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Moisture-wicking technology provides a labor saving solution for food processing facilities due to the reduced need to mop/squeegee condensation formed during sanitation.

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• Avoiding Out-of-Stocks: A Proactive Approach to On-Shelf Availability BY PARIS GOGOS
• Will Your Food Truck Pass an OSHA Inspection? BY BRITISH SOLOMON

Corrections
In the Pathogen Patrol column for the April/May 2018 issue, Nathan Wilson, quality assurance manager, La Tortilla Factory, was misquoted on Novolyze’s SurroNov. Instead of saying, “the water activity of the product from the dough samples tested was 9.2,” his quote should have read, “And at the end, the total log of inoculation was at 9.2 from the 10 expected. The water activity of the dough samples was at 0.96.”

Also in the April/May 2018, Insect-O-Cutor was incorrectly spelled in the Advertiser Index.
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From The Editors

My long-time friend, Dr. A. Elizabeth Sloan, whose business is analyzing and predicting industry trends, recently shared information with me on consumer attitudes pertaining to food safety. The statistics she shared were a bit frightening. Apparently, 35% of millennials and 24% of baby boomers are not confident in the safety of our food supply. Reading through the data, it is obvious that what consumers fear is very different from what food safety experts worry about. Among the items troubling consumers are GMOs, residues, BPA, and consuming foods past the use-by dates. These four concerns are areas that we as a food industry need to address on company websites, press releases, and in other areas.

The National Academy of Sciences published a 400-page report in 2016 that addressed the safety of GMO products, yet these products continue to be feared and referred to as “Frankenfoods.” Consumers worry about residues of all sorts, yet this is low on the totem pole as a far as a food safety issue. Many seem to believe farmers who grow crops dump vast quantities of pesticides on their fields. That is certainly a fallacy. On the other hand, very few realize that organic growers actually apply pesticides to their crops. Yes, Virginia there are pesticides approved for organic growing. And the attention given to BPA is unwarranted. The FDA recently issued a 250-page plus report highlighting the safety of BPA and its uses in packaging systems.

There are other food safety issues that are cursed by misinformation or, to use an un-popular term, “fake news.” The food industry needs to address these issues and communicate with the general public. As someone who worked in food safety for many years around the globe, I noticed most companies have world class food safety programs, yet hardly anyone makes the effort to “blow their own horn.” I’ve been told legal does not want this done due to liability, which makes things even more sad. If the food industry cannot or is afraid to communicate what is being done to ensure the safety of what it produces, the least it can do is make an effort to ensure that good science is shared.

Richard Stier
Co-Industry Editor
Food nourishes, comforts, and sustains us. And it’s up to all of us to protect the quality and ensure the safety of the global food supply chain – and to protect and nourish the food brands your customers have come to rely on. We offer trusted, industry-leading solutions for ensuring the quality and authenticity of your ingredients, and detecting risks to human and animal health from adulteration and contamination. Safer foods, healthier consumers – and thriving brands: These are things we can all savor.

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FDA Updates

The U.S. FDA releases guidance to make the importation of certain live animals less burdensome. The guidance explains that the agency intends to exercise enforcement discretion regarding the application of the FSVP rule to imports of live animals that must be slaughtered and processed at establishments regulated by USDA and subject to HACCP requirements (or at state-inspected establishments subject to requirements equivalent to the federal standards). This means the agency doesn’t intend to enforce the FSVP requirements that these importers would otherwise have to meet. This intent to exercise enforcement discretion accounts for the role of another federal agency with regards to these animals. This is also consistent with the exemption in the FSVP rule for certain USDA-regulated products.

FDA has also created a new web page on the www.FDA.gov site that provides a central source of information for scientists and other stakeholders interested in Foods and Veterinary Medicine’s (FVM) research priorities, activities, reporting, and tracking. Human and animal food safety, animal health, and nutritional science are primary drivers of FVM’s research efforts. The new page includes information about the Science and Research Steering Committee, an inter-center body that coordinates FVM’s activities to maximize resources and impact and avoid duplication of effort. This encompasses a wide range of food and feed research objectives across the scientific disciplines of chemistry, microbiology, toxicology, and nanotechnology.

Delayed Calorie Disclosure Rule Takes Effect for U.S. Food Sellers

As reported by Reuters, many restaurants, supermarkets, convenience stores, and movie theaters across the U.S. are now required to clearly display food calorie counts as part of a push to trim expanding American waistlines and control healthcare costs. The rule—part of the Affordable Care Act of 2010, popularly known as Obamacare—affects food sellers with 20 or more locations that sell ready-to-eat foods. The rule also requires calorie labeling on more than 99% of the nation’s 5 million to 6 million vending machines. Opponents to the rule include companies like Domino’s Pizza and industry groups such as the Food Marketing Institute, which represents food retailers and wholesalers. Opponents argue that the rule piles additional costs and liability risks on businesses.

USDA Wants to Eliminate Redundant Hog Carcass Cleaning Regulation

The USDA FSIS proposes to amend the federal meat inspection regulations to repeal a redundant regulatory requirement for hog slaughter establishments. The proposed rule would remove a redundant requirement that requires these establishments to clean hog carcasses before incising. Establishments are required to have a HACCP system that identifies potential biological, chemical, or physical hazards, and the controls to prevent, reduce, or eliminate those hazards at specific points in the process. Because establishments are required to operate under HACCP regulations and apply HACCP principles, this command-and-control regulatory requirement is no longer necessary to ensure food safety; its objectives are met by other regulations, including HACCP regulations. Comments are due July 16 via www.Regulations.gov.

Insights and Takeaways from GFSI Conference

The Executive Summary now available from this year’s GFSI Conference in Tokyo includes insights and practical nuggets shared by industry leaders, experts, and innovators. It offers actionable takeaways to share with colleagues and implement in operations. Access the summary via https://bit.ly/2LPhTPd.

The next GFSI Conference is scheduled to take place next year in Nice, France on February 25-28 under the theme: Emerging Challenges & The Future of Food Safety.

Business Briefs

Bühler and Microsoft expand their partnership by committing themselves to build an alliance that will enhance food integrity and traceability.

Church & Dwight Co., the parent company of Arm & Hammer Animal and Food Production, acquires Passport Food Safety Solutions of West Des Moines, Iowa.

ReposiTrak partners with U.K.-based, SerTech Exchange to bring ReposiTrak platform to the European market.

GSSI Steering Board announces its recognition of the GLOBALG.A.P. Aquaculture Certification System.

The Scottish microenterprise The Antibody Co. receives funding from Industrial Biotechnology Innovation Center to investigate a technique that uses antibodies bound to gold nanoparticles for detecting food contamination.

To accelerate its expansion in the food industry, FoodLogiQ raises $19.5 million in growth financing from investors Tesco, Tyson Ventures, Pontifax AgTech, Nicola Wealth Management, and Greenhouse Capital.

The Product Inspection Group of Mettler Toledo moves into a new state-of-the-art facility in Pasco County, Florida.

Rite-Hite expands its operations by adding an office location in Milwaukee’s Historic Third Ward.
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¹Dry time measured using Dyson test method 769 based on NSF P335 using a measurement of 0.1g residual moisture.
²In collaboration with Carbon Trust, Dyson has produced a method to measure the environmental impact of electrical appliances and paper towels. The carbon calculations were produced using GaBi software providing by PE International, based on product use over five years and using the U.S. as a representative country of use. Dry times for products were evaluated using DTM 769.
Nearly two years after passage of the nation’s first federal law requiring food manufacturers to disclose the presence of GMO ingredients on packaged food labels, USDA’s Agricultural Marketing Service (AMS) has issued a proposed rule outlining how and under what conditions such disclosures will be required. But the agency also left a few particularly contentious issues unresolved, pending further consideration.

The National Bioengineered Food Disclosure Law (PL 114-216) was signed into law in July 2016. It requires food manufacturers to prominently disclose on the label the presence of any bioengineered ingredient. Companies can choose among three options: text, a GMO symbol, or an electronic link, such as a QR or quick response code that can be scanned by smartphones. There is no penalty for non-compliance. USDA was statutorily required to issue a final regulation implementing the law within two years of its passage.

USDA published the proposed rule on May 4, 2018, with a 60-day public comment period that closes July 3. Because the agency was late in issuing the draft regulation, the comment period will not be extended, USDA said. The agency plans to issue the final rule later this year after evaluating the comments it receives, which are expected to be numerous.

“This rulemaking presents several possible ways to determine what foods will be covered by the final rule and what the disclosure will include and look like,” said Agriculture Secretary Sonny Perdue. “We are looking for public input on a number of these key decisions before a final rule is issued later this year.”

Defining Bioengineering

The law defines bioengineered food as that containing “genetic material that has been modified through in-vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.” This definition is incorporated verbatim in the draft regulation.

In creating the draft regulation, USDA evaluated more than 112,000 comments it received last year in response to 30 questions about the GMO law posted on the AMS website. Questions revolved around such issues as the amount of a bioengineered substance needed for a food to be considered GMO, and whether ingredients that are derived from bioengineered crops, such as highly-refined oils or sugars, must be so labeled even if the bioengineered material cannot be detected.

Responses to these questions “disclosed wide differences in public opinion about how the statutory definition of “bioengineering” should be interpreted and applied” to the law, the draft regulation states. As a result, USDA is proposing a range of options regarding GMO threshold amounts, and is inviting further information and comments on the matter of highly refined products.

Concerning threshold levels, the agency is considering three options for exempting foods from the GMO labeling requirement, based on comments it received to its 30 questions. A food product would be exempt from the label law if:

a) the food contains an ingredient with a bioengineered substance “that is inadvertent or technically unavoidable, and accounts for no more than 5 percent by weight of the specific ingredient,” or

b) the food contains an ingredient with a bioengineered substance “that is inadvertent or technically unavoidable, and accounts for no more than 0.9 percent by weight of the specific ingredient,” or

c) the food contains an ingredient or ingredients “that contain a bioengineered substance [that accounts] for no more than 5 percent of the total weight of the food in final form.”

In addition, USDA categorically exempts “an incidental additive present in food at an insignificant level and that does not have any technical effect in the food.” A “Reserved” place is left open for one additional exemption, without explanation.

Concerning whether highly refined products made from bioengineering should be covered, USDA acknowledges two prevailing, opposing viewpoints: If a bioengineered genetic material has been removed from the food to the extent that it...
is undetectable by common testing methods, the food should be exempt because it does not contain bioengineered material. On the contrary, if a food is produced from bioengineering, it should by definition be covered. Simply because a test may not detect bioengineered material doesn’t mean it’s not present. Some studies have found such genetic materials present in highly refined oils and sugars, while other tests were inconclusive.

To resolve the dispute, USDA is requesting information from additional studies as well as comments on which of the two positions better interprets the statutory definition of bioengineering.

Symbolic Choices
Another still-to-be resolved issue concerns the GMO symbol. USDA is proposing three alternatives: a circle with a green circumference with the capital letters “BE” in white type; a filled green circle with the lower-case letters “be” with the hint of a smiley face and with 10 triangular leaves evenly spaced along the circumference; or a circle with dotted circumference, with the lower-case letters “be” and the hint of a smiley face (see image on page 12). The agency wants feedback on “perceptions, beliefs, or feelings” about each of the proposed symbols, particularly the message each communicates to consumers.

Early comments submitted by the public focused on these symbols. Many disliked them, calling them “misleading” or “cartoonish.” Others said the smiley face was deceptively suggestive of bioengineered food being good or healthy when, in fact, it might well be the opposite.

When the GMO label law was passed two years ago, some critics complained that it too narrowly defined bioengineering and would not allow companies to not disclose GMOs produced by new technologies, such as “gene editing.” At the time, USDA contended that it had sufficient authority to do so. Instead, USDA “recognizes that technologies continue to evolve, and that food produced through a specific technology may or may not meet the definition of BE [bioengineered] food.” The agency says it will consult with other agencies, including APHIS, EPA, and FDA, to keep abreast of the commercialization of new technologies, and will issue annual updates, subject to review and comment.

To reduce the compliance burden on manufacturers, USDA will develop and maintain two lists of commercially produced bioengineered foods. Only foods on either of these lists are subject to disclosure.

One list will include bioengineered foods having a “high adoption rate,” defined as comprising 85 percent or more of U.S. planting or production. Examples include bioengineered canola (90 percent), bioengineered field corn (92 percent), bioengineered cotton (93 percent), bioengineered soybean (93 percent), and bioengineered sugar beet (100 percent). The other list would be bioengineered foods that are “not highly adopted,” or representing less than 85 percent of U.S. planting or production, such as apples, sweet corn, papaya, potato, and summer squash.

While foods from either list must be disclosed, the text wording will differ. High adoption bioengineered foods must be worded “Bioengineered food” or “Contains a bioengineered food ingredient.” Non-high adoption foods must be worded “May be a bioengineered food,” or “May contain a bioengineered food ingredient,” or “Contains a bioengineered food ingredient.”

‘Scan Here’
Instead of text or the GMO symbol, the law allows food manufacturers the option of using an “electronic or digital link,” such as a QR or quick response code. The draft regulation proposes the code be accompanied by such wording as “Scan anywhere on package for more food information” or “Scan icon for more food information.”

The Grocery Manufacturers Association (GMA) said its SmartLabel QR initiative “provides more information that could ever fit on a package label,” and is found on more than 25,000 food and other items. “Digital disclosure by scanning an electronic link on a package is one of the ways to provide the bioengineered ingredient information required by the federal law,” GMA said in a statement.

While many food industry groups such as GMA, the Food Marketing Institute, the National Grocers Association, and the American Farm Bureau Federation largely support USDA’s labeling effort, some consumer and environmental groups continue to find fault with it, much as they did when the law was passed.

“This rule will help keep consumers in the dark, as it is intended,” said Wenonah Hauter, executive director at Food & Water Watch. Digital codes and other technology make it more difficult for consumers to obtain GMO information than simple labels, she said, calling the provision “a gift to industry.”

Andrew Kimbrell, executive director of the Center for Food Safety, said USDA’s own study found QR codes to be “inherently discriminatory against one-third of Americans who do not own smartphones.” On-package text or symbol labeling is “the only fair and effective means of disclosure for GE foods,” he added.

The law instructed USDA to assess potential technological challenges involved in using electronic or digital disclosure methods. While that report has been concluded, USDA has not made a final decision about the issue. The draft regulation, however, proposes a new disclosure option of text messaging for those shopping without a smartphone.

Unchanged from the law are several exemptions. These include food served in restaurants and other retail establishments, very small food manufacturers (having less than $2.5 million in annual sales), food derived from animals that consumed bioengineered feed, such as GMO corn or soybeans, and food verified under the National Organic Program. Meat, poultry, or eggs would require labeling only if the most prominent ingredient would independently be subject to the labeling requirement.

Food manufacturers with more than $10 million in annual revenues must comply by Jan. 1, 2020. Small food manufacturers (less than $10 million but $2.5 million or more in annual revenues) would have an additional year (Jan. 1, 2021). Food importers would be subject to the same disclosure and compliance requirements as domestic companies. USDA is considering recognition arrangements with foreign governments that have established bioengineered food labeling standards. In those cases, each country could agree to recognize each other’s standards as comparable.

Agres is an award-winning writer based in Laurel, Md. Reach him at tedagres@yahoo.com.
Do you remember when Lauren Rudolph, Michael Nole, Celina Shribbs, and Riley Detwiler made headlines? Sadly, these individuals are linked forever with some of the darkest days in U.S. foodborne illness history. They are the four children who died as a result of the E. coli O157:H7 contamination traced to hamburgers served at Jack in the Box restaurants back in 1993.

