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Volume 28 Number 4
AUGUST / SEPTEMBER 2021

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From The Editors

Third-Party Audits

Third-party audits have become an essential part of business in the food industry. It's literally an industry mandate that, at a minimum, a food processor must provide customers with paperwork demonstrating that they have met the requirements of a third-party audit, which in most cases is a Global Food Safety Initiative (GFSI) food safety audit scheme. For the processor, a GFSI audit may be only one of the audits to which they will be subjected; it isn't out of the ordinary for a potential buyer to conduct their own audit as a prerequisite to entering into an agreement. Some operations that conduct their own audits feel that the third-party audit doesn't address their concerns, or they may deem the ingredient that they are purchasing to be high risk, so they want to see the operation with their own eyes.

Many feel that one audit is enough or that any audit is an imposition and something they need to get through quickly. Having conducted audits around the world on six continents, I cannot agree. Audits should be treated as integral elements in a processor's continuous improvement program. The extra set of eyes often sees issues that the processor has taken for granted. It's a pleasure to work with an outfit that believes in continuous improvement and welcomes an audit as one of the tools in their toolbox. These operations usually select the most rigourous audit scheme and really want an auditor who will dig deep and look not only at what they're doing, but at whether their programs are effective. Audit results should be shared with staff so they know that they are included as part of the team and their good work is acknowledged.

With the advent of the COVID-19 pandemic, auditing came to a standstill thanks to travel restrictions, bans on visitors at food plants, and the adoption of in-house programs aimed at protecting workers and minimizing health risks. One solution has been virtual audits—a program in which the auditor observes a facility through a camera or cell phone. The real focus of these audits wasn't on what was happening in the plant, but rather on documents and records. This goes against what many believe is the essence of the audit: spending time on the processing floor and observing what is going on. When in a plant, a good auditor uses all of his or her senses—sight, sound, smell, and touch. The virtual audit really limits what may be sensed, so think twice before going the virtual route. They may be easier and less of a hassle, but will such an audit really help a facility perform better?

I spoke with several people who have conducted virtual audits and later went into facilities they had looked at virtually. Guess what? They observed issues that had gone unseen before. The end result of all audits should be much more than a certificate; audits are part of the ongoing commitment to food safety and need the rigor of an actual plant visit.

Richard F. Stier
Co-Industry Editor

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NEWS & NOTES

FDA Creates Task Force to Combat *Cyclospora* Contamination

BY **KEITH LORIA**

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Over the past three years, CDC has reported approximately 6,000 domestically acquired cases of cyclosporiasis in the U.S., and the agency believes this figure is lower than the actual number of people infected. The first known contamination in U.S. produce appeared in 2018, with the most famous outbreak occurring in McDonald's salads that same year. In 2021, there have been 208 reported illnesses, resulting in 21 hospitalizations and no deaths.

In response to this growing problem, FDA unveiled a new plan earlier this month creating a task force to improve prevention, enhance response activities, and fill knowledge gaps to help prevent *Cyclospora* contamination in food.

Led by multidisciplinary experts across FDA and CDC, the task force's goal is to decrease the public health burden of foodborne illness caused by *Cyclospora* in produce.

"In the area of prevention, the new action plan highlights how we're addressing this food safety issue through the development and delivery of prevention-focused education materials and outreach to stakeholders," Frank Yiannas, FDA's deputy commissioner for food policy and response, said in a statement. "We're also working with industry to encourage the development of rapid test kits to specifically detect *Cyclospora* to better facilitate industry testing and root cause analysis activities."

In addition, FDA plans to partner with others in the industry to find ways to improve control over *Cyclospora* in the environment and on farms, as well as collaborate with CDC to better understand the case distribution of cyclosporiasis across the U.S. and to advance genotyping methods in clinical, food, and environmental samples.

When it comes to improving response, FDA will expand lab capacity to sample and test for the parasite, providing a greater capacity to investigate outbreak events.

"The FDA is also developing a new investigational tool to help guide assessments of farms potentially implicated in a *Cyclospora* outbreak to determine potential sources and routes of contamination," Yiannas said. ■

Are Consumers Ready for Cultured Meat?

BY **KEITH LORIA**

Cultured meat, also called cultivated meat or cell-based meat, involves using lab-grown animal cells to create meat products.

