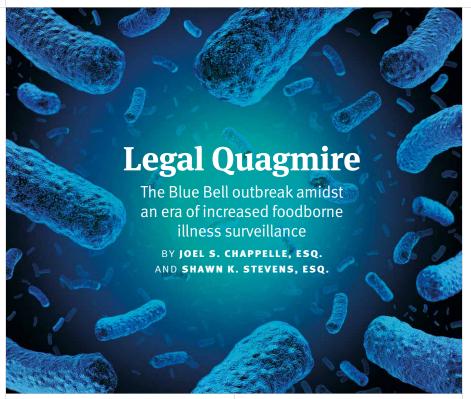


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Legal Update



implicated in an outbreak of Listeria monocytogenes involving ice cream. The outbreak caused 10 known illness from 2010 through 2015. Of those, all 10 people were hospitalized, and three died. The Blue Bell outbreak investigation is an excellent example of the new paradigm of foodborne illness surveillance, one that significantly increases the legal risks that companies face. The events leading up to the outbreak, and the criminal prosecution that followed, also provide a look into the workings of the criminal justice system.

Foodborne Illness Surveillance

Historically, most foodborne illness outbreaks and recalls were linked to products produced during narrow, well-defined periods of time. Often, implicated products were limited to an individual lot or production date. In such cases, the contamination was typically attributed to a specific food safety failure, e.g., employee

cross contamination or a single contaminated batch.

Advances in foodborne illness surveillance, genotyping, and networking have vastly improved our understanding of how foodborne illness propagates and fundamentally changed the landscape of outbreaks and recalls. The groundwork for this shift began the mid-1990s, following the 1993 Jack-in-the-Box E. coli outbreak. After Jack-in-the-Box, a public outcry led to the creation of a national foodborne illness surveillance program. CDC scientists and policy makers recognized that outbreaks could be detected and stopped sooner if public health laboratories employed a uniform standard of genetic subtyping and shared the results across a nationwide network of laboratories. This realization led to the creation of PulseNet.

PulseNet, subject to mandatory illness reporting rules, requires healthcare providers to report certain foodborne illnesses (such as *L. monocytogenes, Salmonella* or *E. coli O157:H7*) to public health officials.

State laboratories conduct genetic subtyping on isolates collected from food samples or ill patients and then upload the isolates to PulseNet, allowing for rapid comparison to other isolates stored in the CDC database. Matching isolates often come from a common source, just as multiple crime scenes with the same fingerprints are likely the result of a single perpetrator. When a potential outbreak is identified, CDC shares information with federal, state, and local officials, who then collaborate to identify a source. Almost immediately after its inception, PulseNet began detecting a significant number of outbreaks, often with a small number of geographically diverse cases, that would have otherwise almost certainly gone undetected.

PulseNet has grown significantly over time. It now comprises 83 federal, regional, state, and local laboratories divided into seven regions. There is at least one PulseNet laboratory in every state, and the database now has more than a million isolates, which has enabled CDC and FDA to solve countless foodborne illness outbreaks.

And, just as surveillance has improved, so have the food safety programs at food companies. Yet, despite the extraordinary improvements over the last 25 years, which have undoubtedly made food safer, the number of recalls has continued to increase. This is likely because the fidelity of the surveillance is so keen that we are identifying outbreaks that we wouldn't have before. Gone are the days when outbreaks were only identifiable if they caused many illnesses, in a short timeframe, over a limited geographic area. Today's outbreaks are readily discoverable even if the contamination is caused by a niche organism in some dark, difficult-to-reach area of a facility. Such pathogens may only intermittently find their way into products before disappearing, only to reproliferate weeks, months, or years later. Then, as sporadic illnesses occur, the genetic isolates are uploaded into CDC's database, where they remain indef-

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initely. This is what may have happened in the case of the Blue Bell outbreak.

The Blue Bell Outbreak

In May 2020, the federal government charged Paul Kruse, Blue Bell's former president and CEO, with seven felony counts for his role in conspiring to conceal *Listeria* contamination from Blue Bell's customers and regulators. By examining CDC's outbreak investigation documents and the federal government's prosecutorial materials, we can begin to understand how the outbreak happened and what missteps the company took.

According to the criminal complaint (called an "information"), Kruse, as of at least 2010, knew that Blue Bell was not following appropriate practices to ensure sanitary conditions at its manufacturing facilities. During the outbreak period, Blue Bell coliform levels were, on occasion, too high to count. Blue Bell laboratory technicians referred to these results as "TMTC" (too many to count) and shipped the products despite the high coliform counts. In early 2011, following customer complaints about the coliform levels, a Blue Bell quality control employee created a program to periodically test high coliform Blue Bell product for the presence of Listeria. In April 2011, Kruse ordered the employee to halt the program. After Kruse issued the order, two products tested presumptively positive for Listeria. Based on Kruse's order, an employee destroyed the testing records and the presumptively positive product was shipped to customers.

In February 2015, South Carolina health officials, during routine sampling, isolated *Listeria* from multiple Blue Bell products. In turn, Texas health officials went to Blue Bell's Brenham, Texas, facility and conducted additional sampling, which led to the discovery of seven different *Listeria* strains. At least one of the positives came from product that had been produced on the same production line as the South Carolina positives.

In March 2015, two people in a Kansas hospital were infected with a matching strain of *Listeria*. When the Blue Bell and South Carolina isolates were uploaded to PulseNet, investigators discovered that three additional cases, which were from the same hospital but were infected with different strains, were a match. In total,

four of the five hospital patients had strains that matched the Blue Bell ice cream tested by South Carolina and Texas. Moreover, all four had consumed milkshakes made with Blue Bell ice cream while they were in the hospital.

Upon notification of the positives, Kruse purportedly told FDA that Blue Bell would be recalling all implicated products. Instead of recalling the products, however, he is accused of directing employees to surreptitiously remove the implicated products from stores during their regularly scheduled deliveries. Prosecutors claim that Kruse also ordered employees not to disclose the reason for the withdrawal to customers, and that he directed executives to forbid employees from disclosing information about Blue Bell's Listeria contamination to customers. In addition, Kruse allegedly: 1) concealed the potential presence of *Listeria* by asserting the withdrawal was due to a manufacturing irregularity; 2) refused to notify the public about the *Listeria* contamination; and, 3) oversaw the issuance of a statement claiming all potentially contaminated products had been withdrawn even as they were still available in stores.

Eventually, Blue Bell did initiate a recall, which ultimately included eight million gallons of ice cream. In the aftermath of the outbreak, more than 1,400 workers were laid off and another 1,400 were furloughed. To be sure, the Blue Bell outbreak involved more than minor oversights and bad luck, and if the allegations levied by the federal government prove to be true, Blue Bell's conduct was egregious and inexcusable.

Even absent the alleged criminal conduct, there are numerous aspects of this outbreak that should be gravely concerning to food industry executives. One is that an outbreak could last for five years. The first known illness was in January 2010. It was followed by two additional illnesses in 2011, one in 2012, three in 2014, and one in 2015. That pathogens could continue to periodically contaminate products for such a long period of time creates enormous potential risk to food companies. From a legal standpoint, it should serve as a warning that ignoring potential microbiological problems can be far more costly than the interventions and actions required to adequately address such problems.

On May 15, 2020, in a bizarre twist, the charges against Kruse <u>were dismissed</u> on procedural grounds. There is some debate over whether the government will be allowed to renew the charges. If not, the case is over. The crimes Kruse stands accused of are subject to a five-year statute of limitations, meaning the prosecution must initiate the prosecution within five years of the last overt act committed in furtherance of the conspiracy, which in this case was May 2020.

For a defendant to be prosecuted, the court must have subject matter jurisdiction, which means a court has the authority to adjudicate the subject of the legal matter. If the court does not have jurisdiction, it cannot hear the case. To confer subject matter jurisdiction, the government must obtain an indictment (or a valid waiver of indictment). In this case, the court system was shut down because of COVID-19, meaning the government could not obtain an indictment. Thus, even though the government filed the charges against Kruse, the court lacked jurisdiction because there was no indictment. In turn, the court had to dismiss the charges. What complicates matters is that the statute of limitations has expired. In turn, it is not clear whether the government will be able to proceed.

Kruse will likely argue that because the case was dismissed, the government did not begin the prosecution and can no longer do so because the statute of limitations expired. Prosecutors will likely argue that by filing the information, they began the prosecution. The government will also likely make the statutory argument that that the dismissal of the information triggers a tolling period that allows the government to seek an indictment—even if the statute of limitations has expired—six months from whenever the next grand jury is convened.

Note: Paul Kruse is innocent until proven guilty and has not been convicted of any crime. The allegations levied by the federal government and described in this article were dismissed on procedural grounds, and whether they will be brought again is unknown.■

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Cannabis Corner



The Challenge of Cannabinoid Potency

Plastic-lined cans, plastic bottles, and plastic jars may degrade their THC and CBD content | BY JESSE STANIFORTH

n June, a statement of claim for a \$500-million class-action lawsuit sent shockwaves across North America's legal cannabis markets. Filed in Calgary, Alberta, the lawsuit alleges that seven of Canada's largest licensed cannabis producers (known as LPs) sold numerous cannabis-oil products whose active cannabinoid (THC and CBD) content was "drastically different" than the amounts listed on product packaging. Some products contained as little as 54 percent of the THC or 51 percent of the CBD they were listed to contain, while others contained as much as 118.5 percent of the listed THC.

The suit's statement of claim argues that many of the cannabis oils in question were sold to consumers in containers such as plastic bottles or those with caps that may have rapidly absorbed or degraded the THC or CBD content within them.

The class-action suit has not yet been certified by a judge, but industry discussion that followed news of its filing was concerned less with the potential lawsuit and far more with the possibility that the plaintiff may be broadly correct in finding that cannabis oil products lose cannabinoids to plastic packaging. If that's true, it's bad news for producers of consumer cannabis oils (which occupy a tiny market share), but it's far worse news for Canada's burgeoning cannabis beverage market-and the legal market for cannabis and cannabis beverages that many analysts expect will open federally across the United States within the next few years.

Cans and Chemistry

Worries about changes to cannabinoid potency have been active since before the class-action suit. Canada's largest LP, Canopy Growth, has long signalled its intention to focus on cannabis beverages. Last fall, ahead of Canada's second phase of legalization (allowing cannabis foods, beverages, extracts, and topical products), the company held a lavish pre-launch for its slate of 16 infused beverages and edibles, due to go on sale in mid-December 2019. After the drinks didn't appear before Christmas, Canopy stunned the industry in January 2020 by pushing back its beverage-portfolio launch. Despite being backed by a \$4 billion investment from U.S. beverage conglomerate Constellation Brands, Canopy ran up against the same problem raised in the class-action suit: The cannabinoid potency in their beverages wouldn't remain stable.

"There is an interplay with the cans and the chemistry in the drink itself," Canopy Growth CEO David Klein told *Yahoo Finance*.

Lagunitas Brewing Company in Petaluma, Calif., determined that a similar problem with potency loss in its Hi-Fi Hops cannabis beers was connected to plastic can liners. Others say the problem is the products themselves. Either way, cannabis products housed inside plastic-lined cans, plastic bottles, and plastic jars tend sometimes to lose the potency of their cannabinoids—the active ingredients in cannabis products.

Though there are more than 60 cannabinoids that exist in the cannabis plant, the two that appear in the highest doses at present are THC (responsible for the "high" associated with cannabis) and CBD (a non-intoxicating compound with various medical effects). Like all cannabinoids, THC and CBD appear as waxy compounds.

"Cannabinoids aren't water soluble, and the beverages they're trying to put them into are basically water," says chemist Mark Scialdone, PhD, chief science officer for Connecticut's BR Brands, which offers a portfolio of cannabis products. "That's why the drinks are losing potency to the side of the can: For cannabinoids, it's a low-energy pathway. Given the opportunity, cannabinoids would rather stick to the liner of the can than to be in the drink the person's consuming."

Dr. Scialdone says that cannabis drinks require cannabinoid oils to be suspended in an emulsion soluble in beverages—but such emulsions are in their very early days. For Dr. Scialdone, the best emulsion to compare these beverages with is milk, which contains fat emulsified by milk's naturally occurring glycolipids, which prevent the fat from separating out. By comparison, existing cannabinoid emulsions are nowhere near as stable as milk, largely because cannabinoids such as THC and CBD are very hydrophobic.

"It's very rare in a soda or a beverage product to have a compound with such a hydrophobic load like the cannabinoid," Dr. Scialdone says. This is a problem because can liners are equally hydrophobic and "like dissolves like," so the less stable the emulsion, the likelier it is for its cannabinoids to leach into can linings. He notes that beverages could instead be sold in glass bottles, but that might not be desirable to producers for a variety of reasons, including an increased cost.

Product Quality

A deeper problem, says Harold Han, PhD, is the quality of the beverage base into which the emulsions are being dissolved. Dr. Han, founder and chief science officer of California-based cannabis-infusion specialist Vertosa, says compatibility between beverage base and emulsifier is a physical issue.

"Some companies say they've solved the water-solubility issue," Dr. Han says. "Yes, you can dissolve many [cannabinoid] emulsions into pure water. It dissolves fast, the flavor is pretty good, and it has pretty good onset. But the water isn't your product; your product is coffee, juice, apple cider vinegar, red wine, rosé. Those products themselves have complex chemistry, and you're infusing an emulsion, which has a complex chemistry also."

Potency, says Dr. Scialdone, is the No. 1 most-desirable attribute in a cannabis product, but maintaining potency may negatively affect important factors in a

beverage, such as flavor or mouthfeel. Yet Dr. Han stresses that maintaining potency requires controlling chemical as much as physical factors. "Chemically, THC has a structure that oxidizes easily, turning it into [non-psychoactive cannabinoid] cannabinol (CBN)," Dr. Han says. "You lose potency that way. To mitigate that, if you're producing a THC-infused beverage, how are you going to control the oxygen levels in the package? If you can't eliminate it, what kind of antioxidant mechanisms can you embed or design to fight oxidation?"

For this reason, Dr. Han says, it's much easier to make a THC-infused soda water than it is to make a THC-infused rosé, which he calls "a complex system."

"Rosé is from the grape, and it's fermented," Dr. Han says. "It has proteins, it has iron, which tends to accelerate oxidation. You may then need to think about how to fight that oxidation."

That's before the more pressing problem of sticky cannabinoids exiting their emulsions to cling to hydrophobic plastic—a problem Dr. Han says can be exacerbated by the high heat and pressure thermal processing required to kill microbes and prolong shelf life. "This is not rocket science," he says, "but it's a special science. It's complex. Inventing an emulsion is easy. What's hard is stably putting it into a base."

As a problem, the loss of cannabinoid potency is an indicator of how incredibly new legal cannabis products are. Legal cannabis beverages have existed for fewer than five years, and, on the illicit market prior to state-level legalization in the U.S., they barely existed at all.

Dr. Scialdone, who spent 25 years as a chemist for DuPont, sees unstable cannabinoid levels as the result of hurried product development. "Typically, what happens in the cannabis industry is they don't really do the full development of the product; they just try to rush it out the door as quickly as they can in order to recoup some of the dollars they've spent on doing so."

Product development, Dr. Scialdone says, is expensive and it can take a multitude of iterations to arrive at a commercial formulation even before companies begin testing the product in a can.

"It's a difficult process when you're trying to do product development and product launch simultaneously," Dr. Scialdone says, but that's essentially what producers have been forced to do in their haste to be first-to-market with infused beverages. "In product development, you want to fail early and often in the prototype development stage. [If] you fail in the marketplace after you've put a bunch of products out there and find out you're losing potency on millions of units sitting on shelves and in warehouses, that's an expensive failure."

What the Future Holds

However, Dr. Scialdone is optimistic about the future of cannabis-infused beverages, provided a few factors in the industry change. First among them, he says, is the lingering stigma traditional businesses feel in working with cannabis companies. In Canada much of this stigma seemed to disappear after legalization, but he says it remains a problem in the U.S., where cannabis is still federally illegal. That stigma is changing, however, with each new state that votes to legalize medical and adultuse cannabis. Many expect some form of federal cannabis legalization within the next few years. As the stigma begins to thaw, Dr. Scialdone sees hope for partnerships with traditional food packagers and aluminium manufacturers he believes will resolve other factors that might hobble the rollout of cannabis beverages. Most of these stem from the disconnection between cannabis producers and traditional food and beverage producers.