Twenty-five years after their tragic deaths at the tender ages of six years, two years, two years, and 17 months respectively, O157:H7 and other Shiga toxin-producing E. coli (STEC) are still a major threat to food safety and public health.

During 2017, of the 24,484 cases of U.S. foodborne illness identified by the CDC FoodNet, 2,050 cases were attributed to STEC (all serogroups were combined) as the cause, with an incidence of 4.2 cases per 100,000 population. Thus, STEC ranked fourth behind Campylobacter, Salmonella, and Shigella, which placed first, second, and third, respectively in both number of cases and incidence rate.

As of May 16, 2018, 149 people infected with the outbreak strain of E. coli O157:H7 associated with romaine lettuce believed to have originated in Yuma, Arizona have been reported from 29 states. Of those, 64 people have been hospitalized, including 17 who have developed hemolytic uremic syndrome. One death has been reported.

“These events are difficult reminders of the importance of the science and produce industries working together towards the continuous improvement of food safety programs,” says Bonnie Fernandez-Fenaroli, executive director of the Center for Produce Safety.

Risk Assessment and Consumer Outreach

The University of Nebraska-Lincoln (UNL) has been spearheading a collaborative five-year project targeting risk assessment and consumer outreach for STEC and beef, courtesy of a $25 million grant funded by the USDA National Institute of Food and Agriculture (NIFA). As a NIFA Coordinated Agricultural Project (CAP), the project is known familiarly as STEC CAP, according to UNL’s Rodney Moxley, DVM, PhD, the STEC CAP project director.

“More than 50 scientists representing some 18 institutions are conducting integrated research, education, and extension projects on eight types of STEC,” Dr. Moxley says. “Along with the best-known STEC, the notorious E. coli O157:H7, seven other non-O157 STEC strains that are not as well understood are being studied.”

The STEC CAP research is focusing on the seven most dangerous serogroups (i.e. O157) or serotypes (i.e. O157:H7) of STEC (O157:H7 and six non-O157), plus a new one, O104:H4, which made its first widespread appearance in an outbreak in Europe in 2011, Dr. Moxley relates.

“Based on the three core pillars of this project, pre-harvest, post-harvest, and consumer research, the long-term goal is to reduce the occurrence and public health risks from STEC in beef using a quantitative microbial risk assessment (QMRA) platform, while preserving an economically viable and sustainable beef
industry,” he explains. “The project’s five objectives relative to STEC in beef are 1) detection, 2) biology, 3) intervention, 4) risk analysis and assessment, and 5) risk management and communication.”

**Accomplishments Aplenty**

Dr. Moxley is quick to boast that the STEC CAP grant, with work ongoing through December 2018, has yielded many significant outcomes and impacts, including at least 104 refereed journal articles to date, not to mention other important activities and outputs.

Relative to **Objective 1, detection**, new reagents and methods for detection and quantification of STEC in the beef chain (culture- and DNA-based, as well as immunological) have been developed, optimized, and validated.

With reference to **Objective 2, biology**, epidemiological studies have generated data and identified factors that influence the prevalence and concentration of STEC organisms in cattle, their environments, and on carcasses.

Focusing on **Objective 3, intervention**, multiple interventions to control non-O157 STEC at different steps of beef processing in plants were validated through research.

“Interventions effective for STEC O157:H7 on non-intact beef were equally effective against the regulated types of non-O157 STEC,” Dr. Moxley mentions.

**QMRA for STEC**

Addressing **Objective 4, risk analysis and assessment**, a working computer model of the QMRA for STEC has been developed. “The QMRA is the STEC CAP’s centerpiece and is what drives all research, education, and extension activities,” Dr. Moxley emphasizes. “The QMRA model estimates the risk associated with each regulated STEC serogroup to provide a basis for decision-making and optimal risk management. In addition, it estimates the value of intervention in decreasing the risk of product contamination and human disease, including the sensitivity of the system to control components.”

In consideration of **Objective 5, risk management and communication**, bilingual (English and Spanish) online training modules on pre- and post-harvest STEC prevention in beef and veal were developed and made publicly available. “The modules are intended for employees in agriculture and the food service industry,” Dr. Moxley mentions.

**Detection with Nanotechnology**

Tuhina Banerjee, PhD, Santimukul Santra, PhD, and James McAfee, PhD, faculty members in the Pittsburg State University (PSU) Department of Chemistry, along with six students, have successfully married magnetic resonance imaging (MRI) technology and fluorescence emission to detect *E. coli* O157:H7 in milk and lake water. The result is hybrid nanosensors that are able to screen quickly for target pathogens.

According to Dr. Banerjee, the PSU nanosensors are composed of special iron nanomaterials...
(Continued from p. 15)

oxide particles blended with an optical dye, plus antibodies that specifically latch onto E. coli O157:H7 cells.

“When mixed into a solution with bacterial colonies, the nanosensors swarm around their target organism’s outer membrane and adhere to any such pathogens that are present, while ignoring nontargeted cells, even other strains of E. coli, or heat inactivated O157:H7,” she explains. “This aggregation is detectable using magnetic resonance. Similar to MRI technology used in human medicine, the bacteria detection procedure launches a magnetic field through the sample. But instead of measuring water molecules, as is the action of medical MRIs, the detector picks up iron-rich nanosensor clumps.”

In the presence of a small number of bacteria (low colony forming units, CFUs), the magneto-fluorescent nanosensors (MFNs) cluster around the bacterial cell, which inhibits their interaction with the surrounding water protons, thus increasing magnetic relaxation (T2) values, Dr. Banerjee elaborates. “However, as bacterial concentration increases (high CFUs), the clustering decreases,” she says. “This causes the T2 signal to become saturated and the ability to quantify bacterial concentration is lessened.”

One huge benefit of the PSU nanosensor technology, Dr. Banerjee says, is its capability to scan both very small amounts of a pathogen, as well as very large amounts. “Magnetic resonance has the ability to detect bacteria in small quantities, but not in large ones,” she points out. “With fluorescence, the opposite is true.”

Another selling point is that the PSU nanosensors are currently able to detect bacterial contamination in less than an hour. “This is much quicker than current gold standard techniques, including real-time polymerase chain reaction, which can take up to 24 hours for data collection, sample amplification, and results,” Dr. Banerjee notes.

With further experimentation, the time required to get test results is expected to be reduced to a few minutes or even seconds, Dr. Banerjee predicts. “Magnetic relaxation is a powerful technique and we start to see a light change within a few minutes when we incubate MFNs with bacterial CFUs,” she relates.

Soon we expect to do multiplex samples for other contaminants besides E. coli in the same sample, so pathogen testing will be even faster then. And if one organism is more prominent than the other, we will be able to detect the less prominent one.”

The next big step, Dr. Banerjee says, is to convert the nanosensor technology into a chip device that will make it quick, easy, and inexpensive for consumers to determine outside of the lab if food or water is contaminated with pathogens. “That will take a bit more time and collaborations with engineers, but we believe the efforts will have long term benefits for the greater society,” she emphasizes. “Besides handy use in retail settings for grocery shoppers, potential global applications include food manufacturing and water analysis in developing countries.”

Liquid Droplet Test
Researchers at Massachusetts Institute of Technology (MIT), Cambridge, have developed a new test for E. coli based on a novel type of liquid droplet that can bind to bacterial proteins.

This interaction can be detected by either the naked eye or a smartphone, according to Timothy Swager, PhD, MIT’s John D. MacArthur professor of chemistry.

In 2015, Dr. Swager’s lab developed a way to easily make complex droplets, including droplets called Janus emulsions.

Two years later, Dr. Swager, his colleagues, and students decided to explore using these droplets as sensors because of their unique optical properties. “In their natural state, the Janus droplets are transparent when viewed from above, but they appear opaque if viewed from the side because of the way that light bends as it travels through the droplets,” Dr. Swager relates.

To turn the droplets into sensors, the researchers designed a surfactant molecule containing mannose sugar to self-assemble at the hydrocarbon–water interface, which makes up the top half of the droplet surface. “These molecules can bind to lectin proteins, which are found on the surface of some strains of E. coli,” Dr. Swager points out. “When E. coli is present, the droplets attach to the proteins and become clumped together. This knocks the particles off balance, so that light hitting them scatters in many directions, and the droplets become opaque when viewed from above.”

The MIT team hopes to adapt its new technology into arrays of small wells, each containing droplets customized to detect a different pathogen and linked to a different QR code.

The MIT team hopes to adapt its new technology into arrays of small wells, each containing droplets customized to detect a different pathogen and linked to a different QR code. “This could enable rapid, inexpensive detection of food contamination in most any venue using only a smartphone,” Dr. Swager emphasizes.

The MIT researchers are now working on optimizing the food sample preparation so they can be placed into the wells with the droplets. “We also plan to create droplets customized with more complex sugars that would bind to different bacterial proteins,” Dr. Swager says.

In their initial work, the team used a sugar that binds to a nonpathogenic type of E. coli, but they foresee adapting the sensor to other strains of E. coli and other pathogenic bacteria, Dr. Swager mentions. Another step would be to make really selective droplets to catch different bacteria, based on the sugar one puts on them.

“We are also working to improve the sensitivity of the sensor, which currently is similar to existing techniques but has the potential to be much greater,” Dr. Swager adds. “We expect to launch a company to commercialize the technology in the late summer of 2018.”

Leake, doing business as Food Safety Ink, is a food safety consultant, registered SQF contract auditor (High Risk), and award-winning journalist based in Wilmington, N.C. Reach her at LLeake@aol.com.

For extensive online coverage of E. coli, go to the June/July 2018 issue at www.FoodQualityandSafety.com.
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According to the FDA, the Food Safety Modernization Act (FSMA) is “transforming the nation’s food safety system by shifting the focus from responding to foodborne illness to preventing it.” As chemical distributors, the members of the National Association of Chemical Distributors (NACD), frequently import, transport, ship, and pack food ingredients that will ultimately go into diverse types of food products.

Food ingredients or food chemicals must comply with the same regulations as a manufacturer of ready-to-eat foods or frozen foods, so chemical distributors are covered by each of the seven foundational rules of FSMA, except for the Produce Safety Rule, which is nonapplicable to their operations.

FDA does not have a definition for food chemical, but it is FDA’s definitions of “food” and “facility” that clearly indicate that if a chemical distributor is packing or holding an article used for food, then that facility and food are subject to FSMA regulations. Chemical distributors also handle food contact substances, which are subject to different FSMA requirements.

Chemical Distribution and Food
Chemical distributors import, purchase, process, and distribute chemicals into almost every market, ranging from food to coatings to cosmetics. Food chemicals tend to be a small part of their overall business, but companies still spend a significant amount of effort to ensure the foods that they do hold and distribute are moved in a safe way. Most chemicals handled by a distributor go into other uses, including industrial, water treatment, energy, manufacturing, automotive, and agricultural purposes.

When FDA wrote the FSMA rules, the agency had the enormous responsibility to create regulations that would apply to the unique variety of food facilities that FSMA would ultimately regulate. To that end, some of the regulations “fit” better with the operations of traditional food facilities than they do with chemical distribution facilities.

Example of a Typical Chemical Distribution Facility
You are walking into a medium-sized chemical distribution facility. You’ve stepped into a large warehouse that is connected to an administrative office. This particular facility is what’s known as “factory-pack,” which means that it doesn’t do any repacking of chemicals into smaller packages or blending into different concentrations. This facility only receives packages directly from manufacturers and then sends them on to customers. The floor is busy—employees are preparing orders for shipment, or unpacking received orders, and trucks are routinely arriving to pick up and drop off deliveries.

Other facilities are more extensive, and some may do processing of chemicals, such as blending or diluting, but most do not manufacture chemicals, which is the creation of a new molecule.

In this facility, the chemicals that go into food may or may not be separated from the chemicals that have other end-uses. The layout of all chemicals will be dependent upon several factors, including other state and local regulations, space restrictions, and the most efficient workflow. Chemicals may be stored in a vast variety of ways, including in 30- or 55-gallon steel drums, 10- or 20-pound sealed bags, and may be placed on pallets or stacked directly on the factory floor. The average NACD member has two facilities with an average of 26 employees, but some distributors have nationwide operations with hundreds of employees.

Regulatory Overlap
Several other federal agencies regulate chemicals, adding complexity to an already crowded regulatory environment. While traditional food facilities are most likely regulated by FDA and the Occupational Safety and Health Administration (OSHA), most chemical distribution facilities are not only regulated by FDA and OSHA, but also the Environmental Protection Agency, Drug Enforcement Administration, Department of Homeland Security (DHS), and the Pipeline and Hazardous Materials Safety Administration.
One interesting and unexpected overlap has resulted between the FDA and the DHS Chemical Facility Anti-Terrorism Standards (CFATS) program for chemical facilities. FDA’s Intentional Adulteration rule shares several elements with CFATS, such as security requirements and back-checks for employees. While the first compliance date for FDA’s Intentional Adulteration rule isn’t until July 2019, the chemical community is already discussing how it will implement the requirements and if coordination between FDA and DHS on these regulatory programs is possible.

**Recent FDA Activity Under FSMA**

In early 2018, FDA announced enforcement discretion for the written assurances provisions of the Preventive Control rules, the Foreign Supplier Verification Program (FSVP), and the Produce Safety Rule. The agency admitted it did not anticipate the vast impacts that the written assurances requirements would impose on industry and decided to consider alternate rulemaking. The agency also announced earlier this year that food contact substances would not be required to comply with the FSVP requirements. Additionally, as part of the third-party accreditation rule, FDA recently recognized two accreditation bodies that can conduct food safety audits of foreign facilities and will continue to review applications as they arrive.

**FDA Inspections at Non-Traditional Food Facilities**

Inspections at chemical distributors are usually conducted in a single day and with minimal involvement compared to a typical food facility. However, many FDA inspectors are not familiar with chemicals and can arrive at a chemical distribution facility unsure of how to do a food inspection at a non-traditional facility. Undoubtedly it is frustrating for an FDA inspector to arrive and realize that he or she doesn’t know how to conduct an inspection, and it can be just as frustrating for companies that spend considerable time and money preparing for an inspection.

Thankfully, FDA recently implemented an initiative called “program alignment” wherein FDA offices will be assigned to facilities based on their expertise instead of the location. Previously, a facility would be inspected by the closest FDA office to its location, which resulted in FDA inspectors having to be experts in every type of facility inspected—food, drugs, devices, biologics, and more. Under program alignment, FDA offices are now divided into one of two categories, “food” or “drugs,” and now food facilities are inspected by the closest FDA food office, which should help concentrate the knowledge about chemical distribution at FDA.

FDA is also in the process of developing a resource library for inspectors that they can access before, during, and after inspections with additional information on the facilities and products that they will be inspecting.

**Foreign Suppliers and Food Safety**

Many chemical distributors also import food from other countries and must meet FDA's goal for FSVP: Imported food that meets the same standard of quality as food from the U.S. Importers must verify their suppliers and document the procedures used to ensure a supplier is meeting its obligations under FSVP. In some cases, verification may mean an overseas in-person audit and in other cases it may mean less stringent procedures, such as a thorough review of a foreign facility’s Hazard Analysis and Risk-Based Preventive Controls plan.

Verification of foreign suppliers is expected of all importers and, just as important, documentation of that verification. FSVP allows importers to use the most appropriate method to verify their suppliers. Most chemical distributors are familiar with importing and conducting due diligence of foreign suppliers, however, FSVP has added a unique challenge as distributors try to be aware of the uses of each chemical they are importing.

**Food-Grade and Intended Use of Chemicals**

The word “food-grade” can be misleading in the chemical world. Chemical distributors frequently purchase food-grade chemicals based on customer demand for selling into industrial or other markets. For example, a customer may wish to purchase food-grade citric acid for use in nutritional supplements, which are regulated by FDA, however not under FSMA.