Unlike plant-based meat alternatives, cultured meat offerings are designed to be identical to conventional meat, complete with the same fat and muscle tissue, but without animal slaughter and with better protection for the environment.

And while the category has seen huge growth over the last five years, increasing from just four companies offering cultivated meat in 2016 to more than 40 companies offering the products today, there are still many challenges, and consumers have lots of questions.

IDTechEx, a UK-based market research firm, has released Cultured Meat 2021–2041: Technologies, Markets, Forecasts, a new report studying the technical and market factors that are shaping the emerging industry. According to the report, the industry has raised approximately one billion dollars in private funding since 2015; however, cell-cultured products are very expensive to produce, and no company has yet to produce them on a commercial scale.

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Consumer Confusion

Darin Detwiler, PhD, associate teaching professor of food policy at Northeastern College of Professional Studies in Boston, notes that, while corporate investment in this market has increased drastically, he has yet to see any significant data that indicate a trend in consumer buy-in.

"When discussions around 'good for the environment,' 'healthy alternatives,' and 'safe' are thrown around as value-add for this option, they need to come with evidence and timeline," he tells *Food Quality & Safety*. "This is especially important, as the report points out that these options will not be cost effective early on."

Dr. Detwiler recalls attending meetings at which major meat brands were discussing these products as a way to diversify, but at least two years later, he has still not seen this growth become reality.

"My take on this is that consumers need to get over the sea of different terms—cultured meat, cultivated meat, cell-based meat, clean meat, lab-grown, realistic meat products, Beyond Beef, etc.," he says. "This has already created confusion at the grocery store and suspicion at restaurants. Existing terms used as differentiators—such as open range, cage-free, grass-fed—may be easy to view as disruptors to the market, but they are still only as good as how they are perceived and understood."

Food Safety Regulation

As for food safety, USDA versus FDA regulatory jurisdiction has been indicated through a memorandum of understanding, but to date, there's no clear policy. "FDA would likely take the lead, and, with their new era of smart food safety, technology is a core element of the FDA's future food safety plans," Dr. Detwiler says. "However, consumers are receiving some mixed messages regarding tech and safety, such as the JBS cyber hack and at least 30 other documented cases within the food industry over the past year. The lack of trust in science and the desire to not get caught up in a food safety nightmare are factors to consider." ■

Washington Report

FDA Calls for Affordable Traceability Technology

A look at potential tools for a more digital, traceable food system | BY **KAREN APPOLD**

Each year, foodborne illnesses sicken 48 million Americans (approximately 17% of people in the United States) and lead to 128,000 hospitalizations and 3,000 deaths, according to the CDC. "Although there have been great improvements in technologies to track and trace foods from farm to table, and remove recalled foods from the market, many are expensive to deploy and maintain," says Emily R. Lyons, JD, senior associate attorney working in the food and agribusiness industry group at Husch Blackwell LLP, in Washington, DC. "This makes them cost prohibitive for smaller and medium-sized businesses."

In light of this problem, FDA issued a New Era of Smarter Food Safety initiative in July 2020, to leverage technology and other tools to create a safer and more digital, traceable food system. Then, in June 2021, FDA asked stakeholders to recommend low-cost or no-cost options in its No-Cost Tech-Enabled Traceability Challenge so that approaches are inclusive of and viable for human and animal food operations of all sizes. "Democratizing the benefits of digitizing data will allow the entire food system to move more rapidly toward digital traceability systems," says Frank Yiannas, FDA's deputy commissioner of Food Policy and Response.

FDA's challenge called on technology providers, public health advocates, entrepreneurs, and innovators from all disciplines worldwide to develop traceability hardware, software, or data analytics platforms that are low cost or no cost to end users.

The deadline for submissions was July 30. The tech-enabled solutions could be new or based on existing systems or datasets. Of those who scored the highest based on the evaluation criteria, up to 12 winners will be announced at a future date.

Yiannas believes that a number of technologies can be employed to track and trace foods. But because the food system is large, distributed, and decentralized, traceability solutions that are simple to use, cost-effective, and interoperable are more likely to be rapidly adopted. "By having an open challenge, FDA may become aware of new technologies and business models that they didn't previously consider," he says. "If FDA limited participants to a specific type of technology or problem to solve, it would most likely restrict the range of ideas brought forth."