"There are packaging needs in the cannabis industry that are unmet, and other industries don't have the answers to them," Dr. Scialdone says. "This is one of those. It's almost like they need to develop a new can just for the cannabinoids industry because of this problem. I'd like to think if the right company saw this as the right opportunity to innovate and come up with a can that solves this problem, they'd have an immediate market. I would believe there's a liner out there that works better than existing liners. But this is outside the supply chain of the cannabis industry; we need to go with what cans large vendors are providing us. They're not providing cans with customized solutions for maintaining cannabinoid potency." ■

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Turn food waste into animal feed: Your guide to laws, regulations, and operations

BY KAREN APPOLD



lobal demand for meat, dairy, and egg products continues to increase as the world's population grows and improving economic conditions allow for better diets and reduced world hunger. The Food and Agriculture Organization of the United Nations projects increases in world meat and dairy production over the next decade of 13 percent and 17 percent, respectively, and, says David Fairfield, senior vice president of feed services at the National Grain and Feed Association in Arlington, Va., a sustainable supply of nutrients for animal food is needed to meet this growing demand.

Carefully calibrated animal feed rations do a superior job of enabling livestock to grow out to slaughter weight in the fastest and most reliable way, says Nicole Civita, JD, LLM, adjunct professor of law at University of Arkansas School of Law in Fayetteville. However, as increasing numbers of farmers, food entrepreneurs, and consumers become aware of and concerned about the environmental and economic problems associated with both livestock production and food waste, there is renewed interest in using food scraps as animal feedstock or as a feed supplement—a practice that has actually been used worldwide for centuries.

"Diverting food away from landfills and instead into a food supply for farm animals is a mutually beneficial practice for regional farms, food businesses, and the environment," says Emily Broad Leib, JD, faculty director and clinical professor of law, Harvard Law School Food Law and Policy Clinic in Cambridge, Mass.

Civita points out that farmers can save money by using food scraps, because feed is often the most costly input needed for animal agriculture, and is certainly a constant need. "Farmers who carefully select types and combinations of food scraps that are nutritionally appropriate for and readily digestible by their animals should be able to simultaneously promote animal health and wellbeing, secure a reasonable rate of growth, and make use of food that would otherwise go to waste," she says.

Additionally, many businesses and institutions that produce, process, sell, and serve food can save money in garbage disposal costs. "Diverting food scraps as animal feed presents the opportunity for significant cost savings [for food processors] in the form of reduced tipping fees that landfills and waste haulers charge to dispose food scraps," Civita says.

Furthermore, diversion of substantial amounts of excess food for use as animal feed may shift commodity demand and reduce the environmental impact it would normally created. The majority of all crops—67 percent of the crop calories grown on farmland in the United States—are dedicated to feeding animals, Civita says.

Along these lines, Broad Leib says that using food waste reduces methane emissions of food in landfills. If scaled up over time, the practice can change the need for and supply of commodity feed production, using land more efficiently. According to a 2016 report from ReFED, an organization focused on reducing food waste, the United States currently sends approximately 63 million tons of food waste to landfills annually.

Getting Started

Laws and regulations at the federal and state levels outline how and what food waste can be repurposed for animal feed. For food waste-feeding operations to better understand and operate under



Diverting food scraps as animal feed presents the opportunity for significant cost savings [for food processors] in the form of reduced tipping fees that landfills and waste haulers charge to dispose food scraps.—

NICOLE CIVITA, JD, University of Arkansas School of Law, Fayetteville

the applicable laws, Broad Leib recommends that organization and business leaders take the following steps:

- 1. Identify the type of animals being fed.
- 2. Identify the type of food that will be fed to animals.
- 3. Articulate reasons for feeding food waste and assess the feasibility of doing so.
- 4. Separate animals that may be fed food scraps from those that may not.
- 5. Develop a plan for acquiring, heat treating (if necessary), transporting, and/or storing food.
- 6. Obtain or ensure that partner facilities have required permits, licenses, and certifications.
- 7. Ensure that a food waste-feeding model complies with all applicable federal laws.
- 8. Contact the relevant state regulatory body to confirm compliance with state laws and for further advice.

Regulations

Both federal and state governments regulate the use of food waste in animal feed by setting requirements that largely concern the type of animals that may be fed food waste and the kind of waste they may be fed. The federal regulations function as a floor, and most state regulations go beyond them, Broad Leib says.

According to Broad Leib, federal laws for using food scraps as animal feed include:

- FDA's Ruminant Feed Ban Rule, which prohibits using animal tissue in feeds for ruminant animals, such as cows.
- FDA's Center for Veterinary Medicine <u>regulations</u> of animal food products, which state that animal feed cannot be filthy or decomposed, be packaged or held under unsanitary conditions, or contain any poisonous or deleterious substance.
- FDA's <u>Final Rule for Preventive Controls for Animal Food</u>, which aims to prevent foodborne illness at the processing stage of food production by requiring certain licensure and practices in facilities that process animal feed.

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(Continued from p. 21)

• The <u>federal Swine Health Protection</u>
<u>Act</u>, administered by USDA, which aims to ensure that food scraps for swine are free of disease by requiring that meat and animal byproduct-containing food scraps are heattreated to kill disease-causing bacteria.

State laws vary widely among states. The Harvard Law School Food Law and Policy Clinic's 2016 report, Leftovers for Livestock: A Legal Guide for Using Excess Food as Animal Feed, provides information about the restrictions on feeding food scraps to animals in all states, and also outlines federal laws and sharing policy recommendations.

A Closer Look

FDA's regulation of animal food falls under the Food, Drug, and Cosmetic (FD&C) Act,

which, in part, requires businesses to register as food facilities. Types of businesses that need to register include those that manufacture, process, pack, or hold food (human and animal) for consumption in the United States unless an exemption applies, says Jennifer Erickson, JD, lead, Food Safety Modernization Act (FSMA) Preventive Controls for Animal Food Regulation at FDA's Center for Veterinary Medicine in Rockville, Md.

Some businesses that send food waste to farms may be exempt from registering as a food facility, such as restaurants and grocery stores. These businesses are subject to the FD&C Act but don't have to register or follow the additional FSMA regulations for animal food, which only apply to facilities registered as food facilities, when sending food waste to the animal food supply, Erickson says. But these businesses are subject to the parts of the FD&C Act that apply to all businesses handling animal food—such as the adulteration and misbranding provisions—even if they don't have to meet specific FSMA requirements. Other requirements, such as the Swine Health Protection Act or other state or local requirements, may apply depending on their activities.

Businesses that are required to register with FDA as a food facility are subject to the Current Good Manufacturing Practice (CGMP) and Risk-Based Preventive Controls for Food for Animals requirements in 21 CFR part 507, more commonly referred to as the Preventive Controls for Animal Food (PCAF) requirements. There are three ways the requirements can apply, Erickson says, depending on the activities that businesses perform on their byproducts:

- 1. Facilities that don't further manufacture/process their human food byproducts for use as animal food only have to follow the limited holding and distribution of current good manufacturing practice requirements.
- 2. Facilities that only perform certain manufacturing/processing activities as outlined in FDA's <u>guidance for industry</u> must only follow CGMP requirements in 21 CFR part 507, subpart B.
- 3. Facilities that perform more complex manufacturing/processing activities must follow both CGMP and Preventative Control requirements, unless another exemption applies.

Additional information on these requirements is contained in Draft Guidance for Industry #239: Human Food By-Products for



Pigs dining on watermelon rinds.

<u>Use as Animal Food</u>. "But this draft guidance is partially outdated because it was issued prior to the <u>guidance for industry</u> outlining when certain manufacturing/processing activities have to only follow CGMP requirements," Erickson says.

Additionally, FDA has a fact sheet for safely distributing human food waste for use as animal food. "While this resource was developed primarily to assist facilities during COVID-19, the same food safety principles apply whenever human food waste is sent to animal food," Erickson says.

Under federal law, food waste containing meat or animal products can generally be fed to animals (except ruminants). The Swine Health Protection Act requires that these scraps be heat treated in a manner sufficient to kill disease-causing bacteria before they

can be fed to swine, Broad Leib says. In practice, this generally means that most animal-based food waste must be heated at a boiling temperature for at least 30 minutes by someone who holds a valid license or permit for the treatment. Some foods are exempt from the half-hour boiling protocol, including certain food scraps containing animal products that were industrially processed or manufactured.

Foreign Import Regulations Related to Food Waste

Regulations for imported animal food, including products from China and India, fall under Foreign Supplier Verification Program (FSVP) requirements established under FSMA. Under the program, importers are required to evaluate known and reasonably foreseeable hazards associated with foreign foods and their suppliers and implement risk-based preventive controls as appropriate, says David Fairfield, senior vice president at National Grain and Feed Association in Arlington, Va.

Imported animal food, such as human food byproducts, is also subject to the requirements of The Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This act requires the registration of human/animal food producing facilities with the FDA, and for prior notice to be provided to FDA for each shipment of imported food before it arrives in the United States, Fairfield says.

Shipments of products regulated by FDA are subject to examination whenever they are offered for entry into the United States. Products found to be in violation of the laws and regulations administered by FDA are detained, Fairfield says. Products that cannot be brought into compliance will ultimately be refused. Animal food imported into the United States must be composed entirely of ingredients judged acceptable for use in such products.

PHOTO COURTESY OF JENNIFER ERICKSON

Changes in Laws

FDA regulation of animal feed has become more restrictive since the 1980s, when several disease outbreaks were linked to animal feed. These include foot-and-mouth disease in swine and bovine spongiform encephalopathy (commonly referred to as mad cow disease). For example, FDA's Ruminant Feed Ban Rule, promulgated in 1997, prohibits the use of mammalian protein in feeds for ruminant animals. Under this rule, producers of waste-based ruminant feed must certify compliance and keep detailed records of their inputs and processes, Broad Leib says.

FSMA also made big changes to the food safety procedures for all food processing, including processing of animal feed, Broad Leib says. For example, this law requires more regular FDA inspections and requires all processing facilities to create a hazard analysis and risk-based preventive controls (HARPC) plan for a facility's safety procedures.

During and after the rulemaking process establishing the requirements in 21 CFR part 507 under FSMA, FDA had multiple interactions with stakeholders to ensure that the requirements reflected the practices that many were already using to ensure that the food waste they sent to animal food was safe and not adulterated, Erickson says. The requirements were also written so that human food facilities that already controlled food safety hazards for human food didn't have duplicative requirements for controlling those hazards in animal food byproducts.

Regulations for Different Animals

The regulations and adulteration provisions in the FD&C Act are the same for all animal food; however, because food safety hazards affect species differently, what is necessary to produce a safe, unadulterated animal food in compliance with the regulations and the FD&C Act may differ depending on the species, Erickson says.

Most state laws only address the feeding of food scraps to swine, with many states requiring heat treatment of all food scraps given to swine, and a few states banning the practice outright. By contrast, only a few states apply regulations to other animals, Broad Leib says. For example, South Dakota doesn't regulate the feeding of food scraps to swine, but it does ban the feeding of any kind of food scraps to cattle enrolled in the South Dakota Certified Beef Program. There are fewer regulations regarding feeding food scraps to poultry, although the laws regulating facilities that produce animal feed still apply to facilities that produce feed for poultry.

Fairfield says that different animals have disparate requirements because the physiologies of different animal species can cause varied responses to the same contaminant or nutrient. For instance, sheep have a daily requirement for copper as a nutrient, but excessive copper can easily cause copper toxicity because their bodies have difficulty excreting excess copper. Copper toxicity within other animal species is rare, however, because the physiologies of these animal species are better suited to handle copper excesses.

Labeling Requirements

Under the FD&C Act, food cannot be misbranded, meaning that its labeling cannot be false or misleading in any way, and it must

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Safety & Sanitation ENVIRONMENTAL MONITORING



Bridging Environmental Monitoring Program Results with Sanitation Practices

One size does not fit all

BY VIRGINIA DIEBEL, PHD, AND KARA BALDUS, BS, MBA

Editors' note: This is part 1 of a three-part series on environmental monitoring. Parts 2 and 3 will publish in the October/November and December/January issues of FQ&S.

t's business as usual in the sanitation department during routine operations. Procedures change when there are out-of-specification (OOS) results from environmental sponge tests—or do they?

Reclean, resanitize, and retrain are three common approaches for corrective

actions. During this time, it could be argued that the same sanitation procedures may be conducted, regardless of the circumstances—just more often.

This will be a three-part series. Part 1 will explore the first steps involved in implementing a cleaning/sanitation process: the selection of chemicals and developing a master sanitation plan. Part 2 will discuss differences in cleaning/sanitation procedures when normal conditions are not occurring, such as when there is an OOS, maintenance, or construction event.

In Part 3, we'll cover procedures for use during extenuating circumstances such as complex maintenance procedures, construction, and pathogen investigations.

During the recent coronavirus outbreak, food companies have augmented sanitation activities, focusing on the well-being of employees. While dealing with these unprecedented times, manufacturers should not lose sight of the sanitation procedures important to the maintenance of sanitary conditions in the production of products.

A solid program starts with the development of two main components: sanitation standard operating procedures (SSOPs), based on four cleaning dynamics, and a master sanitation schedule outlining what is cleaned or sanitized, and how often.

Sanitation Standard Operating Procedures

The goal is to define the activities encompassing cleaning and sanitation. This is a multi-stage process and the documents will evolve over time. First, consider developing general cleaning instructions to efficiently capture company policies. Second, identify soil components for detergent selection,

General cleaning instructions. For efficiency, combine common/recurring SSOP practices (training, storage, responsible parties, chemicals and concentration, and PPE) into general cleaning instructions that are performed prior to or during all circumstances (routine operations, OOS, extenuating circumstances) where cleaning and sanitizing occur.

Identify soil components. Detergent selection is driven by functionality, which, in turn, is driven by the physical attributes of the soil (products/ingredients) and water. Specifically, identifying the pH, mineral content, and type of organic soil will lead to the identification of the best detergent for their removal.

The pH of water is typically between 7 and 8, which usually does not negatively

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Table 1. Water minerals, scale (ppm), and high values that disrupt chemical effectiveness.

Mineral	Scale (ppm)	High
Iron	0.0-1.0	>0.1
Manganese	0.00-0.49	>0.07
Chloride	0–100	>75
Silica	0-40	>25
Barium	0.0-0.16	>0.1

Table 2. Water hardness, scale (calcium carbonate in grains per gram/gpg). Hard water leaves a calcium carbonate deposit, especially when the temperatures of the water are hot, causing precipitation (falling out) of the mineral onto surfaces.

Scale (gmg)	Hardness
0–4	Soft
>4-8	Medium
>8-12	Hard
>12-16	Very
>16-20	Extremely

affect the detergent activity, but it could affect sanitizer selection. The greater deviation of pH from neutrality (pH 7), the greater the potential exists for detrimental chemical effects. Product pH will have similar repercussions. Acid soils, such as citrus, will react with alkaline chemical products, reducing their effectiveness, and vice versa.

Water chemistry should be taken into consideration at the facility. Water hardness may affect the ability of the chemistry to perform by reducing detergent foam formation or forming scale in clean-in-place (CIP) systems. Sometimes, minerals are embedded in a complex matrix of minerals, fats, and proteins and are termed milkstone, beerstone, and waterstone.

A film on a piece of equipment can be identified as mineral by applying an acid to the surface. If the film is removed, the soil is a mineral. Mineral deposits and film can usually be prevented using alkaline detergents that contain sequestering or chelating agents, or an agent that binds to the mineral, keeping it in solution so it is easily washed away during a rinse step. Alternatively, mineral deposits may also be removed by periodic applications of an acid if the water does not have a high silica content (see Table 1). When hot water is used, if the water is hard (>4 grains per gram of calcium carbonate) (see Table 2), there is a greater opportunity for it to precipitate (fall out) from the water and adhere to surfaces, causing a film. This film can serve as a base onto which bacteria can adhere and act as a protectant. This increases the difficulty of their removal and shields them from sanitizers.