Therefore, just because a chemical has the word food-grade used to describe it, does not mean that the chemical is going into a food. Customers of distributors frequently request food-grade chemicals due to another property that the word food-grade meets, such as the concentration or preparation. Oil and gas companies are known to request a food-grade version of a product because it has less impurities in it.

Sometimes the name of a product can be misleading, such as the case with tapioca starch, which can be used in oil and gas applications. A distributor may know exactly how its customer plans on using a chemical, but it is impossible for a distributor to know every potential use of its chemicals—and exactly how each of its hundreds of customers plan to use them. Some commodity chemicals such as caustic soda can have thousands of uses alone. Distributors frequently use a certificate of analysis to help determine how the product will ultimately be used.

**Other Food Safety Standards**

Many chemical distributors have long used other quality standards such as ISO 9000, FSSC 22000, Safe Quality Food (SQF), and Global Food Safety Initiative (GFSI) to establish best practices and industry standards for their food products. NACD’s own environmental health, safety, and security program, Responsible Distribution, has elements that can be applied to food safety, including codes on handling, security, internal audits, and corrective and preventive action.

FDA has recently stated that it is interested in working with GFSI and other private standard-setting bodies to see how private standards could be used to help food facilities meet the verification requirements under the FSVP and Preventive Control rules.

**What’s Next**

FDA has established no less than 64 different deadlines for implementing each provision of the seven rules of FSMA. Although most of the deadlines have passed, chemical distributors are especially aware of the challenges that they face as non-traditional food facilities and stand ready to help supply chain partners learn more about how they meet FSMA regulations.

Tuszynski is manager of regulatory affairs at the National Association of Chemical Distributors. Reach her at 571-482-3063 or atuszynski@nacd.com.
Global regulators continue to focus on food fraud, whether deliberate or accidental. The food industry has risen to the challenge by finding innovative new tools to monitor food and ingredients along the supply chain. Its next step should be to bring the same level of care to the laboratory, where food samples are tested for quality.

Supply Chain Traceability to Mitigate Adulteration
Before discussing the laboratory, let’s look at the example of the supply chain where food manufacturers have been tremendously successful in using traceability to improve the safety of their products.

In the global food system, food supply chains have become complicated. The integrity of the supply chain is only as strong as its weakest link, so food manufacturers are identifying the places on the chain where adulteration is most likely—and then targeting them for special scrutiny.

There are two factors that make it more likely food will be adulterated. The ease of adulteration is one—foods like fruit, vegetables, and whole fish are much harder to adulterate than highly processed foods. A second motivation is financial gain. When crop failures or product shortages drive up food prices, sellers are more likely to substitute a substandard ingredient. That’s why the food industry has an adage about sourcing products, “If the price is too good to be true, it probably is.”

To avoid adulteration, suppliers rely on detailed supply chain management that includes history, audits, and product traceability. Traceability today still relies on paper documentation to some extent, but technologies such as RFI (radio frequency identification) devices or simple barcodes have helped eliminate falsification of records as food passes from one producer to another. Food producers are even using blockchain to ensure secure record traceability. The industry has shown it is ready and willing to adopt new technology to keep food safer.

Analytical Science to Identify Adulteration
But the quality of food products stands not only on the quality of the documentation from the supply chain, but also on the quality of the data from analyzing the product in the lab.

In the laboratory, the scientific community is very good at quickly developing analytical tests for food fraud—but only once a specific threat or vulnerability is identified. Scientists also create analytical tests for unintentional contamination—from poor-quality ingredients, the breakdown of legitimate ingredients, or the manufacturing process. And with heightened concerns about allergens, contamination that may once have been considered “harmless” now needs to be treated seriously. Witness the February 2018 recall of almonds found to contain traces of wheat and soy.

But the volume and reach of the global food chain make it impossible to conduct complex testing on every ingredient or product. As a result, manufacturers often put their faith in certificate of analysis reporting—but that has its own vulnerabilities, as demonstrated by the pet food melanin contamination case.

A more practical approach combines non-targeted screening with statistical analysis of trends and database-matching to look for anomalies. This level of screening usually takes place in governmental or institutional oversight laboratories because it requires sophisticated, expensive instruments like high-resolution mass spectrometers.

The question then becomes, can we rely on the data from these central testing laboratories? Or should we extend the
scrutiny we bring to supply chain distribution records to the laboratory test data that supports food integrity?

Concerns About Laboratory Data

The good news is that the specificity and detection limits of analytical science tools continue to advance. But even with the best tests in the world, laboratories still rely on analysts and laboratory staff to perform tests accurately, reliably, and correctly. And the human element is not infallible.

In extreme cases, staff can be motivated to commit fraud for economic gain. A more insidious problem is when individual analysts feel pressure to “polish” the data, perhaps driven by a desire to meet performance metrics or deadlines, earn recognition, or reduce stress.

It is important to note, though, that the reasons and motivation for adjusting or excluding test results do not automatically indicate fraud. Laboratory procedures must allow for the correction of errors, or for the investigation of incorrect results. Unusable, unreported, or orphan data may be caused by overly simplistic or lax documentation practices, staff inexperience, or particularly challenging analytical techniques. Waters Corp. is partnering with government agencies and universities to combat these problems by creating training centers to educate analysts on how to properly prepare samples, run the instrumentation, and interpret test results and other skills.

Still, it’s known that fraud and data polishing is happening in multiple fields. Analytical test fraud has been uncovered in forensic drug laboratories in the U.S. In the academic world, laboratory testing has been found to be intermittently falsified, driven by the motivation to “publish or perish.” In the pharmaceutical field, the FDA and other global pharmaceutical regulatory agencies are increasingly looking for signs that laboratory analysts may have corrected or hidden results that indicate a study or quality test failure. They are increasing scrutiny of analytical records created by testing laboratories, both those supporting new drug development (GLP and GCP) and quality manufacturing (GMP) monitoring.

These examples show why it’s crucial to bring a new level of attention to the accuracy and trustworthiness of data supporting product or test quality, a concept usually referred to as “data integrity.”

Regulators have lost trust in paper records. Evidence found in “compliance ready” electronic applications (specifically in the area of laboratory automation) have shown the paper records relied on for quality decisions, criminal prosecution, or academic publication do not always constitute a complete and transparent record of the sample tested.

Computerized systems can help by making it much more difficult to tamper with data. Unique login requirements, privileges, and permissions can technically control what users are allowed to create, delete, or change, and comprehensive audit trails can record any activity attributed to those users. Regulators recently acknowledged the value of computerized systems in data integrity. The November 2017 release of ISO/IEC 17025:2017, in sections 7.5 and 7.11, describes the technical expectations for either computerized or non-computerized information management systems that are designed to ensure the “integrity of data and information.”

In 1997, the FDA outlined requirements for technical controls very similar to those described in ISO 17025. The FDA’s 21 CFR Part 11 (known as the Electronic Records and Signature Rule) also includes administrative and procedural controls for ensuring that electronic data is trustworthy. It’s worth noting that the European Union (EU) has a similar regulation, Annex 11. But while the EU regulation specifically covers only data supporting pharmaceutical manufacturing, the FDA regulation applies to data from all predicate recordkeeping requirements across all good practices, including human food manufacturing, packaging and holding (Part 110), cosmetics, and GLPs for Protection of the Environment (40 CFR Part 160).

All three regulations discussed above support commonly applied practices of good documentation, which map closely to the more recent ALCOA principles of data integrity: Attributable, Legible, Contemporaneous, Original, and Accurate.

These principles were established by Stan W. Wollen, senior compliance advisor at FDA. In 2010, a European Medicines Agency reflection paper on electronic data in clinical trials added four complementary terms: Complete, Consistent, Enduring, and Available. All of these terms, like the good documentation practice principles, should apply equally to both paper and electronic records and are cited in almost every data integrity guidance or training.

But there is evidence to suggest laboratory personnel may not be following the practices outlined in these regulations. Regulators have turned up clearly unacceptable practices when they compared results on paper or manually recorded to the complete results digitally logged by the measurement instruments. The electronic records have revealed cases of testing a sample multiple times to obtain the “right answer,” or adjusting the meta data (sample weight, dilution factor, volume) in a calculation to ensure that a specification is met.

Regulatory Oversight and Enforcement

As with any new regulation, including the Food Safety Modernization Act of 2011, agencies tend to focus their regulatory attention on the most urgent risks. The FDA only ramped up its focus on data integrity in the pharmaceutical industry following some high-profile cases in which test laboratories, such as New Jersey’s Able Laboratories, were found to be deliberately falsifying records supporting pharmaceutical products.

Today, global pharmaceutical regulators are inspecting both the quality systems and laboratory records. They’re comparing paper records to the raw, electronic data to search for suspicious or anomalous test results that may not have been reported in official documentation.

Data integrity in the food industry is complicated by overlapping areas of oversight between the FDA, which regulates most processed food, and the USDA, which regulates meat, poultry, and egg production. In January 2018, the two agen-
Imagine a day when you could go to a restaurant and cricket tacos and mealworm frittatas were among your entrée choices on the menu. Or, imagine being able to order a dessert containing the cannabis plant instead of an alcoholic beverage to help you relax and feel good after a long day. Or, what would you think about having the option to custom order a meal that didn’t contain any ingredients you were allergic to using a 3D printer?

These days may actually not be that far away. In fact, in some parts of the world, a few of these food options already exist. Using insects and cannabis as food ingredients, as well as printing out foods three dimensionally, are among some of today’s biggest emerging food trends. Here’s a closer look at each of these trends, why they’re gaining popularity, as well as safety and manufacturing concerns—and possible solutions to these worries.
Edible Insects

Many cultures around the world have been eating insects for generations. In fact, 2,100 species have been recognized as edible and forming some part of a diet in a particular culture, says Robert Nathan Allen, founder of Little Herds, an educational non-profit organization in Austin, Texas, and co-founder of North American Coalition for Insect Agriculture, which educates the public and works to increase the capacity of insect industries. But until recently, there were few examples in western or Euro-centric foods that contained purposeful insect ingredients.

But now there’s a rising interest in insect ingredients due to their numerous health and wellness benefits and environmentally beneficial resource efficiency in the western hemisphere. “They are viewed as an alternative protein that can address nutrient deficiencies and food insecurities in a variety of ways,” Allen says.

Among the most common insects used in North American and western Europe foods are crickets, mealworms, grasshoppers, and silkworms. In other cultures, termites, ants, and beetle larvae are also common choices.

In the last five years, a new wave of insect product-maker startups have begun using ingredients such as cricket powder (dried and ground crickets that were farmed specifically for food purposes) or textured insect protein (think insect-based tofu) to make insect-based chips, crackers, protein shakes, pastas, energy bars, cookies, granolas, crisps, breads, hotdogs, meatballs, and burger patties.

Bug Benefits Abound

Insects are very nutritious and are an excellent source of protein but have a much smaller environmental footprint than other sources of animal protein, such as pork or beef, says Mareike Janiak, a graduate student and teaching assistant in the anthropology department at Rutgers University, New Brunswick, N.J. The exact nutritional value of insects varies widely across different species and different life stages of the same insect.

Allen says consuming insects is a more humane and ethical way to obtain animal proteins than traditional livestock. Most insects contain more protein than beef, more iron than spinach, more calcium than milk, plus vitamins like B12, minerals like zinc, copper, and niacin, great amino acids, poly and mono unsaturated fats, and fiber, Allen says. They have a long shelf life and research is pending on whether they have prebiotic properties. Insects don’t require hormones, antibiotics, or steroids either.

Raising insects requires much smaller areas of land, less water, and less food than raising other livestock, and they emit much less methane than cattle. “With the world’s growing population and the dangers of global warming, we will need to consider alternative protein sources—edible insects may be a good option,” Janiak says.

Insects can be raised organically and don’t need to be genetically modified, and insect ingredients are gluten-free and work well for paleo and ketogenic diets. Some insects are even considered Halal and Kosher, Allen adds.

More People Jumping on Bug Bandwagon

While many people once viewed eating insects as disgusting, people in North American and western Europe are slowly changing their opinions, Janiak says.

Because most insects have a chemical composition that resembles that of shellfish, people who are allergic to shellfish may be allergic to consuming products containing insects.

“Conscious consumers, millennials, green parents, and many other consumer categories are seeking out sustainable, natural, nutritious, and ethical options, especially alternative proteins,” Allen explains. “In the past few years, many athletes, musicians, trendsetters, celebrities, celebrity chefs, and business and thought leaders have promoted them. They can play a big role in opening people up to new ideas and normalizing them.”

Celebrities may have been exposed to the idea when traveling to other cultures where eating insects is commonplace, and experienced it in a positive and receptive environment. Athletes may be early adopters because of the foods’ nutritional density. Some folks want organic or locally sourced or free-ranged food that they view as being more humane and ethical. Foodies are looking for new, interesting foods. “When people have the opportunity to try something and it tastes good, then it’s easy to eat it again,” Allen says. “But it has to be delicious.”

Edible Insect Issues

Because most insects have a chemical composition that resembles that of shellfish, people who are allergic to shellfish may be allergic to consuming products containing insects. Given this, the U.S. FDA requires a product’s label to state a warning against this potential allergy.

The FDA has given clear guidance on steps a company must take to market and use insects in products. “Insects must be farmed for food purposes and must adhere to Good Manufacturing Practices during processing, packaging, marketing, and transporting,” Allen says. For example, they must be cooked in the same way as other food products to prevent microbial growth.

In order to ensure a product’s safety, Allen recommends standard safety testing, supply chain verification, chain of provenance authentication, and good consumer education on intended use and best practices for cooking and storing. The FDA requires laboratory testing.

Cannabis Food Products

As marijuana and hemp, two plants that are part of the cannabis family, are being de-criminalized and more regulated, they along with their extracts are finding their way into scores of consumer products.

The cannabis plant contains many constituent ingredients, the most obvious being tetrahydrocannabinol (THC). The widely known psychoactive ingredient is primarily responsible for making people high when smoked or in other forms, says Chris Bunka,
chief executive officer, Lexaria Bioscience Corp., Phoenix, Ariz., and Kelowna, British Columbia, Canada. But both cannabis and hemp strains are rich in non-psychoactive cannabinoids that are very different and mostly overlooked in comparison to their better-known and often vilified cousin ingredient, THC.

Non-psychoactive cannabinoids like cannabidiol (CBD) have found their way into products such as tea, coffee, hot chocolate, candies, chocolates, soft drinks, cookies, baked goods, sauces, spices, fruit drinks, and entrées. Hemp seed and hemp protein are sold widely across North America and Europe as nutritious protein supplements with healthful omega oil profiles, Bunka says.

Infused versions of products are an increasing trend in the cannabis market. Long-term users of cannabis prefer this form of product delivery because the effect seems to be greater and longer lasting than traditional cannabis when smoked. “Many people develop a tolerance to cannabis when smoked, and no longer experience an effect, whereas edible cannabis seems to always provide an effect that consumers enjoy,” says Stuart W. Titus, PhD, president and CEO, Medical Marijuana Inc., San Diego, Calif. “Generally, it creates exuberance, laughter, and joy while relaxing the body.”

**Reasons Behind Cannabis Popularity**

Some people report that ingesting cannabinoids has helped them mitigate seizures or battle cancer, anxiety, irritability bowel syndrome, Crohn’s disease, or dementia. “The trend is growing in popularity because a sufficient number of people believe they have experienced profound health benefits,” Bunka says.

According to Dr. Titus, science shows that the digestive tract can potentially convert delta-9 THC into delta-11 THC, a slightly different chemical structure that may be responsible for creating a magnified, longer-lasting effect for some regular cannabis users.