Possible Solutions

Tejas Bhatt, MS, CFS, senior director of U.S. and Global Food Safety Innovation at Walmart Inc., in Bentonville, Ark., supports FDA's choice not to be too prescriptive when it comes to the types of technologies that might be suitable, because, he says, the solution won't be one-size-fits-all. "We need the industry to innovate and solve this problem collectively, instead of having data sit in silos using proprietary standards and be closed off to commercial solutions," he says. "Data should flow from one technology solution that might work for a farmer to another technology solution that might work for a larger company like Walmart."

Lyons says current options could be expanded for use in the food system. The key elements of a good solution are automation of data collection and the ability to collect consistent information (known as key data elements) at many different points in the supply chain (known as critical tracking events).

The types of innovations that are necessary will largely depend upon an entity's specific role in a supply chain. Food producers may be more interested in how to generate real-time data regarding their crops and the inputs used to produce them and how to generate that information in a way that can be easily communicated up the supply chain, Lyons says. Manufacturers may desire additional innovations

in blockchain, robotics, the Internet of Things, and in-line sensor technology. Meanwhile, retailers may want tools that help meet brand or consumer expectations for products and ways to communicate that to consumers at the point of purchase.

Consumers are looking for information, such as the raising conditions of products, labor conditions for farmworkers, information about the farmer who produced the product, or details about an ingredient and its purpose in a product, to be presented and shared in a single application, Lyons adds.

Synchronizing Platforms

In addition to addressing the specific needs of primary producers, importers, manufacturers, processors, distributors, retailers, and foodservice establishments, solutions will have to allow for data sharing across platforms used by various segments of the food supply chain, which could be challenging, Yiannas says.

Although synchronizing platforms is not an entirely new concept, it is new in the food sector, Bhatt says. For example, financial institutions synchronize across platforms, allowing consumers to use ATM cards in any ATM worldwide. Telecommunication organizations synchronize the transfer of voice, text, and data across platforms, enabling people to communicate with family, friends, and colleagues around the globe. For the food sector, there will need to be a similar process to develop global open standards.

Benefits Abound

Digitizing the supply chain will enable small- and medium-sized organizations to participate in the food ecosystem. After data is digitized, the next step will be to create transparency. "Retailers such as Walmart and its customers want to know where the food we sell comes from," Bhatt says. "Simultaneously, growers can benefit from knowing where their food ends up in the supply chain, which will give them better market access."

Finally, supply chain optimization will occur, through increased shelf life, reduced waste, improved quality, and ultimately, better customer satisfaction. "The important paradigm shift here is that instead of one type of stakeholder gaining all the benefits, the benefits can be shared across the supply chain or ecosystem," Bhatt says.

Bryan Hitchcock, senior director of food chain and executive director of the Global Food Traceability Center at the Institute of Food Technologists in Chicago, Ill., says the ability to improve public health by reducing foodborne illnesses will be one of traceability's greatest benefits. "Developing and deploying low-cost and no-cost traceability tools will benefit everyone by increasing organization participation, improving data capture and sharing, and accelerating foodborne illness outbreak response," he says.

Lyons says that the availability of more tools for traceability will assist food manufacturers of all sizes to track and trace foods in instances where a recall is necessary. These tools can also help pinpoint exactly what products should be recalled depending upon the depth of the traceability tools (i.e., specific ingredient tracing as well as finished product tracing). These traceability tools will also have the ancillary benefit of increasing transparency within the food system to benefit consumers. ■

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Examining the Blueprint for Smarter Food Safety

FDA's New Era of Smarter Food Safety created a blueprint for the application of technology and smarter tools, while harnessing the collective power of people. "Our food system is evolving rapidly, challenging all stakeholders to adapt," says Bryan Hitchcock, senior director of food chain and executive director of the Global Food Traceability Center at the Institute of Food Technologists in Chicago, Ill. "Creating an enduring regulatory framework which leverages and embraces the latest technology, while also addressing the human aspect of food safety, are critical to ensuring a safe and abundant future food supply."

Here's a closer look at the blueprint's four pillars.