Organic soils (carbohydrates, fats, oils, proteins) require different methodologies for cleaning. For best results, all matrices should be identified prior to chemical selection and cleaning dynamics to SOP development.

- Carbohydrates. Some carbohydrates, such as sugars, may only require water for removal, while others, such as starch, may need a detergent. A cold water pre-rinse is best for starchy soils because a hot rinse can cause the soil to stick to the surface, making it difficult to remove.
- Oils and fats. Oils and fats may necessitate the additional chemical reactions of saponification or emulsification for removal. Saponification, conversion of fat/oils to soap and alcohol, occurs by the addition of alkaline (caustic) and hot water. Emulsification is the suspension of a typically immiscible liquid in another liquid. The process breaks down the surface tension of fat/oils, allowing for mixing of water. Once suspended, the fat/oils are further broken into small fat globules, allowing more mixing into water and permitting easier elimination through rinsing.
- **Proteins**. Proteins are generally the most difficult soils to remove. Routine cleaning of protein processing equipment

is best achieved through the addition of chlorine to an alkaline solution. The chlorine peptizes (breaks down) proteins into smaller amino acids, facilitating removal from the system. Although effective, it is not recommended in all applications such as RO membrane systems or evaporators. Additionally, when proteins are heated, they unfold (denature) and will adhere to a surface. In this state, they can be difficult to remove. Cold residues are easier to purge.

Once the pH, mineral content, and organic content of the soils are identified, the chemistry of the cleaning detergents may be determined and the best-fit product selected. In choosing the chemistry, compatibility with surfaces must be considered. While soil identification might lead to a strong acid product, the equipment may not be compatible with that selection, although some products may have choices within their lineups (e.g., soft metal safe).

Cleaning Dynamics

Once detergents are chosen, the procedures for their use will depend on three additional components: application time, water temperature, and mechanical action. Together, the four components are cleaning dynamics devised by Herbert Sinner in the 1950s and dubbed the "Sinners Cleaning Circle" (See Figure 1). A balanced cleaning process requires a percentage of the components totaling 100 percent. If one component is changed, the others must increase or decrease to balance.

Product labels indicate typical time, temperature, and concentrations, but adjustments may be needed for time constraints or lack of available mechanical action (Figure 2). Increased CIP turbulent action increases solubility of most materials, rendering them easier to remove. Generally, the temperature range of cleaning is between 90°F and 185°F. Temperatures above 185°F may induce reactions that bind proteins more tightly to a surface, and in those below 90°F, (butter) fat remains a solid. If cleaning fats, the minimum effective cleaning temperature is 5°F higher than the fat melting point. A general rule of thumb is that cleaning temperatures should be 5°F to 10°F higher than the processing temperatures.

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Mechanical action will be dependent on the type of action performed. Hand or manual cleaning may require an extended time period to ensure the removal of all matrices. CIP fluid flow applies the force or turbulence as the mechanical action. A fluid velocity of five feet/second for 1.5- to 2.5-inch pipes gives the minimum result for effective cleaning. For three-

inch lines or larger, eight feet/second is recommended. This velocity results in the amount of flow necessary to achieve turbulent flow instead of laminar flow in pipes.

Time is a valuable cleaning process resource. Limiting the time needed for cleaning will only lead to later implications such as ineffective sanitizer action because without removal of soils, the sanitizer will

not reach the microbial cell surface, causing its destruction.

While increased detergent concentration may give the appearance of improved soil removal, there is a minimum amount for effectiveness, and an economical amount. Too much detergent may not be rinsed effectively, leaving a residue.

While dealing with these unprecedented times, manufacturers should not lose sight of the sanitation procedures important to the maintenance of sanitary conditions during production.

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Sanitation

Only after the complete removal of soils can sanitizers be effective for microbial elimination. Selection of sanitizers depends on the nature of the processing environment and biological hazards identified through the HACCP risk assessment. Sanitizers follow the same dynamic wheel as cleaning, except soil removal is substituted for mechanical action. Sanitizer application must be conducted at the strength and time listed on the product label, especially for food contact surfaces, as EPA administers the registration of chemical sanitizers and antimicrobial agents for use on these surfaces.

Sanitizers include chlorine, alcohol, quaternary ammonium, and peroxyacetic acid-based compounds. Each sanitizer has proven efficacy against a broad spectrum of microorganisms and has a different mode of action, which leads some manufacturers to rotate sanitizers. For example, chlorine dioxide is effective against Gram-positive and Gram-negative bacteria but not as effective against yeasts. An oxidation mode of action (chlorine) may be counteracted by cell lysis (quaternary ammonia).

Master Sanitation Schedule

Within each area, items cleaned and sanitized are noted on a master schedule serv-

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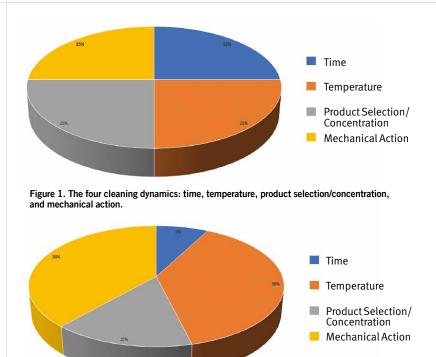


Figure 2. Time constraint is placed on the cleaning process, which shifts the cleaning dynamics.

ing as a checklist or accounting of when items are cleaned and by whom. You can view a sample schedule on our website at foodqualityandsafety.com.

A cleaning and sanitation program involves a chemical analysis of the soils to select the best chemical(s) for cleaning. Sanitizer selection includes the HACCP risk assessment and adds equipment composition to safeguard against damage. Under normal operations, the master cleaning and sanitation can be followed as it is written. In Part 2 of this series, we will address necessary alterations in the cleaning and sanitation regime when a plant experiences OOS results, equipment maintenance, and/or construction.

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Managing Pests During a Pandemic

Tips for re-opening food processing and service facilities amidst COVID-19

BY CINDY MANNES

s a result of the COVID-19 pandemic, businesses have been forced to make critical operational changes for the safety of their customers and staff. While some businesses may have closed their doors temporarily, the majority of food processing and service-oriented facilities have continued to work with limited crews to keep up with the increasing consumer demand for food. With less foot traffic, however, hungry pests have been able to roam unfettered in search of available food sources, entering buildings and creating additional challenges. As closed

businesses prepare to reopen and others welcome back additional crew members, they must address pest issues that may have taken hold to ensure a safe return.

While the CDC maintains there is no evidence that COVID-19 can be transmitted through food or pests, according to the CDC, pests are capable of contaminating food and transmitting other deadly diseases to humans. Rodents, for example, contaminate or consume about 20 percent of the world's food supply and can transmit diseases such as *Salmonella* and hantavirus to humans. Rodents in particular have grown extremely desperate during this time, as

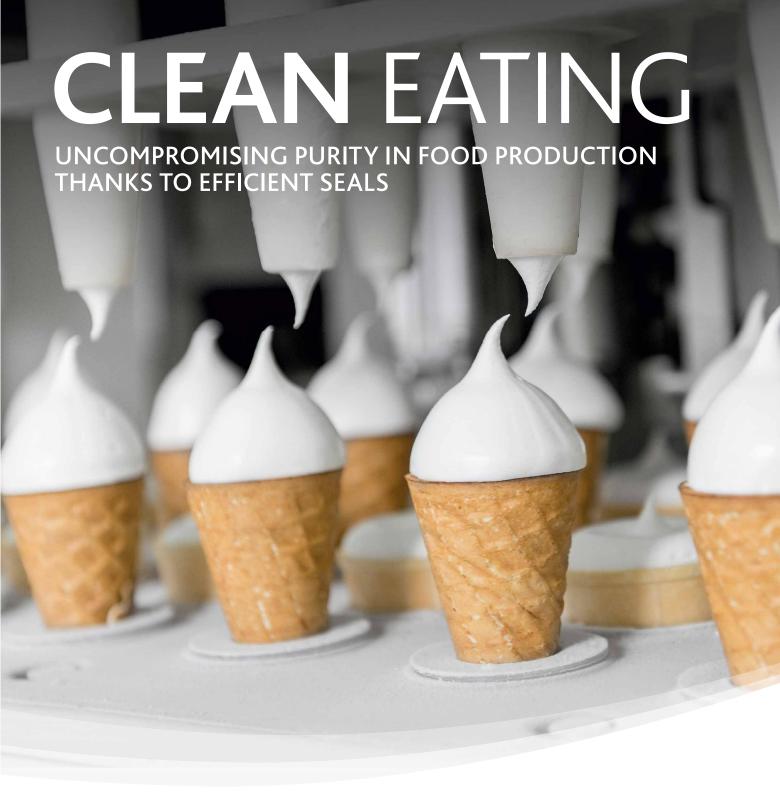
their usual food sources, including restaurant dumpsters and garbage cans, are often empty, forcing them to search for alternate resources in areas such as residential neighborhoods, schools, food processing and service facilities, and even cars. If any food items are not stored properly in these facilities, these savvy pests are likely to find them. Many pests' usual places of refuge have also been cut off, making dark, undisturbed areas with excess moisture ideal breeding and nesting sites.

Due to these changes in pest behavior, facility managers must be diligent in preparing their buildings for reopening or increased occupancy. The very first step in readying any facility is to partner with a licensed pest control company to help implement an integrated pest management (IPM) plan specific to your facility. Using this three-part practice, which consists of inspection, identification, and treatment, pest professionals will assess the property and pinpoint and address any problem areas, helping to protect employees from the diseases and structural damage caused by pests.

In addition to working with a licensed pest control company, managers should also take the following steps to safely reopen or prepare their facilities for the return of additional employees:

- Survey the grounds. Be sure to clear any vegetation that may have grown close to the building, as this can attract pests. Eliminate areas of standing water on the property, as mosquitoes can breed in as little as half an inch of water. Additionally, exterior lighting fixtures that use mercury-vapor bulbs are extremely attractive to pests like spiders, ants, and flies. Opt for a less-attractive option such as low-sodium bulbs whenever possible, or ensure that lights with these bulbs are at least 150 feet away from the facility.
- Examine the building exterior. Repair any cracks or holes on the exterior of the building, especially where utility pipes enter the building, as mice can fit through openings as small as a dime. Also, excess water buildup can attract pests, so ensure that all gutters are clear of debris and direct water away from the building through properly functioning downspouts and splash blocks.

(Continued on p. 53)



Seals used in the food industry have to meet very high requirements. That's because hygiene and the appropriate certifications are critical for the safety of processes and end products. Yet extreme temperature fluctuations, aggressive media such as cleaning agents and grease, and abrasive addi-

tives like nuts or pieces of fruit present a huge challenge. Freudenberg Sealing Technologies has developed special seals made of innovative materials that can withstand these extreme conditions permanently and uncompromisingly — for the clean production of all kinds of food. fst.com







The Disadvantages of Paper Records

How digital quality management systems are a benefit to food manufacturers, especially during a crisis

BY FRANCINE L. SHAW AND KARI HENSIEN

t's 2020 and we live in a high-tech culture, so why are so many food businesses still using paper records to manage something as important as food quality and safety?

As many have now learned, digital tools are especially critical during a crisis, including the COVID-19 pandemic. As businesses shift the way they operate—dramatically elevating their safety and cleanliness protocols—companies that use digital tools will have distinct advantages as they react to and recover from this crisis.

For example: A major food and beverage brand with thousands of locations nationwide distributes a laminated COVID-19 checklist to all their units as a guide to their new protocols. While this is a good place to start, this company has set up a system that isn't flexible and can't be easily updated company wide. That's when antiquated paper-and-pen systems become a huge pit-

fall and, potentially, a costly liability. These problems are only made worse during a global health pandemic.

The Pitfalls of Managing Pen & Paper Quality Management Systems

Serious and concerning issues arise when you are managing quality, safety, and compliance systems at each of your many locations using manual processes:

- You can't quickly update safety and compliance policy across all locations, which is essential when there's a crisis such as the current pandemic.
- Critical paper records can easily be lost or misfiled, opening you up to liabilities, government sanctions, and location closures when health and safety issues arise, such as a foodborne illness.
- It's difficult for the person in charge (PIC) to ensure that essential safety checks

are being performed regularly and correctly; the checks and balances of compliance end up leaning too much on the honor system, and it's unclear when employees need training.

• You have no visibility, and it's difficult to collect and organize data to gain critical insights; manual data management processes are time consuming and error-prone, and you often find insights or corrective action-preventive action (CAPA) items when it's too late.

If you are still using pen and paper, you have probably felt the true burden it is as you've been responding to COVID-19 and increasing your efforts to keep employees and customers safe. The main reason for this feeling is that the pen and paper method is driven by *reactive* action rather than *proactive* action.

When you're always responding to issues as they arise, it becomes more and more difficult to be strategic and complete critical work without being interrupted by eight hours of new issue problem solving every day. While it's important to acknowledge that there will always be reactive pieces to a quality management system (nothing is ever perfect), it's also clear that dedicating the time and budget to becoming more proactive in preventing issues saves time, money, reputations, and, in the long run, even lives.

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This will not happen with any amount of "optimization" of pen and paper systems, because you'll never get the visibility you need to spot trends and fix small issues before they become big problems. On the other side of the spectrum, the right digital quality management system can give you immediate visibility that can drive instant corrective actions.

Elevate Safety & Cleanliness Protocols

Using digital tools offers huge benefits. Digital tools can better gather data from all sources, including audits, assessments, checklists, certifications, and completed training, so you can track and report on critical information from all locations, providing a clear, accurate view on compliance across the enterprise. When you go digital, you can more easily solve the challenges stated above:

- You can quickly update safety and compliance policy across all locations, which is essential when there's a crisis, such as the novel coronavirus.
- Critical records are easily found when issues, such as a foodborne illness, arise.
- The PIC can more easily ensure essential safety checks are being performed regularly and correctly, and can quickly supplement training when needed.
- You have visibility like you've never had before with data that's quickly collected and organized to gain critical insights for proactive planning.

Benefits of Quality Management Software in a COVID-19 World

This "new normal" is our new reality, not just a temporary situation. Because of the virus, you must change the way you operate, train employees on new protocols, ensure compliance, and implement corrective actions. And, you must manage these protocols on a consistent, ongoing basis, knowing that lives are at stake if you and your employees have a misstep. The COVID-19 pandemic has changed the world completely, and it's essential to transition from "the way we've always done things" to a whole new way of operating, including using digital tools.

In our experience, food and beverage companies often resist technology. These businesses often have a systemic belief that their manual systems are fine because it's "the way we've always done things." Additionally, resistance is even fiercer when they believe that digital tools are too expensive, cumbersome, or difficult to implement.

Truthfully, digital tools are now affordable, accessible, and user-friendly, and companies of every size and budget can find a digital solution. Digital tools, such as quality management software and

As businesses shift the way they operate dramatically elevating their safety and cleanliness protocols—companies that use digital tools will have distinct advantages as they react to and recover from this crisis.

auditing apps, allow companies to better manage our new reality and help boost their bottom line.

The companies that are doing amazing jobs with the new, elevated coronavirus protocols have some important things in common: They're using digital tools and being transparent about their commitment to enhanced safety and cleanliness protocols.

Many grocery store chains are excelling at these efforts. They are identifying people on each shift to clean and disinfect, concentrating on high touch areas; implementing new consumer traffic patterns, such as one-way traffic in aisles and proper social distancing; and offering free masks, gloves, and hand sanitizer at the door. They're taking a proactive and authentic approach to a safety culture, showing they care about safety, and are taking proper steps to mitigate risks. Through these actions, they're reassuring a nervous public that their facilities are safe.