Technology now exists to ensure that the better tolerated THC delta-9 can be delivered consistently in edible product formats.

**Cannabis Concerns**

Ironically, the biggest health and safety concerns around cannabinoid delivery are interwoven with the most common former delivery of those ingredients—which was combustion or smoking. “Lungs are for breathing; ingesting anything via combustion and inhalation into the pulmonary system appears to be unhealthy,” Bunka comments. “The gastrointestinal system, on the other hand, is for delivering nutrition from food into the bloodstream.

“Regulation in states such as Colorado and California are the best things to have happened to the cannabis industry in 100 years,” Bunka continues. “Older, poor practices such as lack of cleanliness in food production areas are being replaced by modern food manufacturing processes. Now that cannabinoid ingredients can be properly analyzed at laboratories without fear of black helicopters and SWAT teams on the roof, companies can reliably check that cannabinoid ingredients are free of pesticides and herbicides. This simple evolution of good practices is revolutionizing the industry and raising standards.”

Another manufacturing concern stems from the fact that a large amount of cannabis is grown indoors, which generally requires pesticide usage. “This can allow for residual toxicity to be in the end product,” Dr. Titus says.

**Solutions to Ensure Safe Edibles**

Edible products are one of the best ways to deliver consistent and reliable cannabis experiences because of the nature of plant-based ingredients. “Every plant produces slightly different levels of strength of active ingredients, even when plants are cloned,” Bunka says. This inconsistency from plant to plant and batch to batch can best be dealt with by processing large amounts of plant matter in a single manufacturing operation—once turned into a liquid oil, any number of tiny samples taken from a large vessel of oil will have effectively identical composition. This allows food manufacturers to predictably deliver a consistent product. Small scale production prior to legalization rarely achieved this.

For the same reasons, these samples can be analyzed at the laboratory for unwanted herbicides or heavy metals and rejected prior to use in a food product. “It was previously impossible to take samples from each of hundreds or thousands of different plants to ensure they were all safe,” Bunka says. But contamination issues can be a thing of the past in the cannabis industry with proper regulation and monitoring with standard operating procedures.

**3D Printed Foods**

Simply put, 3D printing involves creating a 3D item from a graphic rendering by printing on X, Y, and Z axis instead of just X and Y like
traditional computer printers, resulting in a three-dimensional object, explains Darryl L. Holliday, PhD, CRC, assistant professor of food science, director of the food science program, and department chair for biological and physical sciences, University of Holy Cross, New Orleans.

All 3D printers use some type of material for building the 3D printed item’s shape and structure. The most common material is a plastic filament, but food companies work with food staples such as sugar, chocolate, pasta dough, cheese, and peanut butter.

Dr. Holliday’s research laboratory uses ground beef as its printing medium because of its universal appeal. “My research has shown that not only can firm objects be produced, but that by using the right medium and printing capabilities, we can print foods that are more traditional such as hamburgers,” he says.

### 3D Loaded with Advantages

The main benefit of 3D printing is customization, Dr. Holliday says. Currently, manufacturers and food professionals can use 3D printing to create shapes and textures that traditional manufacturing methods cannot duplicate. Additionally, switching from printing one piece of item A to one piece of item B is much faster with 3D printing than traditional manufacturing. However, traditional manufacturing is much more efficient at mass producing the same item. Furthermore, 3D printing is an efficient method for mock-up items such as parts, packaging, and food concepts because molds don’t have to be made and lines shut down for research and development.

A goal of Dr. Holliday’s research is to develop fully autonomous kitchens to deploy in disaster areas. “An autonomous kitchen could be easily adapted to create familiar flavor profiles of a devastated area by simply changing the printing medium and its flavors,” he says. For example, a simply seasoned beef hamburger could be prepared in one place and a spicy chicken patty prepared in another to meet different populations’ tastes and dietary requirements.

As technology and speed improve, Dr. Holliday foresees this technology affecting food service operations such as large fast food chains. “By bringing in one beef mixture, they limit the amount of stock-keeping units they have to stock and use a 3D printer to make patties of various sizes based on what menu item is ordered,” he says.

Hod Lipson, PhD, professor, mechanical engineering and data science, Columbia University, New York, N.Y., says the main advantage of printing foods is transparency. “You can see a food being made and the ingredients being used,” he says. “Food printers could combine the convenience of prepared food, and the transparency of homemade food. It’s almost like having a personal chef.”

In addition, printed foods’ nutritional content can be tailored based on personal biometrics, such as glucose levels, metabolic activities, allergies, personal genome, and taste preferences.

### Gaining Steam, Three Dimensionally

Food printers are a marriage of software and cooking—two big aspects of life that have not yet intersected, comments Dr. Lipson. “People are excited about the possibilities of bringing software into the kitchen,” he says.

Providing the capability for complete customization also makes it a popular trend. “New shapes and textures are just the beginning,” Dr. Holliday says. Traditional color printing uses four different ink cartridges. 3D printing has theoretically unlimited variables. Because different food mediums can be printed at the same time, or one right after another, most attributes of a food can be customized in any given system.

“As more research establishes nutrigenomics as a fundamental part of nutrition, nutritional customization will begin to play a greater role in the benefits of 3D printing and its impact on the food industry,” Dr. Holliday says.

### 3D Printing Problems

Most of the same safety concerns regarding any manufactured food apply to 3D printed items. “You have to watch and track chemical and biological hazards,” Dr. Holliday says.

Due to slower printer speeds than normal production speeds, it may be necessary to closely monitor a printing medium’s temperature so that it does not stay in the temperature danger zone too long or be exposed to conditions where an FDA or USDA inspector could find it adulterated.

Food safety issues also stem from food handling and cleaning complex machines, Dr. Lipson says. The potential risk of making unhealthy foods through software errors also exists.

Giving customers the ability to customize foods can lead to serious safety concerns such as cross-contamination of allergens or at minimum, cross-contamination of food mediums affecting dietary requirements, Dr. Holliday says. Additionally, if customers have the ability to add unique nutritional supplementation to a food, based on need or lifestyle patterns, then there will need to be a safety check to ensure that overdosing is prevented.

Automation is the future of faster food preparation, reduced labor costs, and improved consistency, Dr. Holliday concludes. Consumers are also driving the demand for creative control of foods they eat. Companies such as Frito Lays with its “Do Us a Flavor” campaign and restaurants like Chipotle and Smoothie King offering consumers the ability to see and choose toppings or ingredients have already recognized this.

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**Appold** is a freelance writer based in Pennsylvania. Reach her at kappold@msn.com.
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Confronting Food Cyberterrorism

As many food companies rely more on computer systems for managing their businesses, understanding and planning for the threat of cybersecurity risks is paramount

BY NICOLE C.K. JAMES

There is no shortage of risks in the global environment these days. The Barcelona Centre for International Affairs (CIDOB), an independent think tank, has documented the top issues that it believes will shape the international agenda in 2018. One of these issues concerns connectivity and the world order. This connectivity includes control over the means of transporting goods and information, which is a strategic priority for many nations. However, the potential for crisis related to this control appears to be increasing. One of the contributing factors to this crisis, according to the CIDOB, is digital vulnerability. With the tensions mounting between many countries including the U.S., Russia, China, and the Korean Peninsula, this vulnerability could translate into real incidents of cyberterrorism.

Perhaps it is beneficial to start with an understanding of cyberterrorism. As stated by the U.S. Federal Bureau of Investigation, cyberterrorism is any “premeditated, politically motivated attack against information, computer systems, computer programs, and data that results in violence against non-combatant targets by sub-national groups or clandestine agents.” Similarly, according to the Cambridge Dictionary, cyberterrorism constitutes “the use of the Internet to damage or destroy computer systems for political or other reasons.”

Of course, cyberterrorism can involve any information system in any industry and it might be argued that a greater crisis would result from sabotaging highly sensitive information systems, such as those used for air traffic control. So what would inspire cyberterrorists to focus on the systems that are part of the food chain?

As it turns out, these systems are actually very attractive targets for a cyberterrorist attack. An attack of this nature could certainly be far-reaching—the food chain is an entity that unites the world population and touches everyone in some way. The National Cybersecurity Institute at Excelsior College, a center dedicated to the challenges in cybersecurity policy, technology, and education, states that the “Department of Homeland Security [in the U.S.] has labeled the Food and Agriculture industry as one of the 16 national critical infrastructures.”

Potential Threats
According to the World Health Organization, 420,000 people die every year from food-related illnesses and the Food and Agriculture Organization of the United Nations says that more than 1.3 billion tons of food is wasted due to spoilage. An act of cyberterrorism in the food industry (also known as agroterrorism) could increase...
EMERGING FOOD SAFETY AREAS

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these numbers exponentially. There are a number of different avenues that agroterrorism could take:

- Disruption of delivery;
- Alteration of formulations;
- Interception of confidential information; and
- Threat of tampering.

How could these avenues unfold? Let’s discuss each one in some detail.

Disruption of delivery would affect the transportation system that moves goods from place to place, potentially cutting off vital supplies to vulnerable communities.

Alteration of formulations could occur at a food manufacturing facility through the takeover of important pieces of equipment. These days, nearly every step of the food supply chain involves a smart device or sensor that connects to a centralized control system. These devices are known as programmable logic controllers, or PLCs. The programming that makes up a PLC is only as “smart” as the individual who created it. PLCs can’t be relied on to make the distinction between a benevolent programmer and a malevolent individual with the goal of causing harm. PLCs could potentially be accessed remotely with any number of undesirable to disastrous results.

Researchers have already been successful in modeling the takeover of PLCs in a water plant. By using ransomware, they were able to change the monitoring systems, including altering chlorine levels. PLCs can control very significant parts of the manufacturing process. Taking control of PLCs involved in the manufacturing process of a product destined for a highly susceptible population, like infant formula, could result in major changes to the calibrated delivery of the various nutrients that are part of the formulation. The ultimate result is the sickening (or worse) of the youngest segment of the population.

Accessing confidential information is an ongoing favorite of cyberterrorists generally. Look no further than the recent Facebook scandal, where Cambridge Analytica was able to harvest over 50 million user profiles, simply by building a quiz app that collected data not only from the individuals taking the quiz, but also from the friends of these individuals—people who had no connection with the quiz. In another angle, a joint study released by the antivirus software specialist McAfee and the technology services provider Science Applications International Corp. showed that hackers are now looking to gather trade secrets and marketing plans and use that intellectual property to their own advantage.

The threat of tampering might be a method used by cyberterrorists. An example of this can be seen in the subset of cyberterrorists known as cyberactivists. Cyberactivists are those who may disagree with a company’s product or the method the company uses to produce the product. These individuals may threaten initially to use hacking to attack a company’s reputation, disrupt its operations, or maliciously modify its automated processes and then, depending on the response of the company, go on to launch the damage. Criminals may also use the threat of lost profits, caused by the disruption of equipment or transportation, to extort money.

Regardless of the motive, what is universally frightening is that any of these avenues could easily be initiated by cyberterrorists located anywhere in the world. There is certainly no requirement for the person perpetrating a cyberterrorist act to even set foot in the facility that is affected.

Limiting Exposure to Harm

With all of this in mind, it might be surmised that the food industry is arming itself heavily to prevent cyberterrorist acts. Unfortunately, that assumption might not be as accurate as would be desired. A number of factors are behind the fact that the food industry is not the most up to date in tightening its cybersecurity. One is a lack of awareness. Since breaching a company’s computerized systems is not as obvious as a piece of equipment that is not working, or a patch of flooring that requires repair, dedicating the resources to protecting those computerized systems is not the first priority. Those resources, of course, are tied into available money. Many food manufacturers look to their budgets first to improve food safety and quality, as well as productivity, before focusing on cybersecurity, especially if they never had an issue (at least not one that they are aware of). That lack of focus on cybersecurity can result in unnoticed system vulnerabilities. These vulnerable areas could include firewalls that go out of date, remote access portals that are insecure, operating systems that can be more easily corrupted, and staff that is poorly trained and/or unaware of the risks.

Even companies that have realized the importance of having a defense prepared against cyberterrorist attacks will often focus on the protection of their database systems. However, what is frequently overlooked is that professional hackers will use indirect and innovative methods to bypass the gates of even those systems that the companies believe to be secure. One example of a fairly simple way that a hacker can gain access is through the deployment of a large volume of phishing emails, all sent to personnel employed by the company that they are targeting. This technique is akin to the practice of ringing the doorbells of everyone that lives in the same apartment building. While most apartment dwellers won’t allow an individual who they don’t know into the building, the likelihood that one person will allow access increases the more doorbells are rung. And that is all that is needed—just one person—to let the hacker in.

Another method that cyberterrorists might employ is gaining access through a third-party contractor that a food manufacturer
uses. As computer programming and software development requires a very specific technical skillset, many food manufacturing companies will not have this expertise in-house and will outsource to a contractor to help build their computer networking. However, this very act of bringing in outside expertise can expose the food manufacturing company to additional risks. Many of the high-profile cybersecurity incidents that have occurred were a result of hackers accessing the systems of the third-party contractors, which then allowed them a gateway to their true target—the food manufacturing company.

Ultimately, it is key that food manufacturing companies recognize the risks of cyberterrorism to their businesses and the greater food system that they are part of. From there, it is essential to implement a comprehensive cybersecurity program that is actively managed and maintained. Installing an antivirus software that is not updated regularly, with firewalls that are not closely watched, will not stop the highly skilled individuals that either are getting past those walls because they have their own agenda, or because they have been hired by others who are motivated to do harm. Companies must have a more far-reaching approach, where the antivirus software and firewalls are supported by policies, procedures, proper staff training, and regular updating.

Companies should approach cybersecurity in the way that they approach a food safety plan, with a comprehensive risk analysis using a team that is made up of individuals with the appropriate process and technical knowledge necessary in order to develop an effective cybersecurity plan. There must be a plan of defense documented and implemented to manage the risks identified in the analysis. Active management of the plan and regular reviews of the system ensure it remains up to date with the ever-changing landscape of information technology.

Organizations also need to consider innovative ways to stay one step ahead of a cyberterrorist attack. One approach to consider, which is gaining popularity, is the use of “white hat” hackers, who are computer security specialists who break into protected systems and networks to test and assess their security by exposing vulnerabilities before malicious hackers can do so. One of the truly beneficial aspects of utilizing this type of approach is that it goes right to the heart of prevention, instead of reaction.

Food manufacturing organizations, like companies across a broad spectrum of industries, recognize the importance of looking at preventing disaster, as opposed to responding to a disaster that has already happened. As John Ridpath, head of product at the technology educator Decoded, suggests, “The best form of defense is to be proactive and try to breach your own systems.” In the end, food manufacturing facilities that take this suggestion to heart are those that can take control of their cybersecurity, and that can be a huge competitive advantage in a global environment where connectivity is king.

James is a technical scheme manager in supply chain food safety at NSF International. Reach her at nkeresztes@nsf.org.
As giant food processors and ingredient companies reorganize, acquire, and divest their assets to re-position themselves, quality programs are facing the brunt of some of these changes; many companies are having to modify programs to better align with important changes, such as new leadership, loss of technical expertise, and resources being stripped to bare bones. Activities such as these are becoming commonplace and almost expected in the food industry.

Despite these changes, quality and safety are not dispensable in a consumer driven market. Minor changes in quality can influence buyer behaviors; however, safety impacts are not as resilient. As the march continues to further cost reductions through automation in manufacturing, sanitation is on everyone’s radar as a place where innovation may just be the solution we are all looking for.