1. Tech-enabled traceability eventually will be a "system of systems" where each stakeholder will be able to choose the solution that works for them. However, Tejas Bhatt, MS, CFS, senior director of U.S. and Global Food Safety Innovation at Walmart Inc., in Bentonville, Ark., says that all solutions will need to speak the same language, allowing the data to flow from one system to another (with adequate protections) as food moves through the supply chain.
2. Smarter tools for prevention will use the data from tech-enabled traceability and other sources to better predict failure before it happens. "The aerospace and automotive industries already do this; there is no reason to believe that it can't also be done in the food industry," Bhatt says.
3. Retail modernization is happening now and was accelerated by the pandemic. "More of Walmart's customers are shopping online and having their groceries picked up or delivered via the Walmart and Sam's Club app," Bhatt says. "We're better able to connect customers with the supply chain that served them their food, making epidemiological interviews and outbreak investigations easier and more accurate."
4. A tech-enabled food safety culture can deliver the promise of creating awareness for, educating, and modifying the behaviors of all stakeholders of the food system, including customers, to ensure food safety. "Whether it's through social media platforms or home automation, the ability to reach the population in a manner they want to be reached has never been easier," Bhatt says.

Emily R. Lyons, JD, senior associate attorney working in the food and agribusiness industry group at Husch Blackwell LLP, in Washington, DC, sees the blueprint as two-fold. First, it's a call for FDA and industry to implement existing technology and develop new technology to enhance food safety and communicate the safety of the U.S. food system. Second, it's a chance for FDA to learn how to adapt its regulatory schemes and innovative business models such as the proliferation of food meal delivery companies.

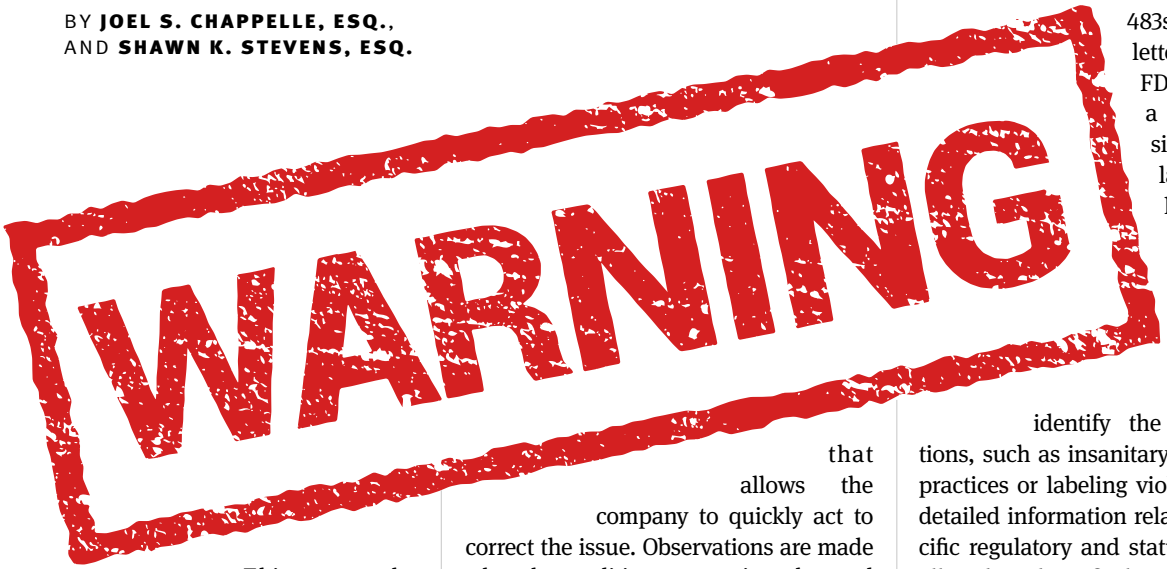
"We're at a point where there is still a lot to learn about how FDA plans to use this blueprint to influence policy, but we're already seeing that FDA is encouraging technology adoption, even without explicitly requiring it, through the FSMA Proposed Rule for Food Traceability," Lyons says.—*KA*

Legal Update

FDA Form 483s and Warning Letters

Achieve regulatory compliance today to prevent regulatory enforcement tomorrow

BY **JOEL S. CHAPPELLE, ESQ.**, AND **SHAWN K. STEVENS, ESQ.**



This year, the available evidence continues to suggest that FDA is becoming more proactive with regard to regulatory enforcement. The evidence suggests the agency is issuing an increasing number of Form 483s and, worse, warning letters.