Going Digital

Digital tools can help you implement new protocols, train staff, audit efforts, assess data, ensure compliance, and trigger onthe-spot as well as long-term corrective actions, as needed. As you adopt digital tools, here are a few tips for navigating our new normal that can be managed via digital quality management systems:

- Elevate your cleaning and disinfecting efforts. Digital tools can track cleaning and disinfecting activities to ensure compliance.
- Implement COVID-19 safety protocols. Use digital tools to enable instant visibility and transparency to gain critical insights across the enterprise (e.g., data can be viewed in a rolled-up manner to look at the operation as a whole or used to drill down to individual locations and areas to gain localized insights).
- Educate employees and customers. Send frequent emails to employees, customers, vendors, and other key audiences explaining the steps you're taking to follow recommended COVID-19 guidelines. Explain how they can be part of the solution, and reiterate these messages on your website and via social media posts.
- Train employees regularly. Utilize tech tools to provide regular reminders and updates to your staff throughout each shift.
- Get information from reputable websites. COVID-19 information is being constantly updated. CDC, FDA, WHO, and NIH offer ever-evolving information on COVID protocols. The RizePoint COVID-19 Resource Center updates COVID-19 information regularly, using data from authoritative agencies and distilling the information into digestible talking points for managers to relay to their teams.
- Ensure compliance. Put policies and systems in place, educating employees about what to do, when, and why. Use digital audits to track compliance and take on-the-spot and long-term corrective actions as necessary.
- Build a better safety culture. Elevate your existing safety culture by enhancing systems (e.g., transitioning from antiquated paper systems to utilizing more accurate, integrated tech tools). This is a must-have effort and no longer optional. Otherwise, the health and safety of your employees, customers, and business are in danger.

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Quality



Frying Studies

A comprehensive study is the key to quality frying and continuous improvement | BY RICHARD F. STIER

Editors' note: This is the second in a series of three articles on frying. Part 1, "How To Ensure Quality in Fried Foods," was published in the June/July issue of FQ&S and Part 3 will be published in the October/ November issue.

n 1991, Blumenthal and Stier stated that optimum frying occurs when the frying process is economic and superior quality fried food is produced. The best means for evaluating a frying operation, whether an operator is a food processor or producing fried food in a restaurant environment, is to conduct a comprehensive frying study. It is simply not possible to optimize a system if the fryer operator doesn't understand the system, or doesn't understand that a fryer operation is a system. Components of the system are the fryer, the food, and the people operating the system. In addition,

frying is the most dynamic food preparation system around, given that the frying oil is constantly changing, thanks to the interactions of food, water, temperature, oxygen, and the condition of the fryer.

So, what are the reasons for conducting a frying study? The first is to establish a baseline for oil degradation under normal operating parameters. Frying studies should include the following elements:

- 1. Evolving oil chemistry;
- 2. Food quality over time;
- 3. Amount of food being fried; and
- 4. Frying operating parameters.

The greater the number of chemical tests that are done, the better one understands the system. When establishing a baseline, one of the operator's main goals is to establish a relationship between the oil chemistry, or chemical markers of oil degradation, and the sensory parameters of the food being fried. So, the operators

need to be involved, as they are the ones who best understand what would be deemed quality fried food.

Once an operator has established a baseline, they have the first tool necessary for optimizing their operation. There is now a yardstick against which they can compare changes to the system: a new oil, a filter system, the use of a new oil additive, a change in food mix, a change in a formulation, or any other change.

The reasons to conduct a frying study using a standard format include the following:

- 1. To ensure proper evaluation of the system;
- 2. To allow the gathering of technical data to demonstrate benefits/concerns to potential users;
- 3. To develop performance data to demonstrate benefits/concerns to potential users:
- 4. To ensure food safety/adequate processing or process lethality;
- 5.To understand the operations to maximize benefits or minimize concerns; and
- 6. To allow operators and users to make intelligent, well-informed decisions on direction.

Developing a Baseline for a Fryer

Prior to conducting any scientific study, it is imperative to establish a baseline. In deep-fat frying operations, this consists of determining the chemical, physical, and sensory parameters of oil and food in existing frying operations. Once this data has been gathered, any changes to the frying system can be evaluated against the baseline intelligently and without prejudice. The baseline for any fryer operator will be current practices. When conducting a baseline study, it is vital that nothing be changed before or during the study. Lastly, prior to initiating a baseline study or any other frying study, the researchers must determine what endpoint will be utilized-that is, a chemical measurement, sensory testing, or a quality parameter.

A frying study can be done in a restaurant, in a technical center, or in an industrial processing operation. When embarking on such a study, operators must be aware that these will be time consuming and can be quite expensive. If conducting

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the work in a restaurant or plant, one of the challenges is to minimize disruption of normal operations.

When putting together a frying study to develop baseline data, the organizers need to determine which chemical tests will be done, which physical tests will be done, how sensory work will be done, and what sampling plan to establish. It's essential that the fresh oil be fully characterized. Tests on fresh oil may include the following:

- Polar materials
- Polymers
- Soaps
- Flavor
- · Free fatty acids
- Oxidative stability index (OSI)
- Peroxide value
- Anisidine value
- Fatty acid profile
- Trace metal

At least two samples should be tested. Once the testing has been completed, the results should be compared with the oil specification to determine whether or not the samples meet established specifications.

Once the fresh oil has been characterized, the next step is to prepare for the baseline study. The fryer must be completely cleaned, which means ensuring that all residual cleaner is completely removed. Rinse with water and check the pH to ensure that the pH of the rinse water matches that of fresh water. The researchers performing the study must also confirm frying times and temperatures, determine the foods to be fried, and decide how records will be kept.

The sampling schedule must also be established. Table 1 (above) shows a recommended sampling schedule.

Testing the hot oil immediately after startup but before frying is initiated is extremely important. It will let the researchers know whether or not the fryer was properly cleaned. If residual detergent and water remain in the fryer, the metals in the detergent will form soaps, which act as prooxidants during frying and will damage the oil.

Collect oil samples at the intervals noted in Table 1 on each day of the study until you reach the endpoint. When it comes time to add oil to or top up the fryer, be sure to collect the sample before adding oil. Adding oil will dilute the oil in the fryer and will affect test results. When collecting samples of hot oil, the person collecting the samples should wear the appropriate personal protective equipment (PPE), which should include gloves, eye protection, and a protective smock of some sort.

Sensory work on the fried food should be done at the same intervals. The sensory testing should be done with input from the company conducting the study. They know the products better than anyone else and are, therefore, the experts on the sensory parameters of food. The oil samples must be collected and placed in properly labeled containers in preparation for delivery to the testing laboratory. The number of chemicals tests that are done depends on the operator. The more tests that are done, the more you will learn about the system. The same tests that were highlighted for fresh oil are the ones that can be done on the heated oils, with the exception of oil flavor.



Final oil before and after filtering.

Table 1. Sampling Schedule

- Fresh oil
- Hot oil before frying
- 30 minutes after frying
- 1, 2, 4, and 8 hours after frying
- · End of shift
- End of day's operation

The focus should be food quality and not the taste of hot oil. At minimum, tests for free fatty acids, soaps, polar materials, and polymers should be conducted. If a company is using a rapid test of some sort, that test should be incorporated into the study.

During frying, be sure to monitor the amount of food fried, frying temperatures, how much oil is added to the fryer, and whether there were any deviations during the study. It's also a good idea to observe what goes on during frying operations. If the oil begins to foam or to become significantly darker, record these observations. It is also useful to record anecdotal information during a baseline study. For example, if a restaurant operator's baseline includes using a system or practice that the workers find hard to use for some reason, record that information and the problem or problems. A proposed change may make life easier for the workforce, and any change in protocol that makes life easier for people will be appreciated. In fact, if something is easier to do there is a greater chance that the procedure will not only be done, but will be done properly.

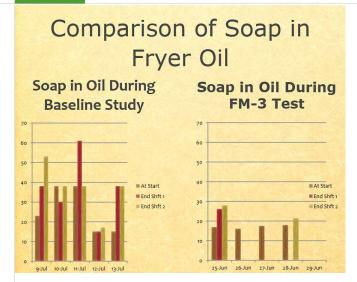
Research personnel should also be available throughout the study to assist and help keep the study on track. This is especially important when working in a restaurant or a food processing facility. The study should continue until you reach the endpoint established prior to initiating the work. This could be poor food quality or one of the chemical markers of oil degradation.

Types of Tests

So, what do the different tests mean? Let's take a look at a few of them.

Free fatty acids (FFA). Free fatty acids by themselves have no impact on the oil or fried food flavor. In fact, it is possible to fry foods in 100% free fatty acid mixtures. Fatty acids are, however, more prone to

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oxidation reactions, which create problems in foods and cooking oils. They're easy to measure, so they're often used as a quality indicator in frying operations, especially in snack foods such as potato chips.

Soaps. Soap is produced in the oil during chemical refining. This is subsequently removed completely from the refined oil using special adsorbents that remove the soap, along with the trace metals and residual phosphatides, from the oil. In frying oils, soaps will form through the reaction of free fatty acids and metals in the presence of water. These metals include calcium, magnesium, sodium, and potassium. Sources of metals are food and residual caustic from cleaning operations. Soaps are surfactants and will be absorbed onto frying food. Many active filter media are designed to reduce soaps in oils. Soap is a detergent. Presence of soap causes rapid rise in FFA in the oil during frying and also causes more rapid oxidation in the oil.

Total polar materials (TPM). The simplest definition for total polar materials is all non-triglyceride materials soluble in, emulsified in, or suspended in oil. Fresh oil typically contains 2 to 4 percent polar compounds but may contain less. Once oil is exposed to frying conditions, conversion of trigylcerides is initiated and is irreversible during the frying process. Proper oil management can slow polar material formation and extend the life of the oil. There are many who consider polar materials the single most important test for degrading restaurant cooking oils. In fact, Spain, Portugal, Italy, Belgium, France,

and various states/ cantons in Switzerland and Germany have established regulatory limits for polar materials in restaurant frying oils. In 2000, the DGF (German Society for Fat Research) stated that polar materials and polymeric triglycerides were the best indicators of oil abuse. This statement was made as part of the

published summary of the 3rd International Symposium on Deep-Fat Frying held in Hagen, Germany. Unfortunately, testing for TPM requires a skilled technician and the test itself is expensive.

Polymeric triglycerides. Polymers are the single largest class of degradation materials in frying oils. They include dimers, trimers, polymers, tetramers, and others, and are formed through both oxidative and thermal reactions. They manifest themselves as lacquers or brown buildup on fryers or in oil. Polymers are complex and generally indigestible. As noted above, polymeric triglycerides, along with polar materials, are excellent indicators of oil abuse.

Para-anisidine value (pAV). For every molecule of peroxide that breaks down, twice the equivalent amount of anisidines are formed; however, some of these will disappear through further oxidation reactions, forming dimers and trimers. This test is valuable for the detection of reprocessed edible oils. If an oil producer further processes their oils to reduce levels of free fatty acids, the end result will be an increased anisidine value.

Once the baseline data has been compiled and reviewed, the operator should have a good idea of how the oil degrades over time. The sensory data and chemistry can also be reviewed, and one or more of the chemical markers of oil degradation may now be selected as endpoint indicator. Operators will also have a good picture of how their frying systems run, giving them the background data to properly evaluate any proposed changes aimed at system optimization.

Frying Studies for System Optimization

Once a food processor or restaurant operator has established a solid baseline for frying performance, they are set up to properly evaluate any change to their frying system. As noted above, the change can be anything, including a different filter system, a change in food formulation, or the addition of an oil additive. The procedure for evaluating the change will mirror that used to establish the baseline data. The only change between the baseline study and the system or material being evaluated will be what is being evaluated. The sampling schedule will remain the same, the test protocol will remain the same, and the way that the data is analyzed will remain the same.

Once the data has been reviewed, the operator will have a good idea of the potential benefits of the change. Among the potential benefits such studies have been able to demonstrate include but are not limited to the value of switching to an active filter system, the problems inherent with multi-pot frying (frying in which products are switched from fryer to fryer), oil life extension by dropping temperatures in a fryer, and the value of adopting a rapid test kit as an endpoint indicator. These are also benefits that operators can put a number on, that is, a return on investment or information that shows a change is not only technically solid, but a cost savings. Figure 1 shows the benefits of the use of an active filter system on controlling soaps in an industrial frying system. This was deemed to be a significant contributor to enhanced shelf life and improved oil life.

Operators that follow this disciplined approach will be able to develop information that is essential for making scientifically sound decisions in a business environment. They can help processors work to continuously improve their operations from a quality and safety standpoint, which is one of the basic principles of the food safety management system known as the hazard analysis and critical control point system.

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QUALITY



Food Fraud Prevention

The steps to mitigating food fraud are right at your fingertips

BY BRIAN WATTERSON AND ALMA DELIA HERNANDEZ

hen I (Brian) was a kid, I remember eating dyed pistachios that turned my fingers pink. While the color was amusing to me then, it turned out that red food coloring had been used by the producer in Iran to cover stains, blotches, and mottled markings that occurred during harvesting and drying. I also remember news of cheap types of fish being substituted for or misbranded as the more expensive orange roughy or mahi mahi, misleading consumers to pay more for a lesser product. Each of these was considered food fraud and, unfortunately, the issue has not gone away.

In fact, due to increased oversight and detection tools, food fraud seems to be happening more than ever and is likely more prevalent in the supply chain than is widely known. As we can see from the

examples above, it is not a new problem either; the practice of adulterating food for economically motivated reasons has been going on for years.

Estimated to cost the industry \$30-40 billion annually, food fraud can take place through various means. The most common of these are adulteration by substitution, omission, dilution, falsification, deception in the production method or its origin, intentional mislabeling, or masking a defect or contamination.

In addition to the industry, brands, and products that can be impacted by fraudulent ingredients, end consumers are also harmed by food fraud. One example that resulted in a food safety issue is the wheat gluten that was contaminated with melamine to inflate its protein content measures and imported from China in 2007. When used as an ingredient in pet foods, it sickened and

killed hundreds of cats and dogs by causing kidney failure in those animals.

Another instance of food fraud that may have occurred was in 2015, when it was speculated that suppliers added cheaper ground up peanut shells and almond husks to ground cumin, a premium quality spice. Meant to "bulk up" the product and make it heavier to increase the supplier's margins, the obvious concern was ingestion by consumers with peanut or tree nut (almond) allergies.

Food Fraud During a Pandemic

The current COVID-19 pandemic has likely further incentivized criminals to commit food fraud. In some countries, stay-athome measures and employee illness have increased the number of employees absent from their jobs. One example was the number of positive virus cases in meatpacking plants here in the U.S., which has led to a reduction in the number of active operators in those plants, with the consequence being a decrease in production. In some cases, this decrease has led to a shortage of raw materials and consumer-ready products, creating a domino effect in the next links in the food supply chain. This shortage and others around the world are then sometimes replaced by fraudulent ingredients and products that don't meet client and consumer expectations.

Dependence on materials imported from countries with food manufacturing workers impacted by the pandemic has also put the continuity of the supply chain at risk. International trade has been hindered due to the lack of appropriate logistics, with closed borders and a decrease in the availability of transportation preventing materials from arriving on time. Each of these has created an opportunity for fraudulent activity.

Further, because the economy in most countries has been impacted and consumers have lost some of their purchasing power, people are looking to buy products at the lowest possible cost. As a result, they may be more interested in a product's price than the brand they are used to or its quality, thus increasing vulnerability in the products they are purchasing.

In each of these scenarios, fraudsters may be tempted to obtain economic gain

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through the intentional adulteration of the food. They may choose to send their clients lower quality materials, or they may replace, dilute, or modify, without declaration, certain ingredients or products just to meet their customer's order. They may also be taking advantage of the fact that clients have fewer personnel to supervise the reception and oversight of those materials due to the pandemic.

Assess, Implement, and Review

So, what can be done to minimize food fraud? Foremost, FDA's Food Safety Modernization Act and Global Food Safety Initiative (GFSI) Benchmarking Requirements require food manufacturing facilities to develop and document a food fraud vulnerability assessment and mitigation plan.