**Listeria**

In just a few months, 2018 has become a record year for listeriosis-related deaths on a global basis. As of mid-May, a record of 204 deaths and 1,033 cases of listeriosis have occurred in South Africa in the largest outbreak in recorded history, where consumers of a popular meat product were struck with illness from consuming the contaminated product. The consequence on employees has been the loss of an astounding 2,000 jobs related to this incident.

Even though approximately 1,600 people are affected by listeriosis each year in the U.S. and 260 of them die, the global burden of *Listeria* is not as easy to quantify. A 2010 study published in *The Lancet* estimates 23,150 cases of illness and 5,463 deaths. *Listeria* contamination has been a sore spot for both frozen and fresh products, both being directly tied to inadequate sanitation practices.

*Listeria* is the top pathogen being targeted by the vast majority of processing sectors from ready-to-eat dairy products to frozen vegetables, refrigerated and frozen meals, prepared fruits, and numerous foods that can harbor *Listeria*. While prevalence data is incomplete at best, there are significant gaps in the actual harborage considerations, ecological niches, and biofilm dynamics that support the prevalence and propagation of *Listeria*, making proper cleaning and sanitization vital to controlling contamination.

Several high-profile outbreaks of listeriosis in recent years, like cantaloupes, packaged salads, caramel apples, and frozen vegetables, have been caused by biofilm accumulation and transfer, or the use of equipment in unintended ways. Moreover, many of these cases could well have been prevented principally by properly planned and executed sanitation programs.

But what does proper planning entail?

**Mastering the Master Plan**

The U.S. Code of Federal Regulations’ guidance on Good Manufacturing Practices (GMPs) can be supplemented by maintaining a well-documented schedule that aligns everyday hygiene with the overall plant and its equipment.

Develop an equipment inventory containing a coversheet of equipment description in written and graphical form with intended use, equipment specifications, manuals, manufacturer and technical support information, date of installation and history of maintenance events (preventative and restorative), and functional and hygienic inspection records.
A master sanitation schedule should include the master plan for the entire plant and a breakdown of each part that requires cleaning and consists of the following at a minimum:

• Each piece of immovable equipment;
• Moveable equipment and implements/tools (forklifts, bins and carts, etc.);
• Facility structures and items used by operators (personal protective equipment, cleaning tools, handheld equipment, etc.);
• Surfaces including walls, floors, and ceilings;
• Utility inlets and outlets (water, air);
• Sanitary facilities and waste disposal areas for both production related waste and trash from all areas of the facility (sewer, solid waste, liquid waste, liquid treatable waste, recyclables, trash, etc.) and their surrounding areas;
• Daily or weekly activities separate from periodic or deep cleaning plan scheduled activities, which should be visible to all personnel; and
• Details of what needs to be cleaned, when it needs to be cleaned, how it needs to be cleaned, who will clean it, using what specific equipment (color coded brushes, pads, hoses, steam, or jetting equipment), for how long with what specific protocols (time and temperature, scrubbing action, etc.), and products (potency and quantity of detergents, water, sanitizers).

Know Your Targets and Gather Data
Listeria is only one of many organisms to be concerned with. Pathogens such as Listeria, Salmonella, Shigella, Shiga toxin producing E. coli, Vibrio, and Campylobacter are all major targets for sanitation. While these organisms are of economic interest to prevent illness, spoilage organisms that are abundant in processing facilities are not regularly sought after through planned swabbing exercises.

Spoilage, however, is of great concern to brand owners who regularly spend time and great amounts of cash buying refrigerated transport and storage to ship more rapidly, or storage in temperature-controlled warehousing, refrigerator units, or shelf space.

Modern sanitation is getting ready to take a turn towards being more data-oriented and there are several approaches that may be quickly adopted. Bacteria, yeast, and mold species that can potentially cause spoilage are everywhere and naturally occur in our environment. Targeting these species through air and water pathways that enter the facility is one means of prevention. Cleaning activities that entail using the seven steps of sanitation paired with targeted prevention methods can make a difference. The view to microbiological control in many sectors is primarily pathogen focused and is in need of a more holistic approach to spoilage. Shelf life is directly affected by many species that do not cause serious illness. In dairy, fresh produce, and food service operations, equipment cleaning, air, and water are key factors in how soon food needs to be used up or thrown out.

Quick tips include:

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In looking at environmental monitoring, however, trended data over a period of time between the networks of swabbing sites can provide birds eye views into resident microflora, persistent pathogens, and their niches and track responses to the sanitation cycles, sanitizer rotation, and resilience patterns. These patterns also serve as indicators as to how well equipment has been designed and fabricated.

Equipment Design and FSMA
The Food Safety Modernization Act’s (FSMA) reach via the Foreign Supplier Verification Program additionally puts pressure on importers to ensure suppliers are in compliance with the basic GMP requirements per the rule. As summarized by Food Quality & Safety’s writer Ted Agres in the February/March 2018 Washington Report column, the FDA Office of Regulatory Affairs cites pest control, sanitation monitoring, cleanliness, HACCP plan implementation, and reasonable precautions as key deficiencies that could trip up importers who buy from foreign suppliers.

Foreign suppliers, buyer representatives, and verifying agencies may find it useful to know just how well foreign suppliers align with FSMA and hygienic requirements. In designing a preventive controls plan, the Preventive Controls Qualified Individual, has many responsibilities; one of which should include an assessment of the suitability of the equipment for the task. Since preventive controls rely heavily on properly functioning equipment, it is important to know if equipment is in good working order and hygienically designed. In conducting this quick self-audit of the facility, the following data can be invaluable in further decision making:

- Properly draining (self-draining) designs that slope away, taking advantage of gravity to remove all water after cleaning cycles;
- Evaluating the suitability of the materials used in the construction of the equipment and their suitability to the task and proposed preventive control strategy;
- Removable or movable equipment, and parts and their potential contributions to physical hazards (glass, rubber, metal, wood, etc.);
- A review of equipment inspections and previous findings or failures for all processing and adjacent equipment, packaging, and conveying equipment;
- Gaskets and connectors and conveying equipment that are suitable for the task, environmental conditions, and product;
- Ceiling and roof inspections and swab collection sites and data corresponding these samples; and
- Details about the equipment, their date of manufacture and installation, and list of maintenance activities/events and failures.

Focus on What Matters to the Customer
Changing business models also means that suppliers and contract manufacturers have to engage in closer relationships with buyers and brand owners whose expectations for quality are closely tied to everyday activities. Sanitation schedules, sampling plans, and environmental monitoring data provide both parties with rich information on the performance of a total quality management system.

In working with buyers or contract manufacturers, maintaining the following data can be of value:

- Pre-op cleaning verification swabs for allergens and indicator organisms;
- In-process equipment sampling;
- Storage vats or tank cleaning schedules and verification testing data;
- Filling equipment monitoring activity schedule and monitoring data;
- Compiled reports on relevant in process, end product, or supplier verification sampling data; and
- Shipping containers, hauling or vessel cleaning schedules, and pre-loading inspection reports.

Many organizations share best practices in sanitation to help their customer or suppliers have confidence in business partners. Working on developing these relationships and partnering up with equipment manufacturers and service providers gains trust and can build the data pool necessary to make quicker, more effective changeovers.

Dr. Anandappa is the founding director for the Alliance for Advanced Sanitation, and a research assistant professor with the Department of Food Science and Technology at the University of Nebraska-Lincoln. Reach her at angela.anandappa@unl.edu.
How Technology Is Transforming Sanitation

Top seven new developments that are shaping the future of managing sanitation chemical programs

BY STEVEN P. WEILAND

The Food Safety Modernization Act and the Global Food Safety Initiative have changed the game for those in the food processing industry. With new regulatory hoops for food safety managers to jump through, sanitation is trending upward as a top concern.

The industry responded with new sanitation technologies that not only meet regulatory requirements, they also allow companies to better manage and monitor their sanitation routines. As part of a well-planned and executed sanitation program, new technologies help control costs, improve food safety, and reduce worker safety risk.

In the midst of this crowded space, how do you decide which advancements provide a usable benefit and have a positive return on investment? Let’s examine seven technical trends that can help a modern food facility manage often-complex sanitation programs in the face of increasing regulatory challenges.

Trends Simplifying Sanitation

1. **Automatic and centralized chemical dispensing.** New options for dispensing sanitation chemicals deliver more accurate and consistent chemical solutions by monitoring and controlling product concentrations and rates. These integrated systems help ensure concentrations are within acceptable and safe limits, reducing worker and food safety risk.

   A centralized chemical handling system can save money by reducing chemical waste and labor costs through more efficient applications. Wall-mounted equipment saves usable storage space and can reduce accidents from chemical handling and mixing.

   Transitioning to this system does take some upfront investment. New food processing facilities are increasingly fitted with chemical handling piping, so these plants often require some forward-thinking and planning to install the computer-controlled system. Existing plants can also incorporate this technology, but be sure to conduct a thorough technical review to determine feasibility and evaluate costs versus long-term benefits.

2. **Digital recordkeeping and chemical responsibility.** In an age where chemicals must be managed and tracked down to the drop, the industry is moving rapidly toward digital recordkeeping and chemical tracking tools to maintain a safe and verified food supply.

   Digital recordkeeping tools allow users to keep real-time reports on usage, ensuring no surprises when it comes time for an audit. In addition to meeting regulatory standards, keeping digital records allows the user to provide valuable information to the end-user as well. With consumer-driven scrutiny over chemical use in the food processing industry, digital records prove that all chemicals are being used responsibly and without worry of chemical residues.

   Digital records have operational benefits as well. Digital chemical inventory systems keep real-time reports on chemical usage to spot inconsistencies that may signal procedural drift. Digital systems also can automate supply ordering for more efficient purchasing and cost management.

   As part of digital recordkeeping, be sure to use calibrated and well-maintained instruments to accurately measure chemical traceability. They not only make the user’s job easier—they can trace back chemicals from suppliers and automatically document shifts in chemical regimens.

3. **Advances in rapid micro-testing.** Rapid microbial testing kits are growing in popularity in food processing to screen for possible contamination in production environments. But it’s important to understand how to use these tests in conjunction with an effective sanitation program.

   Think of these kits as tools to uncover red flags. By screening for different groups of bacteria, rapid tests indicate that something in the plant could be unsanitary. Use these results to step up sanitation in those areas. More thorough follow-up lab tests are needed to verify results and determine if deeper cleaning is warranted.

   As with all new technologies, consulting with chemical and/or sanitation service suppliers can determine how these new sanitation options fit into a specific operation and food safety program.

4. **Chain rail drives automatic cleaning solutions.** Chain oil and lubricants can be an adulteration risk in animal processing plants using overhead rails to transport carcasses. It’s not uncommon for rail lubricants to drip onto conveyors and other food contact surfaces. Yet these areas are often difficult to access for cleaning. New chain rail drives with automatic cleaners solve these problems by delivering controlled cleaning directly to the rails that need cleaning.

   Chain rail drive cleaners can be easily moved or permanently hard-mounted, depending on the need. Systems are programmable with specified cleaning regimens and wash cycles and can be integrated into centralized chemical handling for truly “hands free” operation.

5. **Chemical misting regimens.** There are many places in a plant that can probably be categorized as hard to access and difficult to disassemble. Take spiral freezers, for example. These multi-tiered units are difficult to maneuver for soaking and full cleaning that can over time cause microbial harborage and product contamination. However, with the demands of a daily food production operation, a shutdown and disassembly of the spiral freezer can be costly and time-consuming. The fix?

   Mist or fogging using specialized chemicals can be useful in controlling microbial growth in hard-to-clean areas. A high-quality, well-designed fogging system can help minimize the risks of microbial activity in between scheduled full disassembly and cleaning of a freezer.

   Foggging produces a particle size in the range of 10 to 50 microns, which al-

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Fogging can use a static system, built-in system, or a mobile unit. Under typical conditions, it takes about 15 to 30 minutes for the fog to disperse and an additional 45 to 60 minutes for the droplets to settle out of the air and onto the surfaces. No-rinse sanitizing is becoming more common. To minimize risk of chemical contamination, these systems must use precision blending and customized metering, combined with accurate and consistent chemical sprays. Partner with a chemical supplier or sanitation company to tailor a customized solution before beginning a chemical misting program.

6. Improved clean-in-place (CIP) options. CIP systems have proven to be extremely beneficial for sanitizing interior surfaces of equipment, such as tanks and pipes, which cannot be easily reached for cleaning. Even ground beef processing facilities now include modern CIP systems for sanitizing internal raw meat piping and holding equipment prior to packaging.

CIP continues to evolve in food production with a range of chemical cleaning and no-rinse sanitizing chemicals now available to support these systems.

The latest CIP systems allow chemical concentrations to be adjusted along with water temperature and flow rates inside the closed CIP system. Accurate and real-time monitoring of chemical cleaning conditions inside an operational CIP system makes it easy to validate and record each step in the process for audit purposes.

Newer CIP systems feature improved access and maintenance, and include rugged, chemically compatible metal alloys, gaskets, and seals. However, no CIP system should ever be considered maintenance-free. For optimal function and food safety planning, establish a regular preventive maintenance program. Keeping parts and electronics in working order ensures proper cleaning operations.

7. Boot scrubbing stations 2.0. Worker boots and shoes can be major sources of contamination, which is why many highly sensitive food facilities utilize a captive footwear policy to ensure workers are outfitted with top-quality, clean footwear.

Some plants previously used automatic boot scrubbers for boot sanitation, but automatic stations proved difficult to clean and maintain. The motorized scrubbers often were not practical in day-to-day operations due to maintenance issues.

Though automatic boot scrubbing stations have gotten a bad reputation in the past, their flaws have come under the microscope and led to improved options. Newer footwear scrubbers show better overall hygienic design, ruggedness, and easier cleaning and maintenance. Adding them to high-risk facilities can enhance the value of a captive footwear program and reduce cross-contamination risks.

Weiland, a corporate microbiologist at Packers Sanitation Services, Inc., leads risk-reduction and root-cause investigative efforts in food manufacturing facilities. Reach him at sweiland@pssi.co.

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

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The purpose of supply planning at a high level is to analyze and manage the risks and opportunities in the supply chain to the benefit of the organization. At a more granular level, supply planning can be an inter-departmental function to achieve the same benefits with specific suppliers and materials.

The amount of planning time devoted to supply planning depends on the nature and operational culture of the organization. Some organizations are informal and ad hoc and others are highly organized and detailed in their planning. Whatever the nature of the planning functions, every operation can benefit from supply planning for its ingredients, materials, and packaging.

Supply Planning Review and Specifications
The ideal supplier is one who can consistently deliver fresh materials with maximum remaining shelf life and no food safety risk on spec, on time, in the exact quantities required by production, and at the lowest possible price. In reality, each supplier meets only some of the ideal requirements.

When considering a new material or a new supplier, the starting point of a supply planning review includes establishing the acceptable parameters for each input. These can be differentiated as the required and the desired characteristics. This review document is usually in the form of an extensive specification. The details in the specification inform the planning team of which characteristics are critical to the safety, quality, and functionality of the finished product and, therefore, non-negotiable. These characteristics may be any combination of organoleptic, compositional, microbiological, or functional.

A specification may include other requirements that the supplier must meet. These include standards of operation for food safety and quality, and increasingly, social and environmental stewardship. Other standards may include requirements for Good Manufacturing Practices, Hazard Analysis and Critical Control Points (HACCP), traceability, allergen management, and foreign material control. Additional requirements may be part of a product’s quality, origin, ethical, and environmental stewardship claims. Part of the supply planning activity can be to review performance against all requirements to determine if the supplier is adequately meeting them.