This column will provide an overview and explanation of FDA Form 483s and warning letters, discuss the issuance and implications associated with each, and explain how to respond to them.

FDA Form 483

FDA Form 483 is a document routinely issued to companies at the conclusion of an FDA inspection. It is used to document any conditions that—in an inspector's judgment—may constitute violations of the Food Drug and Cosmetic Act (FDCA) or related regulations. Each of the observations noted on the Form 483 is supposed to be articulated in a clear and specific manner that allows the company to quickly act to correct the issue. Observations are made when the conditions or practices observed are indicative of possible adulteration or suggest that products are being prepared, packed, or held under potentially insanitary conditions that pose a risk to public health.

The purpose of Form 483 is to formally notify a company's management of objectionable conditions observed during an FDA inspection. It's usually presented during the exit interview at the conclusion of the inspection, during which FDA inspectors meet with management to present their observations, findings, and conclusions.

Although recipients of Form 483 are not legally obligated to respond to the observations documented, it is vitally important to do so. Unless FDA states otherwise, the response to the 483 should be submitted within 15 business days and should provide thorough written explanations, with accompanying documentary exhibits, comprehensively detailing the corrective actions the company is implementing to remediate the observations noted on the form. If the written response adequately addresses the agency's concerns, no further regulatory action will result. Conversely, an inadequate response will likely result in the agency issuing a "warning letter," which amounts to the agency threatening to withdraw the company's registration and prevent it from producing product.

Warning Letters

Warning letters are rarer and more serious than Form 483s. A warning letter, issued when FDA alleges that a company has significantly violated FDA regulations, signals potentially significant peril for the receiving company. Warning letters will identify the alleged violations, such as insanitary manufacturing practices or labeling violations, provide detailed information relating to the specific regulatory and statutory violations alleged, and notify the recipient of their obligations with respect to a response.

After receiving a warning letter, companies can expect FDA to engage in thorough and onerous oversight intended to ensure that adequate corrective actions are implemented. The subject matter of an FDA warning letter may be based on previous interactions between the agency and the recipient, or they may be the first word on the alleged violations.

A failure to adequately address the violations described in the letter will result in withdrawal of the company's registration, effectively shutting down the business.

An Ounce of Prevention Is Worth a Pound of Cure

Sooner or later, every company undergoes an FDA inspection. To maximize the likelihood of a successful, collaborative inspection, all companies should begin

taking steps to prepare for their next FDA inspection today.

Taking the following steps can help to ensure that appropriate preparations are in place before FDA investigators arrive, to effectively navigate the inspection process once the inspection is underway, and to appropriately respond to any FDA concerns.

FDA's Office of Regulatory Affairs (ORA) is the lead office for all field activities, including inspections and enforcement. During an inspection, ORA investigators will likely prioritize the following:

- Careful review and assessment of the company's written food safety programs and verification records; and
- Extensive microbiological sampling (swab-a-thon).

To ensure that an FDA inspection is successful, it's advisable to complete the following tasks prior to the arrival of FDA investigators.

First, identify a space within the facility to host investigators when they arrive. This might be a conference room or a vacant office that is well-lit, comfortable, and equipped with sufficient area for inspectors to review voluminous records. The space would best be located in a relatively out-of-the-way area, free of noise and clutter, including any potentially relevant regulatory records.

Once you have identified a meeting place, select at least two individuals for each facility to serve as inspector liaisons. These individuals should be highly knowledgeable about compliance, well informed about company operations, and capable of effectively responding to any requests for information or records. To that end, it is important to ensure that the supporting records for each of the regulatory programs are organized and maintained in such a way that the designated individuals can immediately retrieve at least three months' worth of records for FDA review. Although FDA requires the majority of these records to be maintained for at least two years, FDA investigators will typically ask only to review records for the preceding three months.

Next, ensure that any deviations and the concomitant corrective actions are documented clearly, precisely, and correctly. This means that all documents addressing deviations should include the root cause of the deviation, corrective actions taken to prevent recurrence and, if product safety was not affected, a written conclusion (supported by factual and scientific data) that the deviation "does not create an immediate food safety issue."