Generally, a risk or vulnerability assessment begins by understanding what ingredients are used at a facility to make your products. The Food Protection and Defense Institute defines the top 10 most fraudulent foods as alcoholic beverages, oils and fats, meat and meat products, honey, spices, grains and grain products, coffee and tea, fish and seafood, dairy, and produce. Separately, Decernis' Food Fraud Database defines their top 10 most fraudulent foods as olive oil, milk, honey, saffron, orange juice, coffee, apple juice, grape wine, maple syrup, and vanilla extract.

Many of these ingredients are known historically to be at an increased risk for fraud, which means there is a higher risk of fraud in your supply chain if you are receiving or using these ingredients. As an example, the gap between production and consumption of both olive oil (specifically extra virgin olive oil) and honey has been studied. While the global industry is only currently producing a certain amount of these ingredients, the world consumes more than what is produced. Thus, they are being fraudulently diluted, substituted, concealed, or mislabeled.

When conducting a vulnerability assessment to determine the risk of fraud in your supply chain, consider historical risk as a factor within the assessment. Additional examples of risk factors could include your history or relationship with a supplier and complication of the supply chain, such as how many points along the

supply chain the ingredient goes through until it reaches your facility. Economic factors can also make fraudulent activity more attractive and could include a pandemic or ecological factors such as drought, pestilence, and the nature of the ingredient, such as a powdered or liquid ingredient versus a solid item such as an apple.

Once these factors are chosen, you should develop a risk rating system. These ratings could be Low, Medium and High, or Minor, Major, and Critical; what this would mean for each risk factor must be identified. Next, conduct an assessment using the risk factors and risk rating system established, while documenting your results.

In addition to the high-risk ingredients, look at your most expensive ingredients. Often, those products that have assured status, such as organic, gluten-free, and non-GMO, are most easily susceptible to fraud. Others might be easy to adulterate and/or difficult to test, so manufacturers and suppliers need to stay current with historical and developing threats. Resources to do so are offered through various trade associations, government sources, and private centers. Some also offer access to food fraud databases and free assessment templates.

Once you identify the risk of potentially fraudulent activity for an ingredient during your vulnerability assessment and per GFSI requirements, you are required to develop and implement mitigation strategies to significantly minimize or prevent it. If you identify economically motivated adulteration (food fraud with a food safety issue), then you will need to develop or implement preventive controls. Some common strategies include supplier audits, sampling and testing, final product testing, and approved supplier programs.

Once you've completed your assessment and developed mitigation strategies to address identified risks, there is still work to do. You'll need to review your program on a regular basis, understanding that fraudsters will always look for opportunities. For example, GFSI audits such as BRC and SQF require that a food fraud vulnerability assessment be conducted annually to consider the susceptibility of raw materials.

Further, it is important for suppliers and customers to maintain a close relationship while continuing to oversee supplier approval and evaluation processes. An in-depth, approved supplier program is essential. Processors must continue to carry out analysis that, based on their risk assessment, each has determined is necessary to corroborate the legitimacy and origin of the materials received. You must continue developing rapid and accessible analytical methodologies that identify in a timely manner whether a food is fraudulent.

You will also need to continually review and assess to determine if there is new information that may identify an increased risk of fraud. This process is called horizon scanning. An example of increasing risk of fraud could be the situation we have all experienced with the pandemic. As you scan the horizon, have there been disruptions specific to your supply chain and are you prepared for the next potential disruption?

The Need for Diligence

Unfortunately, there will always be unscrupulous people who will mislead consumers to achieve dishonest profits. These actions severely impact those companies that cannot compete against fraudulently low prices and poor quality, and that are unwilling to put consumers in harm's way. Additionally, it seems that those who are responsible for committing fraud are often one step ahead of the rest of us. Once a possible adulteration case is detected, criminals are already working to go unnoticed again. As long as there is demand for a product, there will continue to be a threat of fraudulent activity related to that product.

However, more information is available today on the production methods used, the regions from which products originate, and the methods that allow for the identification of adulteration. There is also a wealth of information available to assist in planning and executing mitigation strategies.

While food fraud may not always be as easy to detect as red food coloring on your fingers, the steps to mitigating food fraud are definitely right at your fingertips.

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ood adulteration, whether intentional or accidental, poses a risk to consumer health and defames food manufacturers. In addition to maintaining best manufacturing practices, it is crucial for food scientists to develop reliable methods to test food quality, detect traces of unauthorized adulterants, and remain compliant with regulatory requirements. For a variety of food products, carbohydrate components serve as authenticity markers and are often used to validate food quality.

Despite their widespread use, analytical techniques such as liquid chromatography (LC) or gas chromatography (GC) often present challenges when it comes to obtaining accurate carbohydrate measurements, compromising important information at the expense of public health. Here, we explain why it's necessary to choose sensitive and robust methods for carbohydrate analysis within the food industry. We also discuss how using high-performance anion-exchange chromatography coupled with pulsed amperometric detection (HPAE-PAD) can identify food adulterants with increased confidence.

Carbohydrate Detection: The Need for Sensitive and Robust Methods

Carbohydrate profiles in certain foods, such as honey, agave syrups, fruit juices, and coffee, act as markers for authenticity and can be used to detect food fraud. Adulteration of honey or agave syrup can involve their dilution with cheaper, often unhealthy alternatives, such as high fructose corn syrup or saccharose syrup, produced from beets or canes. In these instances, analytical methods that can accurately measure sucrose levels in honey or perform oligosaccharide profiling in agave syrup help distinguish the genuine food products from their fraudulent counterparts.

The familiarity and widespread use of LC and GC prompt scientists to use these techniques as a default approach for carbohydrate analysis; however, these methods aren't the best choice to detect, measure, and study carbohydrates. The high polarity of carbohydrates makes them difficult to reliably retain and separate using reverse phase chromatography. As carbohydrates are weakly acidic, dissolving high concen-

trations of them imparts higher acidity to the samples. At extreme pH levels, metals from the column's surface strip away and adhere to the packing materials, tampering with the column's integrity. Moreover, the inherent viscosity of these samples will also require optimized column heating to ensure a consistent flow through the column. Any fluctuations to lower temperatures can result in changes in viscosity of the sugar samples, causing them to stick to the column surface, generating backpressure and making the method irreproducible.

Additionally, carbohydrates tend to have very few chromophore groups and can't, therefore, be detected with adequate sensitivity using ultraviolet (UV)-based detectors. Switching to refractive index or low-wavelength UV detection methods prevents the use of gradients due to their sensitivity to the eluent and sample matrix components. Gradients can also increase the baseline noise, thereby reducing the signal-to-noise ratio and decreasing the sensitivity of measurements.

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Relying on discrete elution times is also challenging as the monosaccharide components, glucose and fructose, both have the same molecular weights of 180.16 g/mol. When in solution, they also both exist in ring forms, making them indistinguishable, especially given the lack of chromophores. Using a strong base can push the equilibrium to one side and stop the interconversion between ring and chain structures, providing a slight difference in retention time. However, at higher base concentrations, the monosaccharides are not retained for too long and will elute out very quickly.

One option to retain carbohydrates and boost sensitivity for measurement is to derivatize the samples. Though several isomers and chains of a carbohydrate molecule can be derivatized, requiring a summation to yield the total result for one carbohydrate can make method validation complicated, laborious, and time-consuming. Furthermore, due to the diversity of sample matrices used in the food industry, a thorough sample cleanup prior to injection is often necessary to prevent any assay carryovers, making the sample preparation process more tedious.

HPAE, on the other hand, is a chromatographic technique better suited to separate, detect, and measure carbohydrates as food authenticity markers. It takes advantage of the weakly acidic nature of carbohydrates for highly selective separations at high pH using strong anion exchange stationary phases. At higher pH, carbohydrates are partially ionized and can, therefore, be separated by anion exchange mechanisms.

Coupling HPAE with PAD allows direct quantification of nonderivatized carbohydrates at even low-picomole levels with minimal sample preparation and cleanup. The direct form of analysis precludes any biased selectivity toward certain carbohydrate structures, as may be seen in other analytical methods measuring derivatized sugars. This simplifies method validation and brings muchneeded reproducibility to these techniques, enabling intra- and inter-batch testing for quality control.

There are two key reasons why HPAE-PAD is more selective and specific for carbohydrate analysis compared to LC or GC approaches. First, the specific detection voltages used in the pulsed amperometry ensure that it only measures analytes that are oxidizable at those particular voltages. In the case of carbohydrate analysis, the settings provide a sensitivity that is several orders of magnitude greater than other classes of analytes. Second, due to the anion exchange separation, neutral or cationic sample components that may be oxidizable at the same voltages elute into or closer to the void volume of the column, thereby removing any analyte that may otherwise interfere with the carbohydrate analysis.

Food Safety Testing with HPAE-PAD

When it comes to food safety, the data obtained are only as good as the method used. HPAE-PAD methods are commonly used to detect and quantify unauthorized additives in food products that have carbohydrates as their quality markers. Additionally, the method is regularly used to characterize the carbohydrate components present in the food sample to gain deeper insights into their composition, serving as another testing parameter for future measurements. Below, we have listed how HPAE-PAD can be used to perform safety testing and combat food fraud in popular food items.

Honey. Composed of several sugars based on its floral source, honey is tested for adulteration using sucrose as its quality indicator. Adding cheap sweeteners, such as cane sugar or refined beet sugar, can artificially increase the levels of sucrose in honey. The Codex Alimentarius Committee on Sugars has, therefore, specified the maximum value of sucrose as 5 g in 100 g of honey. Carbohydrate analysis with HPAE-PAD can be used to measure these parameters as well as determine the floral origins of honey, using a few minor sugars as a "fingerprint." Using the Thermo Scientific Dionex CarboPac PA210-4µm column in an HPAE-PAD protocol allows for the separation of 15 sugars in honey with minimal sample preparation, 80-120% precision and accuracy, and a detection limit of as low as 10% adulteration with added syrups.

Agave syrup. Another food product that has recently become a target for food fraud due to its growing popularity

is agave syrup. An alternative to traditional sweeteners, such as table sugar and honey, agave syrup has a low glycemic index, causing a slower rise in blood glucose and insulin levels. As most of its sugars are in fructose form with very little glucose, adulteration with high fructose corn syrup is common. The main producer of agave, Mexico, has recently created a governmentally approved guideline for the characterization of pure agave syrup. In the method prescribed by the Norma Oficial Mexicana, HPAE-PAD is used to determine levels of the main sugars (fructose, glucose, and sucrose), polyols (sorbitol, mannitol), and 5-hydroxymethyfural. After the agave syrup is diluted with water, the carbohydrate profiles are analyzed before and after enzymatic hydrolysis with amyloglucosidase and fructanase to measure the content of sugars as well as fructan.

Fruit juices. The billion-dollar fruit juice industry often encounters dilution and blending with inexpensive and synthetic sweeteners, a ploy to achieve higher margins and larger economic gains. A common adulterant known as medium invert sugar, in which one half of the sucrose has been hydrolyzed to glucose and fructose, closely matches the composition ratio of approximately 1:1:2 (glucose: fructose: sucrose) found in orange juice. When cane sugar is the source of the invert sugar, stable isotope ratio analysis (SIRA) can be used to detect adulteration due to the differing ratios of 13C:12C in orange juice and cane sugar. However, if beets are used to produce the invert sugar, the 13C:12C ratio between orange juice and beet sugar do not differ much as the sugars are produced using similar metabolic pathways. In this case, SIRA can no longer detect adulteration by beet sugar, providing a convenient loophole in food fraud.

Scientists have resorted to HPAE-PAD to characterize beet invert sugar and discover several sugar components that are not present in orange juice. One such sugar not found in pure orange juice is raffinose, a trisaccharide of D-glucose, D-fructose, and D-galactose, which has been used as an adulteration marker for orange juice. Additionally, the signature pattern of late-eluting components appearing at about 60 minutes during the HPAE-PAD run can also be used to identify adulteration.

Coffee. Carbohydrates also serve as tracers to assess the authenticity of instant coffee. Although an unlikely candidate for sugar analysis due to its characteristic bitter taste, at least 50 percent of the dry weight of raw coffee beans comprises coffee carbohydrates. As these undergo Maillard reaction during the roasting process, they contribute to the flavor, aroma, and viscosity in coffee. An HPAE-PAD-based method to determine the free and total carbohydrates in instant coffee has been prescribed by the Association of Analytical Chemists (AOAC) Official Method 995.136 and is currently used by the British Standards Institution. In a recent application study, the AOAC method was tested using the Thermo Scientific Dionex CarboPac SA10 column. The former method, which typically has a run time of 80 minutes, was made significantly faster by using the column. The guicker method had a run time of 10 minutes, only needed deionized water for continuous operation, and offered the same level of accuracy and sensitivity,

Analytical methods that can accurately measure sucrose levels in honey or perform oligosaccharide profiling in agave syrup help distinguish the genuine food products from their fraudulent counterparts.

differing only in its total analysis time and number of resolved peaks for coffee carbohydrate analysis.

All the food testing examples mentioned above justify the argument that, with the increasing demand for reproducible, fast, and simple methods to profile a wide variety of analytes in the food industry, HPAE-PAD has steadily emerged as a reliable method of choice to analyze carbohydrates.

Better Methods, Safer Food

As traditional methods used in the food industry start becoming outdated, new and problematic adulterants that are similar in structure to the genuine components can sneak into the food industry by taking advantage of either inadequate sensitivity or lack of specificity. Food testing laboratories will need to continually evaluate, test, and validate new methods to stay ahead of food fraud, while keeping up to date with the regulations. Similarly, upgrading conventional methods with the latest technology makes them more robust and productive. Choosing the most appropriate method to accurately detect carbohydrate-based authenticity markers, such as HPAE-PAD, will result in safer food for the community and sustain consumer trust with the manufacturer. ■

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Testing



Efficient Detection of *Vibrio* spp. in Seafood

Rapid methods can greatly aid in outbreak investigation and management of public health concerns

BY FREDERIC PASTORI AND WEIJIA WANG

ibrio spp. represents a serious threat to human health. Three species in particular are linked to gastrointestinal issues and can lead to infections and septicemia: *V. cholerae* (VC), *V. parahaemolyticus* (VP), and *V. vulnificus* (VV). These pathogens are most commonly found in raw or undercooked seafood such as fish, squid, oyster, and shrimp. *V. cholerae* is the main factor that

causes cholera, which is an important public health problem worldwide.

VP was <u>first identified</u> as a cause of foodborne illness in Japan in 1950 when 272 individuals became ill and 20 died after the consumption of semidried juvenile sardines. VP causes three major syndromes of clinical illness: gastroenteritis, wound infections, and septicemia. The most common syndrome is gastroenteri-

tis. Symptoms of this syndrome include diarrhea with abdominal cramps, nausea, vomiting, headache, and low-grade fever. Strains from this pathogen that are isolated from diarrheal patients produce either the thermostable direct hemolysin (TDH), the TDH-related hemolysin (TRH), or both, while hardly any isolates from the environment have these properties.

In 2009, a *Vibrio* outbreak in Singapore was associated with consumption of Indian rojak (a traditional salad of fruits, vegetables, and seafood). The Singapore Ministry of Health concluded its investigations into the food poisoning cases and identified VP traced to the cross-contamination of rojak and raw seafood ingredients harboring the bacteria as the source of the outbreak. Laboratory investigation confirmed 13 of the cases to be positive for VP, including the first fatal case.

The risk of these pathogens may only be getting worse. Scientists warn that, because climate change causes an increase in sea surface temperatures and a rise in sea levels, VP and VV infections will become more common. This is because warmer, rising waters create an even more welcoming environment for the deadly pathogen. Subsequentially, it is especially crucial that methods to efficiently detect *Vibrio* are developed.

Testing for Vibrio

FDA's Bacteriological Analytical Manual (BAM) (Chapter 9) and the International Organization for Standardization (ISO) 21872-1:2017 are the two standard methods widely used for the detection of *Vibrio*. While these are the standard, there are still many issues that arise with these methods.

Neither of these methods provides a good selective enrichment medium for *Vibrio* species. Instead, different formulations of alkaline peptone water (APW) have been used as the preferred enrichment for certain *Vibrio* targets or food matrices. Still, no single enrichment procedure for classical isolation, by plating or selective media, has been validated by FDA or the ISO for all three strains.