Supply planning must also integrate production requirements into the specification. These include things like lead times for ordering, minimum and maximum order quantities, emergency supply capabilities, and determining how much is going to be required overall for a defined contract period or the upcoming year. For seasonal production, the raw material needs to be available during the season. While the price may be affected by the level of service required, because short lead times may cost more, the capability of a supplier to actually meet the lead times and the risk of failing to deliver must be assessed.

For some functional materials, requirements may also include the availability of technical support from the supplier for day-to-day usage, product development, or troubleshooting modes.

A potential challenge to the supply planning function occurs when each department starts to inflate estimates and narrow specifications to drive “improvement.” This provides a skewed specification to the planning and purchasing team. Realistic numbers versus negotiating numbers should be used to inform the planning process and carry out meaningful assessments and cost impacts.

The impact of operational supply requirements on planning varies according to how dynamic their customer demand environment is. For example, with sta-
ble predictable sales and production schedules (every production manager’s dream), the supply system can be carefully planned and operated to minimize costs and maximize efficiencies. The more dynamic the sales and production environment, the more variable and dynamic the supply ordering process, and the more robust and flexible the supply base may need to be. In this case, minimizing supply costs and maximizing efficiencies may need to be balanced against a need for short lead times and variable order sizes. Another less desirable option is larger raw material inventories, which carry the risk of material expiring before they can be used.

The supply planning function requires knowledge of the organization’s short- and long-term production and development plans. This knowledge helps set priorities for the purchasing group and lets them know what new suppliers or materials may be needed. Potential suppliers can be sourced and assessed in preparation for planned projects. It also prepares the food safety and quality functions that must research specifications and hazards related to new materials.

A potential challenge to the supply planning function occurs when each department starts to inflate estimates and narrow specifications to drive “improvement.”

The planning function should include food safety and quality personnel as part of the risk assessment management process. For a supply planning team to succeed, it must identify and understand potential hazards, threats, and vulnerabilities to the materials, the suppliers, and the supply chain. The planning process should then develop plans to mitigate any high-risk issues. For instance, the best price for an item may be linked to a specific single supplier that is geographically remote. The supplier may have several customers, and competition for the material is increasing, and continuity of supply is not predictable. Supply planning might recommend that having a second supplier available and purchasing some material from this second supplier is a robust strategy that offsets the risk of being shorted by the low-cost supplier. An alternative supplier is sourced and approved. Supply planning analysis may come to the opposite conclusion if there has been a long-standing arrangement with two suppliers. By going through the analysis and risk assessments, a switch to a single supplier may increase service and reduce costs without affecting the risk of running out of materials because the industry conditions that dictated the need for two suppliers have changed.

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The supply planning function thus integrates information on risk to food safety, quality, operational efficiency, and costs. Parts of this risk assessment may also be—and often are—driven by external standards such as Global Food Safety Initiative (GFSI) certification or regulatory requirements.

### Risk Assessment

Risk assessment first identifies hazards. Food safety hazards identify biological, chemical, and physical hazards associated with the material that could potentially harm human health. Quality threats include material variations that cause failure of finished product to meet specifications and expectations. A relatively recent addition to GFSI certification requirements is assessing the risk associated with each supplier—something that the supply planning function should already include.

Low supplier risk usually requires a history of satisfactory delivery of safe material that meets specifications, so initially, new suppliers may be high-risk. Estimating the risk of new suppliers may involve researching recall or other reported databases to determine if there have been any issues with a supplier. Getting references from a new supplier and talking to their existing customers may also be a way to set an initial risk level.

Supplier risks include inability or failure to supply the ordered quantities in the promised time frames, shorted deliveries, damaged goods, and unexpected price increases or lack of effective technical support when needed. Supply and supplier risks are those which disrupt the capability of the operation to maximize efficiencies and meet customer demands, including last-minute orders and special sales.

If supply planning is starting to sound like a huge, time-consuming, and hard-to-manage activity, it doesn’t have to be. The list of materials and suppliers that undergo the supply planning process can be filtered down to the “significant few.” These might include problem performers, problem supply chains, suppliers affected by unusual crop conditions, new proposed suppliers of significant materials, high-cost materials of significance to finished product costs, new product or packaging offerings, planned product development activities, and newly identified “opportunities.”

The selection of materials and suppliers to be incorporated in supply planning analysis might be also be informed by new or emerging hazards, and recently identified frauds or vulnerability threats.

The hazard analysis method used for HACCP can serve the risk assessment aspect of supply planning. Much of this work is already required at regulated sites or sites certified to a GFSI benchmarked standard. Supply planning, like HACCP analysis, cannot be a one-time analysis because of the dynamic nature of the supply system.

For agricultural products, the growing season, the weather, the economy, crop yield/shortages, and market conditions can all affect food safety and quality risks. Poor growing seasons, drought, or disease may cause reduced yields and increase the vulnerability of the crop to damage and infestation. Difficult growing seasons in some supply regions may lead to excess, off-label, more frequent use of agricultural chemicals, or, in certain jurisdictions, use of non-permitted chemicals.

Low yields may tempt suppliers to supplement a poor crop with product from farms that are outside formal contracts and oversight, increasing risk of out-of-specification and less safe product. Another possible risk with some commodities, such as spices, is the dilution with other substances (ground peanut shells in cumin for instance) that may not be food safe. The potential for substitution can increase when supply is short, although the risk of fraudulent dilution for economic gain is always present for some materials no matter what the weather.

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<tr>
<td>1-1.33</td>
<td>Process is capable but may still produce out-of-specification product</td>
</tr>
<tr>
<td>1.33-2.0</td>
<td>Process is capable and less likely to produce out-of-specification product</td>
</tr>
<tr>
<td>&gt;2.0</td>
<td>Process is robust and not expected to produce out-of-specification product</td>
</tr>
</tbody>
</table>

The supply chain for agricultural materials can also be affected by market factors such as consumer trends. As the demand for GMO-free and/or organic product increases, the pressure on the supply chain goes up, which also increases potential hazards from new or unproven suppliers. For instance, the current price increases of natural vanilla have been affected by the decision of the major players to change to natural vanilla flavoring.

### A Supplier Assessment Tool

A statistical process control tool that may be used to assess suppliers is \( C_{pk} \), which measures the capability of a process to meet specifications. Some suppliers request that \( C_{pk} \) for each batch is reported on a certificate of analysis. Others may require that a specific process \( C_{pk} \) is reported routinely as a KPI used to monitor supplier performance.

\( C_{pk} \) can be used to assess risk of a supplier not meeting a particular specification or to compare the capability of different suppliers. It can also be used to determine if sampling and testing should be done. Some customers may require a \( C_{pk} > 2 \) (or higher) for critical materials in which defect rates are likely to be extremely low (\( C_{pk} = 2 \) defects per 3.4 per million opportunities or 99.999966 percent defect free), see Table 1.

Food safety and quality managers should consider including statistical process control in their supplier requirements. It can be a powerful tool. Sites that use statistical process control are likely to have a better understanding of their processes and a continuous improvement approach to production.

Whether applied in a limited tactical way or routinely as part of supply management, supply planning can be used to improve and enhance the purchasing and supplier management processes. The supply planning process complements existing regulatory or GFSI benchmarked standard certification requirements. Using the expertise from quality, food safety, and production personnel, supply planning continually improves the management of suppliers and helps develop a more robust, safe, and reliable supply base.

Wright is a technical manager of training and education services at NSF International. Reach him at iwright@nsf.org.
It won’t be long until we name the 2018 Food Quality & Safety Award winner. Watch this space and learn more online at foodqualityandsafety.com/award.

This prestigious award honors the dedication and achievement of a food quality and safety assurance team that has made exceptional contributions to their company’s commitment in supplying safe food products.
Keys to a Successful Outsourcing Partnership

Companies need to establish a robust contract, open channels for communication, and performance criteria

BY RENATA MCGUIRE

With product innovation and development moving at a more rapid pace than we have ever seen in the industry, outsourcing services together with processing and packing has become an excellent option for many divisions in a food organization.

There are many motives for an organization to outsource activities, including:

• Accelerating the innovation cycle;
• Freeing internal resources for other project work, or utilizing the expertise needed for a specific task;
• Accessing technology, including process methods such as high pressure processing and different formats of packaging;
• Increasing production or personnel capacity;
• Accessing a geographic advantage gained from a strategic partner to open availability to a market or manage regulatory restrictions that can be imposed by import/export;
• Testing innovation for market success before investing in infrastructure; and
• Avoiding the investment in a manufacturing facility or contracting manufacturing to fully focus on brand development.

To be specific, outsourcing is the contracting of any service or process step, including packing, undertaken by another company. This requires a great deal of trust to be established and maintained in the outsourced partnership, especially when food safety and quality are essential. Success has been found in outsourcing all or parts of manufacturing, packing, product development, labeling, regulatory reviews, auditing, testing, and product evaluation. Outsourcing needs to be treated as an extension of your brand and your company.

When considering a partnership:

• Look for companies with compatible goals;
• Look for partners with special expertise or skill sets that you may not possess;
• Identify the best solutions for your need before cost considerations; and
• Check references! A great outsourcing partner will have clients willing to share their experience.

Developing a Positive Partnership

Food safety and quality elements are well established in the requirements for the Global Food Safety Initiative (GFSI) benchmarked standards. Specifically reviewing the British Retail Consortium (BRC) and Safe Quality Food (SQF) standards, the following trends can be identified in regards to outsourcing.

Legal. Ask the tough questions when drafting a contract such as: Who is responsible when a recall takes place? Who owns the formulation? Can substitutions of equipment or materials be made? Identify who is accountable for outlining the requirements for food safety and product requirements, including the product, ingredient, or packaging specification, and any relevant safety, quality, regulatory, or authenticity requirements. Has this contract been developed with the use of expertise in this field? Ensure changes to contractual agreements are approved by both parties, agreed with customers where necessary, and communicated to relevant personnel.

Risk. It is important to understand risk by having a defined set of food safety criteria with which to benchmark potential partners. Understanding that food safety management is a continuous journey, it is expected that the benchmark be reviewed and improved regularly. Is this benchmark certification to a GFSI standard? Are the outsourced process steps/packing included in process flow diagram? Are the food safety risks fully managed?

Communication process. As a starting point, over communicate. Be reliable. Set and communicate expectations. Review results. Spend time to understand the strengths and limitations of each party. Internally, consider carefully who needs to be involved in setting up and managing the outsourced partnership. Share the expectations developed in the contract. Communication tools could include the contract, clear specifications, a regular meeting to review performance, and future needs and expectations.

Audit. For an ongoing partnership, audit at least annually by visiting the contract manufacturer to confirm its compliance with food safety and quality requirements. A regularly scheduled audit will also make you aware of any changes to the outsourced process, as well as to any new developments, innovations, and challenges the outsourced partner is managing. This may also be an opportunity to review plans for how the partner intends to manage any disruptions in its operation as these can affect its ability to supply. Current SQF guidance notes that in situations where the auditor feels there is product risk

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from the contracted facility, the auditor may require a visit to that facility to confirm compliance to the SQF standards and the agreed arrangements.

**Verification.** Develop a set of performance criteria to identify the checks that will be completed to ensure product has met food safety and quality expectations. This may include visual inspection; chemical, microbiological, or allergen testing; and hold/release requirements for the specific material (e.g., to allow additional testing or quality assurance checks).

Consider who is authorized to accept conforming materials and reject non-conforming product, and the action to be taken in the event of a non-conformance. In the case of contract packing, the procedure should clearly define who is authorized to release product to customers.

Like any successful long-term relationship, clear expectations and open communication channels for communications are critical. A written legal contract, well-defined specifications, and regular review of product characteristics are the keys to a positive partnership.

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McGuire is an operations supervisor of food consulting and technical services at NSF International. Reach her at rmcguire@nsf.org.

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**Outsourcing Partnership**

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Check references! A great outsourcing partner will have clients willing to share their experience.
Developing, documenting, implementing, and maintaining the necessary documentation to properly maintain a food safety management system (FSMS) is an integral part of doing business for food processors, ingredient manufacturers, and packaging suppliers large and small. Yes, even the very small operator who might not be mandated to have such programs will, most likely, be asked to show it has a food safety system in place for its customers. The bottom line is fairly simple: Without a FSMS, a business will suffer and may even vanish. The expectation is each and every operation shall have a fully documented system that includes procedures, work instructions, and the necessary recordkeeping forms for all elements of the food safety plan.

Creating procedures and implementing them is not easy nor is something that can be accomplished overnight. As an example, a company may have what it considers to be a well-documented FSMS, but updating that system to meet the requirements of one of the Global Food Safety Initiative management schemes or the ISO 22000 food safety standard could take 12-18 months (see Table 1). For a small company or startup that is developing everything from scratch, this is probably an unrealistic timeline. Why? The equation for building your program was highlighted above: development, documentation, implementation, and maintenance. Implementation includes the training element, which must be properly documented. This takes time, commitment, and lots of work. So, what can be done to help meet these challenges?

Meeting Challenges Head On

First and foremost, management must be committed to the project, which includes providing the necessary resources and support to get the work done. Management must also be patient since the work is not going to be completed overnight. The following steps will help overcome documentation challenges.

1. Appoint a document control officer.
2. Develop a standard format for procedures and work instructions.
3. Create a master list of the programs that need to be documented.
4. Develop a plan for developing these programs.
5. Assign responsibility for developing protocols.
6. Create the procedures.

Hiring or appointing a document control officer should be a task for top management and one that the food safety or quality manager needs to emphasize the importance of. Be cognizant of the fact that this would be a permanent appointment, not a temporary position. Document management will remain an ongoing task throughout the development process. The document control officer’s role is not to write the procedures but to manage the process of developing the necessary documents. He or she could be the quality manager, but that need not be the case.

The Nuts and Bolts of Proper Documentation

Every operation requires a documented system that includes procedures, work instructions, and recordkeeping forms for all elements of the food safety plan

BY RICHARD F. STIER

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The document control officer could be someone from IT, but above all, must be someone who is organized and has computer skills. The document control officer should be responsible for:

- Making sure all procedures and work instructions are created using the standard format;
- Ensuring documents are created by approved persons;
- Determining that all new documents are reviewed and edited as needed;
- Tracking changes to existing documents;
- Tracking non-controlled documents;
- Maintaining a master log of all documents and records;
- Ensuring all new protocols and revisions have been properly reviewed and approved;
- Controlling distribution of new and/or revised documents and maintaining a record of distribution; and
- Collecting and destroying old documents and forms.

This is an ongoing task and not one that should be eliminated once the program is up and running.

Food processors need to create a standard form to be used for all procedures and work instructions. Table 2 is an example of what might be adopted. The standard should also include either a header or footer to indicate the procedure number, the date it was adopted, who created the document, and whether it is an original document or has been revised. One element many processors fail to do when developing procedures is include corrective actions. If product safety is potentially compromised, the corrective action needs to address how that product will be handled. For example, calibration is an essential program for ensuring that monitoring devices are working properly. If an instrument such as a temperature monitoring device is found to be out-of-calibration, there is a chance product safety was compromised. The calibration procedure must address that concern.