Engaging with inspectors, behaving diplomatically, seeking to work collaboratively, and asking good questions about what is required to fully address the agency's concerns will show the agency that you are serious about achieving compliance.

Among the best ways to prepare for an FDA inspection is to conduct a mock inspection. This would typically entail hiring FDA consultants and/or attorneys who can visit your facility and play the role of an investigator. This sort of exercise would typically require consultants to review your programs and identify any regulatory shortfalls, and work with you to implement strategies that will strengthen your programs and reduce your regulatory exposure.

Responding to Warning Letters and Form 483s

No matter how well prepared you are, it's not always possible to avoid regulatory enforcement actions. In turn, when FDA issues a Form 483 or warning letter, it will be critically important to maximize your likelihood of success by responding effectively.

Most importantly, take the process seriously and respond comprehensively. This means that every written response should be accompanied by adequate supporting documentation. For instance, it is not enough to simply state in your response that you corrected a problem by "conducting additional employee training." Rather, in addition to stating that you completed the training, FDA will expect to see an attached training log or other document establishing that the training was completed.

Next, do not be argumentative. You may disagree with an inspector's observation or an allegation contained within a warning letter, but the response is rarely (probably never) the place to litigate that disagreement. The agency wants to know you are going to remedy the problems, and wants concrete information establishing proof that your products and processes do not pose a threat to public health. Your job is to provide clear and compelling evidence that your processes are safe, not that inspectors are misunderstanding the regulations.

After drafting the initial response, have your regulatory attorney work with you to fill in any gaps, add any regulatory language, and massage the particulars. Your responses to the agency might also be discoverable by opposing lawyers in the event of future litigation, whether related or not. Allowing an attorney to fine tune the responses will keep your company from making potentially damaging assertions that, while forthright and seemingly harmless, can be unfairly leveraged by skilled attorneys in the future.

Be collaborative. In the vast majority of cases, regulators want to be helpful and want to work with companies to help them improve the safety of their products. Engaging with inspectors, behaving diplomatically, seeking to work collaboratively, and asking good questions about what is required to fully address the agency's concerns will show the agency that you are serious about achieving compliance. That, in turn, will often result in a significantly better outcome.

Although there are countless variables that will ultimately affect how your next FDA inspection unfolds or determine whether your company needs to respond to a regulatory enforcement action, the information provided will help you navigate the most common pitfalls likely to arise. In the meantime, we cannot overstate the importance of doing the right thing today, to prevent difficulties from arising tomorrow. ■

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Global Interests

Follow the Science!

But, what *is* science?

BY **AURORA A. SAULO, PHD**

The world has lived for more than a year trying to develop effective methods to manage the SARS-CoV-2 virus, the microorganism responsible for the dreaded COVID-19 illness. Much information about the virus and the illness it causes is now available on the web. Almost on a daily basis, the media, policy makers, celebrities, and heavily credentialed scientists give updates on the virus, aspects of the illness, therapeutics, and seemingly infinite stories about the administration and effects of the vaccines. Conversation in social media abounds. Today's situation features a broad spectrum of information on COVID-19 and, not surprisingly, serious disagreement on how the information should be used and how recommendations should be implemented to guide a return to "normal" life.

There are well-known organizations, some with the words "public health" or "science" in their names, that are assumed to practice responsible reporting. Others use the word "science" to lend credibility to the information or instructions they disseminate. The word "science" is used because it is "highly esteemed" and invokes a sense of infallibility, according to a book called *What Is This Thing Called Science?* (Hackett Publishing Company; 2013).

But what is meant when experts say "follow the science" or "it's science"? When the word "science" is used in these cases, there usually is no reference to specific scientific studies or data, which is what most scientists use when they communicate scientific information to support their contentions. And how about the individuals to whom the "scientific" information is directed? Is science the same for these individuals as it is for the scientist and the communicator? What is science to them?

The Meaning of Science

On April 12, 2021, two researchers, Eric Grunfeld, a researcher at Brown University in Alpine, N.J., and Hollis Belger, an independent researcher based in California, used an app called BimiLeap that employs the emerging science of mind genomics to create a mental picture of what science is, even when study respondents cannot articulate their understanding of it.