Finding a single enrichment procedure that works for all three different strains is an important challenge faced by seasoned microbiologists today. The preferred enrichment temperature for VC is 42°C, but the preferred temperatures for VP and VV

differ at 35-37°C. Furthermore, some food matrices containing high background flora or inhibitory compounds, such as bacterial growth or PCR inhibitors, might require alternative enrichment schemes. In addition, the duration of enrichment and plating efficiencies of presumptive isolates could affect classical confirmation, making them difficult. Overgrowth of competing organisms might occur if enrichment duration exceeds 20 hours. This makes it difficult to isolate Vibrio on selective agar plates. Thiosulfate citrate bile salts sucrose (TCBS) agar is widely used as the main selective agar for isolation of the three target species by both the FDA-BAM and ISO methods.

Cultural confirmation is also a challenge. Not all isolates of the target species exhibit the same growth properties. Different isolates of the same species have shown as much as two logs differences in plate counts on TCBS plating efficiencies. This difference could be attributed to factors such as boiling time or depth of the poured media. Another challenge is that the Vibrio species might be subject to a biological phenomenon known as "viable but non-culturable." When in this state, the pathogen is not able to be detected by traditional culture methods but is able to cause infection. A third challenge is that there are several atypical isolates of the target species, specifically for VP. Because of this issue, molecular-based methods, such as DNA sequencing, PCRbased methods, or matrix assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) are good alternatives because they can confirm atypical Vibrio results, ultimately improving accuracy.

Standard methods are also labor intensive and rely on microbiological/biochemical identification. For seafood processors and inspections, current methods require at least three to five days for results and subjective interpretation for the screening of negative samples.

Food testing laboratories in the seafood industry are in need of a fast and accurate method to reliably detect the three main *Vibrio* species. An easy-to-use and rapid method that can reliably report results would allow seafood to safely get to market faster. Because climate change causes an increase in sea surface temperatures and a rise in sea levels, *V. parahaemolyticus* and *V. vulnificus* infections will become more common. This is because warmer, rising waters create an even more welcoming environment for the deadly pathogen.



Real-Time PCR Detection

The advantages of real-time PCR are highlighted when used for the detection of *Vibrio* because of the challenges outlined above, such as the background flora naturally present in seafood matrices and the enrichment protocol challenges.

Since its invention, real-time PCR technology has been greatly improved so that it is more stable, accurate, and rapid for specific applications. As the technology evolved, new chemistries were developed based on fluorescence detection.

This evolution allowed for real-time PCR kits to achieve a high level of specificity and sensitivity when detecting *Vibrio*. Each test well can be used to detect all three important strains of the pathogen at the same time, decreasing the time it takes to get a result. A PCR kit may be able to detect the pathogen in 94 samples in less than two hours, rather than the typical three to five days. Further, the workflow is often optimized to be simple and user friendly.

While real-time PCR methods often offer quicker turnaround times than many of the standard methods, they can be prone to false positives due to free DNA from dead cells found in the sample. Emerging PCR-based methods should address this limitation.

Recently, Bio-Rad Laboratories received AOAC validation for its <u>iQ-Check Vibrio assay</u>. The assay uses a single-step enrichment followed by real-time PCR for the multiplex detection of VC, VP, and VV. This method provides rapid qualitative detection and differentiates among all three strains in seafood products. The solution also has an optional Free DNA Removal Solution that can address ambiguity caused by dead cell DNA by removing free DNA in the sample with a simple non-toxic protocol, while the intact DNA in living cells remains unaffected.

This method was evaluated and approved by the AOAC Performance Tested Methods (PTM 032002) program. Results of the AOAC-PTM validation study demonstrated no differences between the iQ-Check *Vibrio* method and the U.S. FDA BAM *Vibrio* reference method.

The assay and the Free DNA Removal Solution were validated for use with 125-gram test portions of cooked and raw shrimp, raw mussels, raw oysters, and raw tuna. The assay was approved for use with Bio-Rad *Vibrio* Enrichment Broth (after a seven- to nine-hour enrichment period) and alkaline phosphate water (after a six- to 18-hour enrichment period), giving the user flexibility to optimize the method to their lab workflow, while significantly cutting down the traditional three to five days it takes to get results with standard methods.

Rapid methods like this one can greatly aid in outbreak investigation and management of public health concerns. The ability to obtain results in a shorter amount of time, particularly when it comes to pathogens such as *Vibrio* species, can be critical in reducing the impact from a food safety event.

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In The Lab



Fire Up Your Next Food Authenticity Project

Method development and routine deployment of food authenticity methods using LC/Q-TOF

BY KAREN E. YANNELL, PHD, DANIEL J. CUTHBERTSON, PHD, AND FRANK KUHLMANN, PHD

ood fraud is the manipulation of a commodity or product in some manner, intentionally or unintentionally, that isn't known to the consumer. Typically, it's when a high-end expensive product is diluted or replaced with a lower end cheaper product. This practice is on the rise, as premium ingredients are becoming more expensive, but remain in high demand. Economically motivated food fraud is estimated at more

than \$10 billion annually in the U.S. alone. Additionally, manipulating or misstating ingredients in a food product may result in health consequences to some consumers, such as when allergens are present. Laboratories need to test for food authenticity, because consumers want confidence in the products that they're buying.

One approach to food authenticity testing is to monitor the molecular composition of the foodstuff with liquid or gas

chromatography coupled with mass spectrometry (LC/MS or GC/MS). Traditionally, food authenticity testing has been performed by searching for one or more adulterants or impurities, which are then quantified to determine fraud. However, this only works if the adulterants are known a priori. Further, fraudsters can always find new adulterants to add. An increasingly common approach for this analysis is to profile small molecules, or features, in a commodity with high resolution MS, using many of those features to indicate if a product is adulterated. Using authentic food samples, a statistical model is built; when a new sample is tested, its features are compared with the model and the sample is classified into a group. Because this method does not use information from specific adulterants and does not even need to identify the features, it's nearly impossible for fraudsters to manipulate.

Although profiling, model building, and classification of samples sounds complicated, it's becoming increasingly routine with user-friendly workflows and software available for laboratories to begin this type of testing. But, before you start your analysis, there are some concepts and best practices you should understand.

Samples

Well-defined and verified samples of food products grouped by type are critical for building statistical models. These should include as many individual samples in each group as possible to capture enough sources of variability and to reduce potential non-measurement biases from the model. An example of this could be providing different lots of honey from different production sites for each type of honey grouped in the model. This would reduce bias in the model toward a specific lot of honey or toward a specific manufacturing line and focus only on features that are separating the different types of honey. You should also plan to acquire an additional number of authentic and adulterated samples to be withheld from the model at creation and used to test, or validate, the model later.

Samples must be extracted in a manner that is reproducible for the endogenous metabolites that are of interest. Try to maintain simple protocols, if possible. For example, a liquid extraction of a ho-

mogenized sample with an organic solvent is a good protocol to begin with, as this will extract the compounds of interest with few steps, avoiding the introduction of potential contamination and error. However, the complexity of some samples may require additional sample preparation. If a liquid extract is still too high in matrix for routine analysis, try altering the pH or temperature of the extraction to produce a cleaner extract before testing a solid phase extraction (SPE) approach. SPE protocols may inadvertently remove analytes of interest for the analysis or introduce too much sample handling variation for a robust model to be built.

Instrument Platform

Although there are other platforms that are desirable for authenticity testing, when beginning research for a model, consider a high-resolution instrument such as a quadrupole time-of-flight (Q-TOF) to ensure enough resolution to differentiate analytes and increase the specificity of the model. This instrument also allows for untargeted models that are harder to cheat than targeted models. A Q-TOF has an extended dynamic range, which is important for analyzing complex samples at a range of concentrations in a heavy sample matrix because it allows you to detect small amounts of analytes that are coeluting with high abundant analytes. Also, try to avoid instruments that use ion-trapping capabilities due to limitations in their dynamic range and ion capacity, which can leave critical analytes out in complex food matrices. Ultimately, in complex food matrices, a Q-TOF will generate the most reliable and robust data for model building and subsequent authenticity screening.

Quality Control

External and internal standards should be used to monitor instrument performance and help troubleshoot any acquisition issues that might arise. These standards are not intended for any peak area correction, but rather to monitor peak area and retention time reproducibility. During method development, mass accuracy, area counts, and retention time should be tracked and proven stable. Incoming data

that does not meet quality standards may need to be discarded. If reliable quality characteristics are not initially achieved, sample preparation, acquisition parameters, or instrument maintenance should be reevaluated to achieve a stable data acquisition.

> Quality control (QC) samples need to be created from the model samples. These are pools of

samples from the different groups in the model, e.g., types of honey, and a matrix pool of all the samples, e.g., all honey samples. The samples should be pooled before sample preparation and the QC should undergo the same sample preparation as

the model samples. It is possible to also make an adulterated QC by mixing the group QCs in a known manner. Injecting the same pooled QC sample multiple times at the beginning of development and periodically through the development is advised to ensure that reproducible retention times, mass accuracies and area counts are achieved. If not, it's appropriate to adjust the methodology at this stage to make those values as reproducible as possible.

Data Acquisition

Consistent and reliable methods are required to produce robust measurements for using a model. For this purpose, MS-only data acquisition is sufficient when using high resolution mass spectrometers. Compound identifications generally aren't required for food authenticity modeling but, if identification is required, MS/MS experiments can be done with a Q-TOF. The most important thing to optimize is the acquisition rate, or scan speed, so that enough data is collected across the chromatographic peak widths for robust integration.

Diverting the flow from the mass spectrometer to the waste line is an important aspect of an acquisition method that is often overlooked. In reversed phase LC, the first 0.5 min, the high percent organic

and equilibration portions of the run are dirtier, irreproducible fractions. Diverting these to waste can go a long way toward maintaining the performance of the mass spectrometer. Besides this, features eluting at these time points can be inconsistent and not desirable for building the model.

Capturing variation in the method development is crucial to building a good model. Not only does variation in the model samples need to be captured, but so does variation in the sample prep and data acquisition. This is accomplished by acquiring your model samples in different batches processed on different days. Additionally, if you use more than one mass spectrometer, analyzing the model sample set on both systems is important.

Chemometric Statistics and **Model Building**

The model is built by evaluating the relative intensity of only a certain number of features, which proved to be significantly different between the classes based on the statistical analysis. Feature extraction, statistics, and model building need to be done to develop the full method before moving on to validating. The model samples will go through this process as a batch of data, while the unknown samples will be processed individually using the developed method and routine software, MassHunter Classifier.

Features in the model samples should be extracted using a recursive extraction methodology, such as the one in Profinder, for a high-quality extraction of the features in your model samples. All the discovered features are moved into a chemometric software such as Mass Profiler Professional (MPP), where they are filtered down and a model is built. The statistics performed should result in very robust features that can resist instrument or method drift over time. Often, simple statistical methods such as t-test and fold change are all that is needed to figure out what features are significant to the groups. Using a high threshold at the fold change step is important to remove low abundant features, as these will likely be the least reproducible over time. Models then use only these features in a supervised fashion, using the groups of samples known to the model. Varying the filtering and statistical analysis param-

(Continued on p. 44)

eters is suggested to optimize the separation of the classes. Using these strategies will help you build robust, longer-lasting models, but it cannot overcome variability from experimental design, sample preparation, and data acquisition as discussed above. Once a statistical workflow in MPP is established, these steps can all be automated and easily shared with colleagues and collaborators. It also permits you to execute and build models easily, more frequently, and with less error.

While there are many model types available, principle components analysis (PCA), partial least squares discriminant analysis (PLSDA), soft independent modelling of class analogy (SIMCA), and various types of decision trees are commonly used. In principle, the model type should be selected based on your experimental design and the desired validation outcome. Decision trees, among the simplest types of models, make a series of "if/ then" statements about sample class and feature abundance. A PLSDA model will give one prediction per sample, assigned as authentic or non-authentic, and a confidence score for the prediction. A SIMCA model gives each sample a distance score for each group, rather than a confidence score. The lower the distance score, the more closely it resembles that group. The distance scores can also indicate if the sample is pure or may be adulterated. If adulterated, the distance scores of the other groups could indicate with what substance it is adulterated. For routine use, it's best to calibrate confidence and distance values with known QCs or known authentic and adulterated samples.

Validating a Model

Validation, or rigorous testing of the model, is important to understand the sensitivity and specificity of the model. The QC samples for each group should be processed several times and treated as test samples. Additionally, if a new set of authentic samples is procured, those can be used as test samples in the model. These pure test samples should be used to determine the confidence value of a pure sample. Similarly, adulterated QCs or authentic adulterated samples should be used to determine the confidence of classifying a sample as adulterated. Running

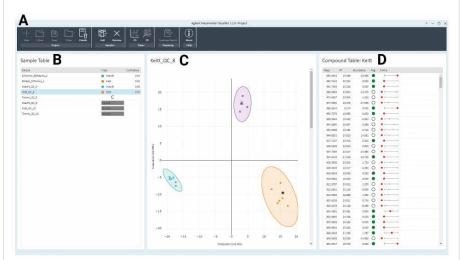


Figure 1: MassHunter Classifier software has easy-to-understand analysis and reporting. Start a new project (A) and enter the method and samples to test (user interface not shown). All the samples submitted appear in the Sample Table (B) along with their identification and confidence scores. 2D or 3D PCA plots are displayed, showing all the model samples, and the selected unknown sample is plotted as a black diamond (C). Finally, individual features are compared to the model in the Compounds Table (D), indicating whether their abundance is within the range for the predicted class (green) or not (white). PDF reports are generated by selecting Generate Report (A).

several of these samples after your model samples will allow you to set the confidence or distance value for your model and provide a manner to calculate the sensitivity and specificity of the method.

Deploying a Model

When using the model in a routine manner to run unknown samples, it is important to run the same acquisition method and the same feature extraction steps. It is easy to give an analyst the acquisition method and analysis model and have them use a routine software, like MassHunter Classifier, to produce the adulteration results. There is no need for an analyst to do any statistics, feature extraction, model building, or plot interpretation; the answer is given only by the class label and confidence or distance value reported in the software (see Figure 1).

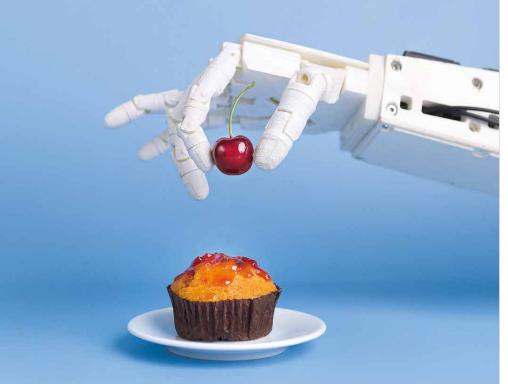
Rebuilding a model is common practice in classification, and model longevity will vary from project to project as new data is gathered and new components used for adulterations are discovered. Over time, the model needs to be tested to determine if it is still working by running pure QC samples and adulterated QC samples, along with any unknown samples. If the QC samples are classified correctly, then the model is still working for known sample groups. If there is a discrepancy in the QC classification or the confidence is out of bounds, then an investigation into

the data needs to occur. In this case, the internal standards in your samples can be interrogated easily to see if a data acquisition error took place. If the internal standards are good, the model may need to be rebuilt to account for other variables in the data. Authentic samples injected regularly throughout the batches of unknowns is strategic so that the model can be rebuilt quickly and efficiently using these new model samples. The analysis likely remains the same, and the automation in MPP allows for quick reproduction of the initial analysis on the new data.

The need for food authenticity testing will continue to grow as adulteration becomes more prevalent and manufacturers need to protect their brands from consumer safety issues and the cost of fraud. For any lab considering getting into food authenticity, authenticity models must be built with an experimental design that maximizes longevity and robustness. Key components of that design are leveraging software that is not only easy to use but makes authenticity testing routine and LC/Q-TOF instrumentation that performs reliably and robustly in difficult food matrices.