<table>
<thead>
<tr>
<th>Table 1. Timeline for Implementation.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>July – August 2018</strong></td>
</tr>
<tr>
<td><strong>September – October 2018</strong></td>
</tr>
<tr>
<td><strong>October – November 2018</strong></td>
</tr>
<tr>
<td><strong>December 2018</strong></td>
</tr>
<tr>
<td><strong>January 2019 – June 2019</strong></td>
</tr>
<tr>
<td><strong>June – December 2019</strong></td>
</tr>
<tr>
<td><strong>January 2020 – June 2020</strong></td>
</tr>
</tbody>
</table>

Table 2. Example of Procedure/Work Instruction Form.

| Subject: |
| Objective: |
| Procedure: |
| Responsibility (ies): |
| Corrective Actions: |
| Recordkeeping (Include Required Forms): |
| Verification Activities: |

(Continued on p. 44)
Operators must create a master list of all the procedures and work instructions that need to be created. The FSMS needs to include protocols for the Hazard Analysis and Critical Control Point (HACCP) plan, the supporting prerequisite programs, food defense, and more. For a partial list of what a processor might need to develop, see the List of Procedures to be Developed at left. There will also be programs in which different levels of procedures will exist. The primary example is cleaning and sanitation program. This program would include general procedures that describe the expectations of the program, define the master cleaning schedule, and establish a means to both validate that cleaning procedures are effective and verify that the work was done properly. The cleaning program would also include specific work instructions that defined how each piece of equipment and each area/part (floors, walls, drains, overheads, etc.) of the plant would be cleaned.

The next step is to create a plan for developing and documenting each of the procedures defined above. The schedule highlighted in Table 1 could serve as a model. When this plan is created, priorities and scheduling should be developed based on risk. When developing the implementation plan, the team should assign responsibility to specific persons within the company to develop and document each element on the master list. If a person has been doing a task, he or she would be the logical choice to be assigned the task of developing the procedures for that area. A word of warning: It is a bad idea to hire someone from the outside to develop and document each of the procedures. This can be a real challenge for companies since there are many who are not comfortable when it comes to writing or sitting in front of a computer. There are ways around this. One is give the person assigned with creating the protocols the freedom to record the work using a voice recorder to talk through the protocols. The procedures on the recorder can then be typed up and edited by someone within the company.

Which brings us to the last step: developing and documenting the individual procedures. This can be a real challenge for companies since there are many who are not comfortable when it comes to writing or sitting in front of a computer. There are ways around this. One is give the person assigned with creating the protocols the freedom to record the work using a voice recorder to talk through the protocols. The procedures on the recorder can then be typed up and edited by someone within the company.

Getting things on paper is only part of the whole equation. Remember the mantra from the start of this piece: develop, document, implement, and maintain. There is always an issue with creating procedures. Are they well-written and will they be easily understood by those responsible for conducting the work? One means for ensuring this is to run draft procedures by non-technical types. If they can grasp what is wanted, there is a very good chance the procedures will be acceptable and easily understood by those who will do the work.

Don’t forget, procedures, work instructions, and record-keeping forms are constantly evolving. They will be upgraded, updated, modified to meet changing demands, and developed anew as operations expand and seek to do things better. This is one reason why appointing a document control officer was the first step in this procedure. Their task or tasks won’t go away.

Stier, industry editor for Food Quality & Safety magazine, is a consulting food scientist with international experience in HACCP, plant sanitation, quality systems, process optimization, GMP compliance, and food microbiology. Reach him at rickstier4@aol.com.
the number of food product recalls in North America, Europe, and Australasia have been growing for years. From 2015 to 2017, plastic and rubber contamination events increased recalls by at least one-and-a-half times. The most frequently reported recalls for plastic and rubber contamination are in the food sectors that use higher levels of mechanical methods, such as poultry and red meat processing, cereals and bakery, and confectionary.

Various plastics can be the culprits. The plastic contaminants identified in 2016 and 2017 recall notifications include: pieces of a polycarbonate chocolate mold, pieces of a margarine blender, plastic packaging, PET fibers 1-2 centimeters, blue safety goggles, pieces of pen, sharp white plastic lollipop sticks, plastic hairpin, harvested field rubbish, body of an inspection torch, a poultry meat machine scraper blade, a blue hygiene glove, and cheese-forming mold. Plus, multiple mystery pieces of black, red, yellow, blue, green, white, and clear plastics.

What’s on the Line
The cost of a recall can be split into several parts: The value of the product, cost of advising the trade and public, shipping and reimbursing of cost and trading loss to the wholesalers and retailers, and the costs and penalties from public and civil litigation.

The biggest cost of all if a consumer finds plastic in their food is the loss of the company’s reputation as a trusted producer of safe product. Losing the trust of consumers is evident in the drop of sales after a recall. The size of that decline and, more importantly, the time it takes to recover trust depends on the speed, openness, and extent of a company’s response.

An international confectionary company recently received a complaint that a small piece of red plastic was found in one of its products. Excellent traceability meant it was a no-brainer for the confectionary company to identify all the batches of product at-risk and it rapidly initiated a massive voluntary recall. This assured consumers that the products remaining on the shelves were safe to eat. It also probably added more to the company’s reputation of trustworthiness than was lost when the recall was initially announced.

But where did the plastic come from? How did it get into the production line? The company pieced together many plastic materials to identify the source equipment and implemented actions to prevent it from happening again. But would this be enough? Food processing companies and their suppliers now use enormous amounts of plastics in their machines, tools, and in packaging materials. As plastic usage in food processing grows, so does the frequency of contamination.

Making Plastic Safe
Metal detectors have reduced incidents of metal contamination in food since they were first used by Mars in the U.K. over 50 years ago, but many ordinary plastics cannot be identified by metal detectors or X-ray inspection systems. Fortunately, modern detectable plastics are made from food-safe materials, which include fine metals that trigger metal detectors and additional materials that raise the density levels of the plastic to make it visible to X-ray inspection systems.

The levels of additives must achieve detectability without detracting from the performance of the parts or equipment made from the plastic. Care must also be taken to ensure the correct level of detectability is produced throughout the material. Detectamet, for example, uses a patented system to help ensure the traceable elements are evenly present throughout the whole molded product. This allows for (Continued on p. 46)
greater potential in detectability when the smallest broken pieces pass through the detection systems.

Detectability is also governed by other factors, such as the nature of the contaminated product, line speed and orientation, and the settings of the inspection machines. In principle, if the target metals are detectable at a significant size then detectable plastics will also be identified and rejected. It is good practice for food producers to test detectable materials by deliberately placing them in their products and using their metal detection or X-ray inspection systems to detect.

Metal or plastic pieces that contaminate can be of various sizes. All detectable plastic products, in whole or part, are detectable, but like metals there is a minimum size that the material cannot be identified, even with correctly configured metal and X-ray inspection systems. In fact, the latest consultation document from BRC Global Standards (Issue 8) proposes, “Pens used in open product areas shall be controlled to minimize risk of physical contamination (e.g. designed without small parts and detectable by foreign body detection equipment).”

There is no 100 percent guarantee of zero risk, but the smallest undetectable pieces are likely to be under the threshold of threat to the consumer.

There are many variations between inspection machines, products, and packaging, making it essential for users of detectable plastic materials and equipment to carry out their own tests on site to validate the detectability of the products.

An audit of the plastic tools and materials used in processing areas can identify the extent of the risks, tools, and materials that need to be replaced by detectable alternatives. There are many detectable versions of standard tools available today. Tailormade designs can also be produced. Examples include a recently developed detectable plastic pig for cleaning food and beverage pipelines, and a detectable tray and lid system designed for specific processing needs, which is now offered for general sale.

These products satisfy the need for detectability in metal and X-ray inspection systems, but don’t forget that the designs must also perform as well as the standard plastic products they replace.

Also remember color coding detectable plastic helps restrict use of tools to specific areas or shifts to heighten the level of control of microbial cross-contamination. More users of detectable tools are specifying a unique identity engraved on products to improve security and provide a means of tracing the origin of misplaced tools.

For food manufacturers that are supplying private or own label products, the power of the buyer to dictate the food safety standards becomes a key stimulus of plastic management. Several retailers and food service companies have their own set of standards, such as the U.K.’s biggest retailer Tesco and Walmart in the U.S. that demand certification by third-party auditors who adhere to standards set by the Global Food Safety Initiative.

Blunden is the marketing and communications consultant at Detectamet Ltd. Reach him at derrick.blunden@detectamet.com.

Table 1. Food Recalls Triggered by Plastic/Rubber Contamination.

<table>
<thead>
<tr>
<th>Region</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2015 to 2017 % Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australasia</td>
<td>3</td>
<td>1</td>
<td>5</td>
<td>70%</td>
</tr>
<tr>
<td>European Union</td>
<td>16</td>
<td>30</td>
<td>42</td>
<td>160%</td>
</tr>
<tr>
<td>North America</td>
<td>8</td>
<td>22</td>
<td>23</td>
<td>180%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>27</td>
<td>53</td>
<td>70</td>
<td>160%</td>
</tr>
</tbody>
</table>

Sources: Recall Data primarily from European Commission RASFF Portal; Food Standards Australia New Zealand; Food Standards Agencies U.K.; U.S. FDA.

Table 2. Test Performed by a Detectable Plastics Manufacturer.

<table>
<thead>
<tr>
<th>Product</th>
<th>Detectable Threshold</th>
<th>Product</th>
<th>Detectable Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tie wrap</td>
<td>3.0mm</td>
<td>Tie wrap</td>
<td>2.5mm</td>
</tr>
<tr>
<td>Earplugs</td>
<td>3.0mm</td>
<td>Earplugs</td>
<td>2.5mm</td>
</tr>
<tr>
<td>Label</td>
<td>3.0mm</td>
<td>Scraper</td>
<td>2.5mm</td>
</tr>
<tr>
<td>Elephant pen</td>
<td>3.0mm</td>
<td>Elephant pen</td>
<td>2.5mm</td>
</tr>
<tr>
<td>Tote bin covers (metal detectable only)</td>
<td>4.5mm</td>
<td>Clip (plastic)</td>
<td>3.0mm</td>
</tr>
<tr>
<td>Clip (plastic)</td>
<td>4.0mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glove</td>
<td>3.0mm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Detectamet Limited

Table 3. Breakdown of 2017 Recalls by Processing Sector.

<table>
<thead>
<tr>
<th>Food and Drink Sectors</th>
<th>No</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cereals and bakery</td>
<td>11</td>
<td>15.71</td>
</tr>
<tr>
<td>Meat</td>
<td>11</td>
<td>15.71</td>
</tr>
<tr>
<td>Poultry and poultry meat</td>
<td>8</td>
<td>11.43</td>
</tr>
<tr>
<td>Confectionary</td>
<td>8</td>
<td>11.43</td>
</tr>
<tr>
<td>Fruit and vegetables</td>
<td>8</td>
<td>11.43</td>
</tr>
<tr>
<td>Milk and dairy products</td>
<td>8</td>
<td>11.43</td>
</tr>
<tr>
<td>Prepared dishes and snacks</td>
<td>6</td>
<td>8.57</td>
</tr>
<tr>
<td>Soup and sauces</td>
<td>4</td>
<td>5.71</td>
</tr>
<tr>
<td>Cocoa, coffee, and tea</td>
<td>1</td>
<td>1.43</td>
</tr>
<tr>
<td>Dietary foods and supplements</td>
<td>1</td>
<td>1.43</td>
</tr>
<tr>
<td>Drinks and beverages</td>
<td>1</td>
<td>1.43</td>
</tr>
<tr>
<td>Fish and fish products</td>
<td>1</td>
<td>1.43</td>
</tr>
<tr>
<td>Infant food</td>
<td>1</td>
<td>1.43</td>
</tr>
<tr>
<td>Non-alcoholic beverages</td>
<td>1</td>
<td>1.43</td>
</tr>
</tbody>
</table>

Sources: Recall Data primarily from European Commission RASFF Portal; Food Standards Australia New Zealand; Food Standards Agencies U.K.; U.S. FDA.
AFTER more than two years of declining sales and flat traffic numbers, the restaurant industry is scrambling to find solutions. Delivery services have been hailed as one of the industry’s biggest hopes for redemption, capitalizing on always-connected consumers’ need for “on-demand” everything. While some sectors of the restaurant industry have always relied on delivery—pizza, for example—as a way to generate revenue, delivery is a new frontier for other sectors, such as quick service restaurants and casual dining. And just like any new frontier, there are hurdles that need to be faced and decisions to be made.

The biggest hurdles for delivery are ones that can significantly impact consumer perception of a brand: speed, safety, and quality. Finding ways to deliver food, selecting a delivery partner, maintaining quality, and keeping it safe for consumption, all while doing it in a timely manner, can create unseen operational challenges for restaurants. So what factors should be top of mind for you and your team as you branch out into delivery?

Optimize Your Kitchen and Restaurant for Delivery

Operators can be unprepared for the sheer volume of orders that delivery services can add to peak times and non-peak times alike—and that can not only slow a kitchen to a crawl, but back up an entire operation, leading to customer frustration in the restaurant, in the drive thru, and for customers on the receiving end of deliveries.

Start by examining your order taking process. How are orders managed? Is there an ability to throttle orders at peak times? How do you deal with situations when the kitchen has more volume than it can handle? Re-working the kitchen to accommodate these to-go orders can help. Every operation is different but consider adding a special delivery staging area where orders can be packed and verified.

Add staff to accommodate orders at peak hours. Delivery peaks can mirror peak restaurant times, such as Valentine’s Day or Mother’s Day, but can also create new business peaks for at-home occasions, such as rainy days or big events like the Super Bowl or the Academy Awards. And be sure to determine staffing protocol. For example, if your business offers table service and servers are also responsible for preparing food items, what will the protocol be for delivery requests when these workers will not be tipped by patrons in the restaurant? Workers who feel as though they are not being properly compensated for their efforts may, in turn, have less motivation to prioritize orders.

It’s likely your kitchen staff already has a solid foundation of food safety knowledge and food quality standards. However, (Continued on p. 48)
that training may need to be extended to include new elements of food safety that come into play with delivery. Order packers also need to understand food safety, and what is acceptable in terms of food quality for menu items. For example, your standard to-go box might not be adequate to maintain temperature and presentation for deliveries.

It’s nearly impossible to correct an already delivered order, so accuracy checks should be increased. Imagine ordering a salad and someone forgot to include the dressing. Additionally, if using internal drivers, they might carry with them a supply of accompanying items (condiments, plastic utensils, straws, etc.). But when using a third-party deliverer, these would always have to be included in the initial packing of the meal.

If working with a third-party delivery company, develop a clear, defined pickup and order verification process for drivers and clearly communicate it to those companies and their drivers. Some restaurants have begun designating special parking spots for delivery drivers, allowing the restaurant staff to easily identify drivers and get orders out the door fast.

**Maintain Food Quality and Safety in Transit**

In the 1980s, Domino’s pizza did something unprecedented: It launched a 30-minute delivery guarantee. If a pizza didn’t arrive within 30 minutes of order, it was free. It was a game changer in the pizza delivery business and forced the competition to rethink their strategies. It also made Domino’s a model for pizza delivery everywhere because it had figured out how to keep pizza fresh and piping hot as it arrived to the customer.

With delivery expanding into new sectors, maintaining the quality and safety of food in transit gains some new wrinkles. As the range of products available for delivery expands, the challenges of keeping hot foods hot, cold foods cold, preventing cross-product mingling, avoiding soggy buns and wilted lettuce, preventing spilled drinks, and more become operational and logistical in nature.

There is no silver bullet to solving these challenges. It’s a multi-step process that will require constant re-evaluation as new menu items are added into the mix. But those who get it right might reap similar rewards to what Domino’s did with its unprecedented delivery model.

Begin with a complete review of all your products for delivery, determining what it will take to maintain quality and food safety in transit. In review, you may find there are some menu items that cannot be offered for delivery due to quality control issues.

Develop and implement standards for maintaining the hot and cold chain, and ensure all delivery partners have the tools and materials needed, such as insulated bags, ice packs, and more.

Examine—and re-examine—the packaging and be sure it’s designed to maintain the integrity of the product.

**Develop a Clear Policy for Customer Action**

In a sit-down restaurant, take-out, or drive-through situation, customers have an immediate opportunity to examine the quality of their food. The steps to take when food doesn’t meet their standards are usually fairly cut and dry: talk to a staff member, send the food back to the kitchen, etc.

In a delivery model, that course of action may not be clear. Many delivery drivers aren’t employed by the restaurants for which they are delivering—and let’s be honest, complaining to the driver may not always deliver the result a customer wants. At a Datassential event in August 2017, Jason Rusk, vice president of alternate platforms at Red Robin, reported that some customers griped about rude delivery drivers and late orders.

Left in a (possibly literal) sticky situation, what actions is a customer to take when a delivery order is not to his or her liking or is just plain incorrect? If the customer is left with a bad taste in his or her mouth, whose business will suffer—your restaurant’s, the delivery company’s, or both?

These questions could be easily answered by ensuring you have a few items in place before delving into delivery. First, establish clear standards for acceptable quality and safety, and what actions will be taken if those standards are not met. For example, how food is presented to the customer, if a delivery driver is involved in an accident, is significantly delayed, if they cannot locate the delivery address, etc. If depending on third-party delivery companies to deliver food, you may not have control over some of these items.

Therefore, be sure a customer feedback course of action is available on your
website, so customers looking for information on what to do can easily find it and follow the necessary steps. Consider including information in every delivery on what customers can do if not satisfied. This could be as simple as a sticker on the order or language on the receipt. However, making it stand out may help with overall customer satisfaction if a problem is encountered.

Ensure that all frontline staff is prepared to handle customer complaints. Whether it’s arming all staff members with the information on where to redirect complaints or empowering them to resolve an issue on their own, quick and uncomplicated resolution to problems is what customers want.

And watch out for uncontracted partners. A number of restaurants have experienced issues with third-party delivery services that advertise working with a restaurant—unbeknownst to the restaurant. This makes it difficult to maintain quality and safety standards and can lead to unhappy customers without a restaurant’s knowledge.

**Measure Results and Continually Re-Evaluate**

The key to improving a delivery program is to continually measure results and take action to bridge gaps, tweak standards, and adjust policies as necessary.

Periodic evaluations and updates of online surveys to include questions regarding the delivery process can ensure that both staff and any contracted delivery services are adhering to your standards. Employ a third-party audit provider to perform announced or unannounced food safety or operational assessments, or mystery shop programs to evaluate the standards. Food safety and operational assessments can validate the work being done in your own operations on a number of levels and provide your busy location-level staff with an additional coaching resource to keep standards on track. Mystery shop programs assess product quality and delivery standards at a number of levels, from point of order to quality and safety upon delivery.

Most important, however, is to act on the data that these types of services deliver. Use the results of an audit or mystery shop program to improve the delivery program. That may mean making changes to long-held standards or beliefs. A robust audit program will have experts who can help roll out and evaluate a policy change, as well.

The potential revenue and business to be earned by entering into delivery is too big to miss for most operations. That said, failure to execute well can quickly lead to unhappy customers. With careful planning and consideration, you can have answers to delivery dilemmas mapped out and build a successful program from day one. 

Boyles, the vice president for The Steritech Institute at Steritech, holds a MS in microbiology and BS in biology from the University of North Carolina at Charlotte, and the Certified Professional—Food Safety credential from the National Environmental Health Association. Reach him at chris.boyles@steritech.com.
In 2007, the Joint Institute for Food Safety and Applied Nutrition released its “Effective Cleaning and Sanitizing Procedures” whitepaper that stated the following:

Cleaning tools like brooms, mops, squeegees, buckets, sponges, scrapers, foaming equipment, water guns, etc., should be cleaned and sanitized. Cleaning tools can be a significant source of microbial contamination [in a commercial kitchen] if not cleaned. Cleaning tools should be washed and sanitized after every use.

This is quite similar to other studies that have concluded cleaning tools, especially floor mops, can be a source of contamination. This means these cleaning tools have the ability to spread pathogens and germ-causing diseases from one surface to another.

For instance, in a 1971 study published in Applied Microbiology investigating microbial contamination of mops and cleaning cloths in a hospital setting, researchers reported that mopping floors or wiping surfaces with contaminated tools can cause harmful pathogens to spread from one surface to another. These pathogens can then be touched by patients, causing disease through cross-contamination.

In regards to floor mopping, the study declared:

It was found that mops, stored wet, supported bacterial growth to very high levels and could not be adequately decontaminated by chemical disinfection. Laundering and adequate drying provided effective decontamination, but a buildup of bacterial counts occurred if mops were not changed daily or if disinfectant was omitted from the wash-water.

Mops and Water Retention
This study primarily found mops can and do spread health-risking contaminants in hospitals and these contaminants can spread from floors to other surfaces. The same can be said for using mops in food service facilities, restaurant kitchens, school cafeterias, and so on.

The study also found mops are often stored wet, something that again is true in all types of settings. This contamination cannot necessarily be eliminated with chemical disinfection. The only option, according to the researchers, is to change mops daily.

However, let’s look at this advice a bit more closely. The reality is, mops and the cleaning solution in mop buckets often become further contaminated and collects soil and debris, the efficacy of the cleaning solution declines. This is true of most cleaning solutions as well as disinfectants.

1. As the mopping process continues, and the mop and mop cleaning solution become further contaminated and collects soil and debris, the efficacy of the cleaning solution declines. This is true of most cleaning solutions as well as disinfectants.

2. What is referred to as quat absorption often begins, which applies specifically to disinfectants. The active ingredients in disinfectants—quats—that kill germs and bacteria become absorbed into the mop. As this happens, effectiveness declines even more.

Therefore, the use of floor mops is not the best option for cleaning a commercial kitchen floor. Furthermore, any cleaning aid that retains water—cleaning cloths, sponges, wipes, etc.—should not be used for food service facility cleaning on a regular basis.

There are alternatives for all these tools and specifically floor mops, which will be discussed later. But first, let’s get a better understanding of the new tools.
understanding of food soiling and the types of soiling and contamination that can impact commercial kitchens and food service facilities.

**Food Soils**
Cleanliness to protect human health is always the goal, but is rarely achieved. This is because surfaces are continually becoming soiled, whether in a hospital, school, or a food service facility.

The food service industry needs to grasp the following basic facts about food soils.

- Soil is unwanted matter on a surface.
- Soil can be classified as visible or invisible. The latter, which includes contaminants and pathogens, is the troublemaker.
- Some food soils can be dissolved and removed with just plain water. In fact, water can be one of the best cleaning agents.
- Other food soils need the alkalis, acids, or surfactants* found in cleaning solutions to dissolve and help remove visible as well as invisible soiling.
- One more type of soiling that may occur in a food service facility should be noted: the growth of biofilms. Biofilms are a collection of bacteria, all growing together under the protection of a polymeric substance matrix. In other words, they are covered with a protective shell, making them more difficult to kill or remove. But they still can spread contamination and contaminate stored foods, which means they must be eliminated from surfaces, including floors (see Biofilm sidebar).

**Alternative Floor Cleaning Methods**
The professional cleaning industry has read these reports and is aware of the need for more effective ways in cleaning floors without mops to keep floors healthier. As a result, over the past two decades, different types of tools and equipment have been introduced to address this problem. Here’s a few, along with some pros and cons of each system.

- **Dual-buckets.** The goal of dual-buckets is to help keep cleaning solution clean longer. The mop is dipped in one bucket for cleaning solution and the other for rinsing. This helps slow contamination of the mop and cleaning solution but does not prevent it.
- **Steam vapor.** These are commercial systems, which means the water is heated much higher than a home system, purchased at a mega-retailer. They essen-

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*Surfactants help loosen soils, allowing them to be wiped away or washed away under pressure from water.

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Antimicrobial Coatings: Built-In Hygiene

BY GUY CHARTERIS

To help mitigate risk of cross-contamination, antimicrobial additives can make food industry equipment inherently resistant to microbial colonization. Additives can be integrated into plastics, paints, fabrics, paper, and ceramics to protect products from microbes, such as bacteria and mold. The additives employ multiple modes of action, such as damaging proteins, disrupting cell membranes, causing oxidative stress, and interfering with DNA replication. Able to be incorporated into virtually any material, antimicrobial additives don’t require any changes to instrument design to achieve a high level of protection.

Employing antimicrobial technologies in farm-to-fork products could lead to a marked improvement in hygiene and a potential decrease in the number of cases of foodborne illnesses. In fact, a case study conducted by BioCote Ltd. investigated *Campylobacter* bacteria. It found poultry crates designed and treated with antimicrobial technology were less contaminated than untreated crates, throughout all stages of the decontamination process. Although the large investment required to replace equipment means the use of antimicrobial additives will take time to become widespread, its adoption can already be seen in the design of kitchen utensils, food temperature probes, and food-storage containers.

Switches and buttons are also ideal candidates for treatment with an antimicrobial protection, as these are “high-traffic” areas. Unlike the rest of an instrument casing, staff routinely and repeatedly press these controls when using equipment, and it is these “repeat contacts” that carry a high risk of contamination and ongoing transmission. Routine decontamination protocols are obviously one way of reducing this risk but in a busy kitchen or factory environment these crucial cleaning steps can easily be accidentally missed. Antimicrobial additive’s wide-ranging protection does not require a maintenance protocol or additional burden on staff.

Focusing solely on human error can only take the food industry so far towards preventing foodborne illnesses. In order to improve hygiene, it might be time for the food industry to embrace the possibilities afforded by the promise of antimicrobial materials and create whole anti-microbial kitchens—from light switches, to floors, to refrigerators.

Charteris is partner development manager at BioCote. Reach him at Guy.Charteris@biocote.com.

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Spray-and-vac. Using a wand, a spray-and-vac system applies cleaning solution to floors and all surfaces to be cleaned. The same areas are then pressure rinsed, removing soils from surfaces. These machines have built-in vacuum systems to vacuum up the moisture and soils, allowing the floor to dry very quickly.

**Scrubbers.** Different types of scrubbers are available for cleaning floors in a food service facility or commercial kitchen. A traditional, rotary pad, automatic scrubber applies cleaning solution to the floors, agitates, and loosens contaminants, which are then vacuumed up. These machines require some training and can prove effective, but they tend to be costly.

Cylindrical floor machines use brushes, not rotary pads. This allows them to dig deeper into grout areas, removing soils. Some vacuum up moisture as they are used. Less training is needed, but cost can be an issue.

Autovac systems dispense cleaning solution directly to floors. A pad at the back of the machine helps loosen soils for removal. Once again, a vacuum collects all moisture and soils. These systems are relatively easy to use, have found a place in restaurant kitchens, and tend to be cost-effective.

Except for the dual-bucket system, what these floor cleaning alternatives all have in common is that no mops are used. The goal is to eliminate mopping when cleaning floors in food service facilities. Using these floor cleaning alternatives will help the industry move a step closer to keeping a commercial kitchen or food service facility as clean and healthy as possible.

Charteris is partner development manager at BioCote. Reach him at Guy.Charteris@biocote.com.

(Kravitz is a frequent writer for the professional cleaning industry. Reach him at robert.kravitz@outlook.com.)
## NEW PRODUCTS

### Molecular Method for Campylobacter
The Molecular Detection Assay 2—Campylobacter with 3M Campylobacter Enrichment Broth helps users safeguard against this key pathogen associated with poultry production and increases laboratory productivity. Unlike traditional Campylobacter enrichment protocols that can take 11 or more steps, the company says the 3M Campylobacter Enrichment Broth requires only five steps. The broth eliminates the need for microaerophilic incubation, supplements, blood, organic solvents, or autoclaving the broth—only requiring the addition of sterile water. 3M Food Safety, 888-364-3577, www.3m.com/foodsafety.

### Conveyor Lubricant
NSF certified Super Trolley Lube for meat processing applications doesn’t contain water and doesn’t require water for dilution, so it reduces the risk of microbial growth while reducing drag. This completely waterless formulation keeps dry areas dry, can be used in areas with or without floor drains, and it reduces effluent emissions. According to company, there is no sticky or gummy residues that are common with silicone emulsion lubricants, and it’s easily cleaned with water. Lubricant can be used in food and beverage plants as an H1 lubricant with incidental contact, and is well suited for use as a protective anti-rust film, as a release agent on gaskets or seals of tank enclosures, and as a lubricant for machine parts and equipment in locations where there’s exposure of the lubricated part to food. It’s best used for trolleys and conveyors where smooth transition of carcasses and other products is necessary. Madison Chemical, 812-273-6000, www.madchem.com.

### Air-Operated Double-Diaphragm Pumps
Typical applications for the MM Series AODD pumps include the transfer and filling of beverages, sauces, and toppings; dosing of food and beverage ingredients; and processing of meat, pastry dough, smoothies, fruit pulp, and candies. Pumps feature food-grade wetted materials and a construction that enables CIP and sanitize-in-place capabilities. The design incorporates soft redirections without rotating parts and shaft seals in the product chamber, ideal for hygienic operations. Additional features include a pumping principle that offers gentle displacement, stainless steel housing, wetted surfaces with a surface roughness of max. 3.2 µm (0.8 µm as option), easy disassembly of the fluid path, and self-priming and dry run capabilities. All the pump’s materials comply with the hygienic standards of the FDA, and pumps equipped with PTFE diaphragms and ball valves also comply with EC1935/2004. Almatec, www.almatec.de.

### Entry-Level Automated Titrators
The Orion Star T900 Series of potentiometric laboratory-grade titrators consists of four automated titrators, three designed to enable dedicated pH, redox, or ion potentiometric measurements, and one all-in-one unit that consolidates the analyses of all three parameters. As automated systems, the company says these titrators facilitate easy and intuitive setup and operation, regardless of experience level. Titrators enable quick reading of results and a multi-lingual interface further enhances usability. Analytical methods can be customized to meet varying application needs, while up to 10 methods can be saved within the system to support repeatable titration procedures without the need to repeat setup. Methods can also be transferred to a USB drive for backup and sharing across multiple titrators, for example, when a system needs to undergo routine maintenance. Thermo Fisher Scientific, 866-356-0354, www.thermofisher.com.

### In Other News

**The Acheson Group (TAG) and SafetyChain Software** release the TAG Risk Assessment Tool to allow users to make more informed decisions on supplier, product, and overall risk tolerance protocols.

**StateFoodSafety**’s www.statefoodsafety.com/food-safety-manager-certification proctoring service allows food managers to take their certification exam from home with a remote proctor.

**ReposiTrak** introduces Speed Retail Platform, which consists of three product families: Compliance & Risk Management, Supply Chain Solutions, and MarketPlace Sourcing and B2B Commerce; delivered via one technology platform, all the applications are mutually reinforcing and work synergistically to help quickly create a positive impact across the entire enterprise.

**SCIEX**’s food allergen screening method using mass spectrometry receives official method classification from the AOAC International.

**Clear Labs** launches a pilot program to bring a routine pathogen testing platform based on clinical-grade next-generation sequencing to food brands and service labs.
Moment of Reckoning …
(Continued from p. 21)

cies announced an agreement to work together to “increase clarity, efficiency, and potentially reduce the number of establishments subject to the dual regulatory requirements of the USDA and the FDA.” The increased coordination between the agencies will increase the focus on data integrity in the laboratory. One area that deserves further exploration is how to securely share the original electronic data from testing food products and ingredients. This would boost confidence in the authenticity of quality data shared during “business-to-business food ingredient transactions.”

When humans create the data, calculate results, and then transcribe the “final results” into the record, there is always opportunity for errors to occur, but seamless and automated data creation and transfer can minimize accidental errors. Be wise to always remember when the analytical data are too good to be true, they probably are.

Longden is the senior marketing manager for Informatics Regulatory Compliance at Waters Corp. Reach her at heather_longden@waters.com.

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