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Manufacturing & Distribution



Automation after COVID-19

The pandemic presses the urgency for food manufacturers to automate

BY KAREN APPOLD

espite being essential businesses that have been allowed to remain open during the COVID-19 pandemic, some food manufacturing plants—most notably meat processing plants—were forced to close due to outbreaks of the virus among employees.

The closures brought to the forefront the vital role that automation could play in the food manufacturing industry. Specifically, automation could allow plants to continuously operate without heavy reliance on manual labor.

Automation is currently used in some areas of food manufacturing to increase

productivity, maintain worker safety, and ensure quality food production. Recent improvements to robotics and sensor data, combined with data processing and the interpretive power of artificial intelligence, have led to smarter, more efficient ways of moving food through the supply chain, says Daniel Bruce, founder and chief artificial intelligence officer at Vinsa, a West Palm Beach, Fla., company that provides computer vision solutions for food manufacturers. Processing plants and warehouses use robotics and automation to transport raw materials, reducing manual handling.

Bruce is also seeing manufacturers use computer vision to monitor and optimize

the throughput of products in manufacturing lines. For example, different products require different amounts of time to freeze as they go through chillers. Because a belt's speed and a chiller's temperature are configurable, manufacturers are hoping to use the technology to automatically detect product coming through, learn optimal settings for speed and temperature, and adjust accordingly.

Furthermore, Pete Zimmerman, a software sales manager at <u>VAI</u>, an enterprise resource planning (ERP) solution provider in Ronkonkoma, N.Y., that provides automation capabilities to food manufacturers and distributors, says that many food manufacturers have adopted automation practices in their daily operations for processes such as entering orders for electronic data interchange or streamlining complex manufacturing processes using programmable logic controller platforms.

For example, managing sufficient supply levels is a critical aspect for food manufacturers. With automated tools and forecasting applications, Zimmerman says manufacturers can determine precisely what goods need to be produced and how much material should be purchased based on supply and demand planning. In the food industry, automated tools in warehouse management that measure things like temperature control, alerting, and inventory levels are increasingly crucial to maintaining food safety compliance.

Automation is also prevalent in most high-volume areas where products and packaging are consistent, such as cereal in boxes or soup in cans, says Tom Steininger, market development director for Dematic, an Atlanta-based company that provides automated solutions for manufacturing, warehouses, and distribution centers. However, meat processing—due to the inconsistent product size, weight, cuts, and so forth—remains mostly manual.

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Slow to Adopt

Despite its capabilities and advantages, the food manufacturing industry has not been quick to jump on the automation bandwagon. "Although the food manufacturing industry has made significant technological advancements over the years, the food supply chain has simultaneously become more complex and demanding and requires the entire supply chain to automate in order to meet demand," Zimmerman says. In addition, food safety regulations and recalls are still a concern for manufacturers and compliance continues to be a top priority. "With better tracking and warehouse technology, however, companies can work toward eliminating recalls or instances of foodborne illnesses."

Although food manufacturers have actively used robots for years for packaging, palletizing, cutting, dispensing, and sorting, the use of robots in other areas, such as picking, has been slower to develop. "With improvements in robotics technology, such as grippers, collaborative robots (which can accurately and uniformly pick and pack products, even fragile produce), and mobile robots, we will likely see many more applications going forward," says Jeff Burnstein, president of the <u>Association for Advancing Automation</u> in Ann Arbor, Mich.

The Impact of COVID-19

The coronavirus pandemic has significantly impacted the food manufacturing industry, including upending food manufacturing operations, halting production, and slowing economic and technological progress. Simultaneously, the outbreak has highlighted serious gaps in the food supply chain. "Many of these gaps are a result of an increasingly spread out and complex supply chain, as well as high demand for faster processing and transparency, which is especially crucial in response to COVID-19," Zimmerman says.

To address these gaps and create a transparent, fully efficient supply chain, companies should invest in solutions that help simplify business processes and increase operational efficiency. A centralized ERP system, for example, can provide insight into the supply chain where shipments are reported by lot number and loca-

tion. "This solution also provides helpful tools such as temperature regulation in which alerts are sent to food manufacturers in real time, so they are conscious of any sudden changes," Zimmerman says.

Future regulations will likely tighten after COVID-19, giving food manufacturers an early warning to implement solutions that will help control their supply chain operations.

-PETE ZIMMERMAN, VA/

Manufacturers can also implement blockchain technology to track products by the unit. Information is placed on a transaction record that can't be altered. Blockchain records the location and time of shipments, helping manufacturers to locate any issues that may arise—which helps to save time and money within the supply chain, Zimmerman says. Additionally, going forward, personnel will likely be placed in a way that includes social distancing on the shop floor. Or, robotics might replace some of them.

Along these lines, Burnstein says he expects to see the adoption of robots accelerate in food manufacturing and processing due to COVID-19. Robots can help with social distancing, reduce human touches on items, grow food in indoor environments, and keep facilities running during a pandemic.

Biggest Benefits

All areas of food manufacturing could benefit from automation and robotics in different ways, especially now, Zimmerman says. Different food manufacturers, such as baking or meat processing, have unique operations that require different tracking capabilities. For example, technologies such as blockchain and ERP can provide complete insight into the supply chain with automated tracking, helping to avoid contamination and potential recalls.

As warehouse worker safety is currently top of mind, warehouse automa-

tion could be the key to food processors meeting food safety standards without a hands-on approach from employees. "Given required temperature levels, demanding supply chains, storage requirements, and transportation—it's already difficult for workers to track and manage everything on their own," Zimmerman says. "By implementing automation technology, it takes some of the burden of manually tracking product information out of the equation and keeps workers safe."

To keep consumers and businesses safe, food manufacturers must diligently follow food safety regulations. Applying technology solutions such as blockchain and ERP can help companies remain compliant in the supply chain. These systems track important factors such as expiration dates, temperatures, and precise origins such as a crop row on a farm, which can reduce the size of a recall, thereby reducing costs. "Future regulations will likely tighten after COVID-19, giving food manufacturers an early warning to implement solutions that will help control their supply chain operations," Zimmerman says.

Other food manufacturers, especially those impacted by seasonality, may benefit from supply and demand applications. If a manufacturer experiences issues with shipping expired products or a surplus of products in the warehouse, this solution helps to track order trends and invoice history—which keeps unused products at a minimum. Additionally, supply and demand applications have the ability to complete purchase forecasting, helping manufacturers ensure that they are stocking necessary products. This eliminates waste from warehouses and enhances supply chain operations.

New Advancements

As the food supply chain becomes more sophisticated and digital, it's imperative that food manufacturers use automated tools to speed up processes and keep up with demand, Zimmerman says.

Sean M. Riley, senior director of media and industry communications at PMMI, The Association for Packaging and Processing Technologies, based in Herndon, Va., says that the trend toward smaller, more compact robots has expanded the potential application areas for robotics in general. Smaller robots are a less bur-

densome capital investment, opening up robotics to operations that previously couldn't afford them. In addition, the precision and dexterity of smaller robots allows them to be used in industries that were previously a poor fit for robotics.

Sanitation concerns have recently been addressed with new hygienic, wash-down compatible robots now being evaluated and added farther up in the production line. These robots can provide tangible benefits to food producers by reducing operational costs, improving food safety, and eliminating tasks that pose an injury risk to human operators. They have also drastically reduced the maintenance costs of robots operating in harsh industrial environments. These robots claim to reduce maintenance costs on individual units by up to 60%, Riley reports.

Adoption Strategies

When looking to adopt automation into a manufacturing facility, companies should begin by having automation suppliers review the material and information flow of their operation and identify opportunities to implement equipment and software that will streamline systems. "Using data, automation companies can right-size automation appropriately to meet a business's current requirements and those in the future," Steininger says.

After learning more about available solutions, companies should investigate the potential for a return on their investment inside and outside of their facilities—paying special consideration to soft-cost

paybacks such as employee availability, retention, training costs, work loss due to illness, product damage, and waste, Steininger continues. Finally, companies should work with a supplier with the capability and interest to be a long-term partner. Being able to count on support before, during, and after implementation will overcome a lot of barriers.

When looking to automate, keep in mind that adopting automated capabilities is an incremental process. "It's impossible to go from a traditional manufacturing structure to a fully-automated warehouse overnight," Zimmerman says. "By starting with smaller projects, such as enhancing barcoding with RFID and automated order entry or automated analytics tools, food manufacturers can begin to see automation's benefits."

A modern ERP system can serve as a good way to start integrating automated tools and applications. "With operational insights and real-time data visibility, ERP solutions speed up capabilities and open the door for more sophisticated warehouse tracking and automated processes," Zimmerman says.

Sean T. Riley, a senior global industry director of manufacturing and transportation at Software AG, which provides software solutions to food manufacturers, says the key to successful adoption is maximizing current automation resources and understanding the true cost of product per each production zone. "While this can be difficult with manual processes, manufacturers already have a significant amount

of data in their process histories," he says. Advanced analytics can analyze, monitor, and predict the operational performance of production processes and the expertise of process engineers, giving food manufacturers the ability to exactly quantify the impact that advanced robotics will have on production processes.

A higher level of training is essential to cultivate the skills required to design, integrate, and maintain the advancement of robotics, he points out. Problem solvers, intuitive thinkers, and trained specialists are needed to fill the skills gap. Automation installations represent the largest improvements at food manufacturing facilities, with more than half of food manufacturers turning to automation to fill the void of diminishing worker availability.

Overcoming Challenges

To overcome barriers to automation, food manufacturers should make incremental improvements to start automating capabilities at a smaller scale. "By seeing the benefits of automation, manufacturers can build their way up to full-scale automation over time," Zimmerman says.

Because cost is often the No. 1 barrier to implementing automation and robotics, original equipment manufacturers and machine suppliers can benefit from collaborating with robotics providers to design more efficient packaging line configurations, Sean M. Riley says. For instance, robotic product handling to feed a flow wrapper can manage delicate and odd-shaped items like baked goods, placing them in the proper orientation for packaging without breakage. With fully integrated sensors, a connected flow wrapper and robotic packing arm can also communicate changes in packaging counts, allowing the flow wrapper to meter the precise number of products needed per cycle to the robotic arm.

Furthermore, development teams must ensure that all departments and C-suite leaders are on board. Many times, barriers to adoption come from a lack of communication across a company. "It's crucial to have everyone on the same page from the beginning to make sure business goals and technology goals align," Zimmerman concludes.



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Thinking Beyond the Firefight

Automating quality management with SPC software

BY STEVE WISE

ata present the foundational elements for any good quality assurance program. Collected process data can tell food manufacturers how their lines are performing, when there's a concerning issue or trend, and whether or not products ultimately meet quality and safety standards. With so much insight waiting to be uncovered, it comes as no surprise that most plant-floor teams would want to collect as much data as they can from their various gauges and other equipment.

What that data collection typically involves is far from ideal. Often, you'll find operators furiously scribbling down measurements onto paper. Some input their handwritten data into spreadsheets. But, given the time-consuming nature of these largely paper-based methods and the sheer

amount of information they collect, teams have little time to understand what their data are telling them while production is in process. Thus, many relegate themselves to only a final review after finished goods come off the line.

The challenge with post-production reviews, though, is that if an issue is discovered, teams must shift into firefighting mode, searching far and wide to corral the necessary papers and spreadsheets to understand what went wrong upstream and then (hopefully) contain the problem. Such constant firefighting isn't the best use of quality and process data, not when manufacturers want to—and can—glean greater operational insights through more advanced, automated means.

Today, food manufacturers can automate many aspects of quality management

on the plant floor, including not only data collection, but also process monitoring and even analysis with modern statistical process control (SPC) software. These cloud-based solutions enable quality teams to break away from reactive firefighting and enact real-time, proactive quality control and process improvements.

Automate Data Collection and Issue Detection

In the April/May issue of Food Quality & Safety in an article entitled "Temperature and Humidity" (p. 53), I explained that SPC is an industry standard methodology for measuring and controlling the manufacturing process that involves taking collected process data and plotting it to graphs against pre-determined control limits to identify process variations and ensure optimal quality and consistency. But, rather than having quality professionals produce these graphs themselves, SPC software can do the heavy lifting for them, automatically generating data visualizations for users to review in role-based dashboards. All that remains is for quality professionals to interpret and act on the presented performance information.



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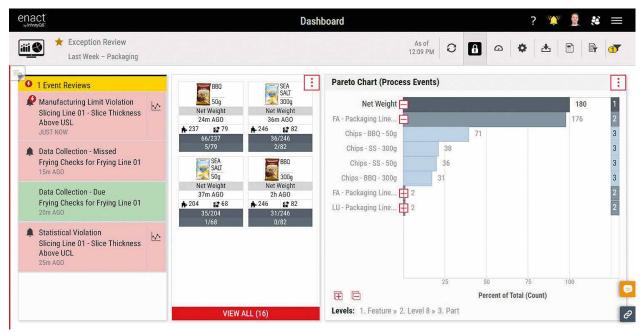


Figure 1. From their dashboards, operators can readily see if they have a queue of events in need of attention.

Taking full advantage of SPC software and these data visualizations requires manufacturers to drop the paper and pencil and adopt new methods for real-time data collection that goes directly into the system's own unified data repository. SPC software has advanced backend analysis engines that plot data as it comes in. So, when teams get real-time process- and quality-related data streams into this repository, the data instantly become actionable by identifying sources of process variation, enabling timely detection and remediation of quality issues while production is in process, not after. No more firefighting.

Notably, there are numerous solutions now available for manufacturers to facilitate real-time data collection. There are smart devices, part of the Industrial Internet of Things (IIoT), that can wirelessly collect all the data you need off the production line. Some SPC software directly integrates with a manufacturer's digital measurement devices, capturing and storing readings into a centralized database.

For those who would prefer to have their operators perform data collection and entry, SPC software can also provide automated notifications to remind them when their next data collections are due. When operators are recording their measurements, pre-defined parameters within the software can enforce best practices, reduce risk of entry error or missed information, and ensure standardization of data entry, with standardization being critical if manufacturers want to conduct any form of comparative analysis between lines, products, or sites.

Automated Alerts & Problem Resolution

From wireless devices to automated notifications, no matter the method for facilitating data collection, they all benefit quality teams at the end of the day. Operators don't have to worry about getting timely, accurate process information. They also don't have to glance at the clock constantly to ensure that they make their rounds for quality checks.

Similarly, when it comes to monitoring and identifying process variations from the data, operators don't have to sit and stare at their dashboards and charts waiting for something out of the ordinary to pop up. That's because—in addition to role-based dashboards that present the most important information to users according to their job—SPC solutions can automatically catch potentially harmful events and send alerts to the appropriate team members—alerting them to go in and review the problem. It may be that a process is out of specification or there was a missed or late data collection.

From their dashboards, operators can readily see if they have a queue of events in need of attention (see Figure 1, above). Defined workflows then take the guesswork out of problem resolution with prescribed actions that walk them through the necessary remedial steps, ensuring consistency in the proper handling of issues. Additional documentation noted on each event can also provide contextual information to prevent reoccurrences.

Dashboards for quality or plant managers would be slightly different; they would offer more oversight across operations, including events that are currently outstanding and team members who need to take action. This fosters better accountability so that individual events are quickly addressed before they escalate into larger quality concerns.

Automate the Grade

When quality teams are free from worrying about firefighting, missed data collections, and constant process monitoring, they can dedicate more time to examining their data to find ways to improve their processes and prevent issues, as well as to prioritize where to expend their resources. At the same time, though, trying to figure out where these opportunities lie can be overwhelming, given the huge volume of data coming from the production line. It's

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like looking for a needle in a haystack or digging for buried treasure without the benefit of a treasure map.

"Stream grading" is one innovative way that SPC software can help manufacturers dig through the deluge of data and surface process improvement knowledge. Stream grading is a function in which the software automatically processes unique streams of data from different products, lines, and features and applies SPC methods to provide a letter-number grade representing the expected and potential yield for a specific stream. When manufacturers standardize on an SPC software and centralize data collection across multiple plants, they can achieve enterprise visibility to compare the grades (i.e., performance) between sites and reveal opportunities for global improvements.

Here's how the letter grades work: A grade of A, B, or C indicates the potential yield of each stream. In other words, how wide is the distribution compared to the specification limits? Grade A means the stream's distribution is very skinny and could potentially fall well within the specification limits. Conversely, grade C indicates the stream's distribution does not fit within the specification limits. For

the numbers, a rank of 1, 2, or 3 represents the stream's actual yield performance—in other words, how well the distribution is centered within the specification limits. A value of 1 means that the process is perfectly centered, 2 means it is off center, and 3 shows that it is *way* off center.

Combined, an A1 grade is a high-yield stream that is meeting its full potential, while a C3 grade is a low-yield stream that is not meeting its potential. The greatest opportunities for improvement are the A3 grades, which demonstrate that a stream is highly capable but is currently very off center. Small adjustments here can present huge returns in process improvement. The grading's simple letter–number combinations (and color coding) make it easy for quality professionals to quickly uncover insights buried within their data and, in an agile way, prioritize their efforts and resources for continuous improvement.

The function can also go a step further, allowing users to select a stream and drill down, layer by layer, to access the granular information that's behind the grade. From this vantage point, quality teams can understand the root cause of poor performance and determine which fixes are the easy wins, requiring minimal effort but possibly leading to significant improve-

ments in operations. For instance, the fix might be something as simple as a tweak to some equipment settings. Other corrective measures may be more expensive, such as replacing the equipment entirely. Insight into root causes and the level of effort required for improvement can help manufacturers better plan their budgets based on return on investment and, ultimately, lead to better resource management across lines, processes, products, and the enterprise.

At its core, automation through SPC software is all about empowering quality teams, allowing them to think and act more efficiently. The key is for quality professionals to receive the information they need, when they need it. It's about enabling direct, timely action on the plant floor, effective comparisons of process output against specifications and control limits, and strategic, data-driven decisions. Those who choose to automate their quality management and analysis can go beyond the piles of paper and the endless firefights of yesterday and truly see the meaning behind their data—and the best actions to take in response to that data—to optimize product quality and manufacturing operations. ■

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Waste Not, Want Not (Continued from p. 23)

include required information. FDA cooperates with state and local partners—in particular, the <u>Association of American Feed Control Officials</u> (AAFCO)—to implement proper labeling to ensure the safe use of feeds, Broad Leib says.

In general, a feed label should contain information describing the feed product and any details necessary for the safe and effective use of the feed, including the name and place of the feed manufacturer, packer, or distributor; certain warning statements; and statements of artificial flavoring, artificial coloring, or chemical preservatives, Broad Leib says.

Additional labeling requirements exist under other federal laws and regulations. For example, FDA's Final Rule for Preventive Controls for Animal Food requires that, when distributing byproducts, facilities

Under federal law, food waste containing meat or animal products can generally be fed to animals (except ruminants), as long as these scraps are heat treated in a manner sufficient to kill disease-causing bacteria before they can be fed to swine.

use labels to identify byproducts by their common name.

Animal feed products are also subject to state laws regarding labeling. Many state regulations mandate that feed labels include the brand name (if any), product name, purpose statement, guaranteed analysis, list of ingredients, and directions for use, among other requirements, Broad Leib says. Animal feed producers can find more information on state labeling require-

ments by contacting the state where products will be distributed or by consulting the AAFCO.

The bottom line is that there are many benefits to diverting food scraps to animal feed. Entities wishing to do so should begin by reviewing applicable rules and regulations, to see if it's the right fit for them.

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NEW PRODUCTS

Balance Enclosure Workstations

The SSE balance enclosure workstation is designed to position on an island or peninsula location with access on two sides for student labs and light duty procedures. The SSE is offered in 24", 36", and 48" widths to accommodate an analytical balance and other small-scale lab processes and is constructed of chemical-resistant metal framing and 1/4" thick clear acrylic side panels and viewing sash. Includes an efficient air flow design with airfoil and bypass, so the workstation directs contaminates to baffled exhaust. The ergonomic sash is angled 15 degrees for ease of viewing comfort with 8" reach in opening height. Sash swings up to provide 20" of access opening. Two service ports are in lower right and left rear wall. HEMCO. hemcocorp.com.



Residual Surface Antimicrobial Coating

The Microbarrier Elite is a supplemental registered residual surface antimicrobial coating for the protein food processing market. It uses Bioprotect RTU antimicrobial technology, an antimicrobial by ViaClean Technologies, and can be left on food processing machinery and equipment after its application during the sanitation process to provide long-term residual surface protection. PSSI, pssi.com.



Traceable Temperature Sensors

To help food industry professionals maintain operational effectiveness, uphold quality assurance, and meet regulatory compliance, Sensaphone offers NIST traceable calibration temperature sensors. These certified sensors are necessary for facilities that need to have an audit trail proving their products and inventory are continually stored at specific temperatures. They are used by operators of food manufacturing, processing, and storage facilities; research and testing laboratories; and food service and retail businesses. Sensaphone, sensaphone.com.

Automated Data Stream Monitoring

The Dynamic Remote Alarm Monitoring Service (DRAMS), a new Microsoft Windows-based tool, is designed to expand the real-time quality control capabilities of ProFicient Statistical Process Control (SPC) software. This cloud-hosted version of the InfinityQS quality management solution monitors data streams from all manufacturing processes to detect control and specification limit violations and generate quality alerts in real time. Powered by an SPC analysis engine, the solution automates data collection and analysis to surface actionable insights that help in maintaining product quality, reducing waste, and meeting production goals. Installed alongside ProFicient or PoD, the system can automatically review all active data streams coming into ProFicient's centralized database and compare the incoming data with the appropriate set control and specification limits. If a process or quality issue occurs, the system will then trigger an email notification to alert critical quality team members. InfinityQS, infinityqs.com.

X-Ray Re-Inspection Program

allows companies to re-inspect the quarantined product on-site using an X-ray system, identifying and removing any contaminated product, then allowing uncontaminated re-inspected product to be delivered to customers. This re-inspection takes place at the manufacturer's facility, off-line, without shutting down ongoing production, continuing to maximize productivity. A service engineer will guide the manufacturer's operators through the re-inspection, providing training and technical support throughout the process. When the re-inspection is complete, the manufacturer will receive

pi.reinspection@mt.com, mt.com.

Mettler Toledo's new X-ray re-inspection program



NEW PRODUCTS

(Continued from p. 51)

Polyurethane Flooring

FasTop Multi Systems is a set of hard-wearing, hygienic, chemical- and slip-resistant polyurethane flooring solutions with beneficial application properties. These systems are engineered for long-lasting performance, low-temperature cure, and fast return to service in environments such as food and beverage plants, breweries, commercial kitchens, dairies, manufacturing facilities,



garages, warehouses, and chemical processing plants. The system is composed of six systems: two self-leveling solutions, two screed flooring solutions, a cove base system, and a topcoat. It enhances flow and leveling properties and reduces pinholes, minimizing rework for applicators and installers. The system is offered in updated packaging, including a universal base and hardener, aggregate filler, and a new color pack system with an expanded color selection. Sherwin Williams., sherwinwilliam, sherwinwilliams.com/protective.

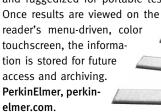


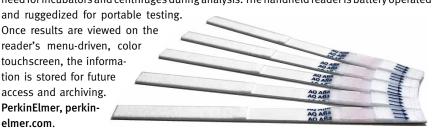
Stainless Steel Vacuum Pump

Lyco Wausau has introduced a stainless steel liquid ring vacuum pump with a close-coupled stainless steel washdown motor (Model 101-40-3SSM or Model 102-40-3SSM) that can be used in food processing plants, where frequent washdowns are required. The compact pump can provide vacuum up to 28 inches of mercury or move up to 52 cubic feet of volume per minute. Lyco Wausau, lycowausau.com.

Mycotoxin Analysis for Grain Commodities

The AuroFlow AQ Mycotoxin Platform includes strip test versions for total aflatoxin, deoxynivalenol (DON), fumonisin, ochratoxin A, zearalenone, and T-2/HT-2. Lab professionals, technicians, and farmers can use the platform for first-round screening of corn and wheat for key, regulated mycotoxin compounds. Results are delivered in six minutes or less with detection levels as low as 2 ppb, depending on the mycotoxin being detected. The kits use a single-step, water-based extraction method with lateral flow testing at room temperature. This removes the need for incubators and centrifuges during analysis. The handheld reader is battery operated





It is available in metallic and non-metallic.

AFC Cable Systems, afcweb.com.

Liquid Tight Conduit

The Splash Zone Liquid-Tuff Liquid Tight Flexible Conduit is designed specifically for splash zones, making it ideal for food equipment and devices, meat packing, restaurants, food processing, and poultry packing. The conduit features a moisture-, oil-, and sunlight-resistant polyvinyl chloride jacket that inhibits bacteria growth and won't degrade due to washdown/ splash zones with bleach agents. This allows food manufacturers to clean and sterilize using bleach without the risk of product degradation. Additionally, the conduit is compatible with AFC's food grade liquid tight stainless steel fitting, which comes with polyester elastomer compression seals to prevent ingress of food or bacteria. The conduit is UL listed and CSA NSF 169 component compliant, meeting standards for material safety, design, construction, and product performance in the food industry.

Diary Testing Supplement

The PIF Supplement is for the enrichment of Enterobacteriaceae, in particular Salmonella spp. and Cronobacter spp., in powdered infant formula (with or without probiotics), dairy ingredients, and cereal. It can also be used in testing environmental samples from production areas. The supplement was developed to be paired with Bio-Rad's iQ-Check Real-Time PCR Test Kits and RAPID'Chromogenic Media. The supplement meets the growing demand from dairy producers, such as infant formula manufacturers and service labs, to test for Salmonella and Cronobacter in large sample sizes. To optimize recovery of the pathogens, the supplement inhibits background flora, such as lactic acid bacteria, bifidobacteria, and other gram-positive bacteria. Using the supplement, users can enrich Salmonella and Cronobacter simultaneously from a single enrichment broth for samples up to 375 grams. Bio-Rad Laboratories, Inc., bio-rad.com/pif.

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Managing Pests During ... (Continued from p. 28)

- Look for signs of infestation. Keep a close eye out for the telltale signs of a rodent infestation, such as live or dead rodents, nests, and gnaw and rub marks. Be sure to pay extra attention to kitchen and bathroom areas for signs of a cockroach infestation, such as droppings or eggs, as these areas are particularly attractive to such insects.
- Scrutinize upholstery. Check for any signs of a bed bug infestation, such as small red to reddish brown fecal spots, molted bed bug skins, their white, sticky

eggs, or empty eggshells. Pay close attention to the seams of furniture and upholstery in break rooms and other communal areas.

• Clean common areas. Sanitize and vacuum all areas, including offices, hallways, lobbies, kitchens and public bathrooms on a daily basis. Wipe down counter tops and sweep floors to remove crumbs and residue from spills. Additionally, ensure that any food products are stored in sealed containers to prevent pests from contaminating them.

Facility managers have been working tirelessly to keep employees safe and healthy amidst the COVID-19 pandemic. By following the steps outlined above, in addition to all CDC guidelines, and by working with a trained professional pest control company, facility managers can help to ensure that employees and facilities are protected from the threats posed by pests.

Mannes is vice president of public affairs for the <u>National Pest Management Association</u>. Reach her at cmannes@ pestworld.org.

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9-1

NAMI Meat Industry Food Safety Conference

Virtual Event

Visit meatinstitute.org/events.

14-24

AOAC Annual Meeting & Expo

Virtual Event

Visit aoac.org/annual-meeting-exposition or email aoac@aoac.org.

22-23

North American Food Safety & Quality

Virtual Event

Visit foodsafetyna.com.

OCTOBER 2020

19-22

Food Safety Summit

Virtual Event

Visit foodsafetystrategies.com.

25-28

IAFP Annual Meeting

Virtual Event

Visit foodprotection.org/annualmeeting.

NOVEMBER 2020

8-11

Pack Expo International

Chicago, III.

Visit packexpointernational.com

10-1

European Food Sure Summit

Milan, Italy

Visit foodsureeurope.com.

JANUARY 2021

26-28

International Production & Processing Expo

Atlanta

Visit ippexpo.org.

MARCH 2021

1-3

Beef Industry Safety Summit

Denver, Co.

Visit bifsco.org.

6-10

Pittcon

New Orleans, La.

Visit pittcon.org.



APRIL 2021

11-16

Conference for Food Protection

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Visit foodprotect.org.

26-28

IAFP European Symposium on Food Safety

Visit foodprotection.org/ europeansymposium.

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SCIENTIFIC FINDINGS

For access to complete journal articles mentioned below, go to "<u>Food Science Research</u>" in the August/September 2020 issue at <u>foodqualityandsafety.com</u>, or type the headline of the requested article in the website's search box.



ARTICLE: Colorants in Cheese Manufacturing

Colored cheddar cheeses are prepared by adding an aqueous annatto extract (norbixin) to cheese milk; however, a considerable proportion of such colorant is transferred to whey, which can limit the end use applications of whey products. Different geographical regions have adopted various strategies for handling whey derived from colored cheese production. For example, in the U.S., whey products are treated with oxidizing agents such as hydrogen peroxide and benzoyl peroxide to obtain white and colorless spray-dried products; however, chemical bleaching of whey is prohibited in Europe and China. This review provides a critical analysis of pertinent scientific and patent literature pertaining to colorant delivery in cheese and various types of colorant products on the market for cheese

manufacturing and considers interactions between colorant molecules and cheese components; various strategies for the elimination of color transfer to whey during cheese manufacturing are also discussed. *Comprehensive Reviews in Food Science and Food Safety.* 2020;19:1220-1242.

ARTICLE: Fate of *Listeria* on Various Surfaces When Treated with Bacteriophage

The study objective was to determine efficacy of a bacteriophage suspension against Listeria spp. when applied to three common types of materials used in food manufacturing facilities: two food contact materials (stainless steel and polyurethane thermoplastic belting) and one noncontact material (epoxy flooring). Coupons of each material were inoculated with a cocktail containing L. monocytogenes and L. innocua. Treated samples were held at 4°C or 20°C for one and three hours to determine the effect of temperature and treatment time. Higher phage concentration, longer treatment time, and a processing area temperature of 20°C showed a greater reduction of Listeria on the stainless-steel and polyurethane thermoplastic belting coupons. Journal of Food Safety. 2020;40:e12775.



ARTICLE: Inhomogeneous Salt Distribution in Beef Frankfurters

Inhomogeneous salt distribution is a promising strategy for salt reduction. This study investigated the effect of inhomogeneous salt distribution using a salt edible coating



on the physiochemical and sensory attributes of beef frankfurter sausages. The results demonstrated that this method significantly reduced the salt content in frankfurter sausages by 60 to 81 percent without affecting consumer perception of saltiness intensity. Among the coated samples, 7.5 percent and 10 percent salt coating samples showed the best performance on the product quality. However, the problems associated with high cooking loss and hard texture of the salt-coated sausages need to be further addressed. This research has potentially developed a new method for manufacture of salt-reduced food. International Journal of Food Science and Technology. 2020;55:2911-2919.



ARTICLE: Effects of Different Freezing Methods on the Quality of Conditioned Beef Steaks

This study aimed to evaluate the effects of three freezing methods (refrigerator, immersion, and plate freezing) on the qualities of conditioned beef steaks during storage. Results showed that the freezing rate of immersion freezing was highest in three groups. The thawing loss, juice loss, and thiobarbituric acid reactants values of conditioned steaks in immersion freezing groups were lowest during frozen storage. It was also found that samples in the immersion freezing group had the most compact structures of muscle fibers. From the aspect of the texture of the steaks, the immersion freezing group is superior to the plate freezing and refrigerator freezing groups in terms of hardness and elasticity. In consideration of product quality, these results suggest that immersion freezing is the optimal way to freeze conditioned steaks. Journal of Food Processing and Preservation. 2020;44:e14496.





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