They created a narrative comprising four silos (or questions or categories), with four answers (elements) provided for each question. This 4 x 4 matrix resulted in 16 elements, which were then combined by an experimental design that mixed and matched ideas or concepts into vignettes. A full experimental design of 24 vignettes was created for each respondent in order to identify their emerging definition of "science." Each vignette was unique and statistically independent of the others, and all 16 elements appeared equally often but covered a wide range of combinations. The experimental design eliminated interviewer bias and any respondent's attempt to "game" the researchers.

The app presented the vignettes to the respondents and instructed them to rate the combinations on a scale. Respondents gave their insights intuitively. The app pooled their responses, measured the response time, and conducted the designated statistical analyses. The final product was delivered within six hours of the launch of the fieldwork in the form of complete reports in Excel and PowerPoint.

The full results of the Grunfeld and Belger study will be published in *Psychology Journal: Research Open*, Volume 3, Issue 3. Some of their results are shared below.

Results

A total of 108 respondents participated in the study, and a total of 24 x 108 vignettes were presented. The respondents were approximately two-thirds female and one-third male. Males defined science as "performing an experiment to see what occurs," and they perceived the outcomes as clearly under their control for improvement. The females were not as clear as to what science was to them, aside from their belief that "science assists (our) evolution through time."

Although the respondents were grouped into five age groups, I grouped them further to have fewer age categories. Approximately 85% belonged to Gen Z (aged 1-22 years) and 15% were Millennials (aged 23-39 years). Results indicated that, with increasing age, the respondents tended to define science as "performing an experiment to see what occurs." They looked at the outcomes and believed that those were within their control and could, therefore, be improved.

About 34% of the respondents were high school students, and about 54% were in college or graduate school; 20% of the respondents were not students. College students, as might be expected, defined science as "performing experiments" and, as they gained more life experience, they looked at science outcomes as something that they could control for improvement. Surprisingly, there was disagreement on the idea that science "delivers groundbreaking health care solutions" or "can lead to a new world with zero global emissions." There seemed to be distrust of the scientific information given by "subject matter experts," "scientific organizations," or "university publications." There was, however, strong agreement among the respondents that scientific information from the "medical community and doctors" is trustworthy.

What emerges most importantly from this simple mind genomics study are the elements that drive the answer to the question, "What is science?" The study identified two mindsets and ways in which the respondents define science:

> Scientific information may change with technology, available information, and even interpretation by experts. It is through science that knowledge is improved. We must continue the discourse even in the presence of difficult discords.

Mindset 1 (52%) are inner directed and Mindset 2 (48%) are outer directed. These two almost equally populated mindsets are characterized by radically different responses to the question, "What is science?" These differences may come as a surprise to the reader.

Mindset 1, the inner directed, define science as information that originates from performing experiments and understanding the outcomes, with the ability to use the data to improve and, perhaps, to evolve.

Mindset 2, the outer directed, appear to feel that science is not so much about the process and results as it is about their trust in the authority delivering the information. To Mindset 2, the medical community and physicians deliver more trustworthy scientific information than do policy makers and politicians, more than do their family and friends, and more than do educators and professors.

So, What Is Science?

According to the results of the Grunfeld and Belger study, science is defined in two radically different ways by two distinct mindsets. If the two mindsets are looking at the same scientific information, science to Mindset 1 (the inner directed) consists strictly of the results obtained from performed scientific studies. To Mindset 2 (the outer directed), science consists of the information disseminated and interpreted by the authority they trust. If the trusted authority of Mindset 2 were to go by the results only (i.e., behave similarly to Mindset 1), then the two groups would define science in the same way. If the trusted authority of Mindset 2 included other data interpretation not in the results, then the two groups would define science differently and may disagree.

The preponderance of negative news around the world may also indirectly contribute to this disagreement by influencing the behavior of either or both mindsets. Investigators recently confirmed in a 17-country, six-continent experimental study on psychophysiological reactions to real video news that there is indeed a propensity for negativity biases in human behavior. In a 2013 article, I reported that people perceive positive information to be self-serving, biased, and even inaccurate. People believe negative reports more than positive ones because negative reports also aid in their decision to avoid losses.

For example, people know that food, food ingredients, and medications are not absolutely safe. There are risks involved in eating food and taking medications. People use negative reports on these substances to assist them in deciding what the risks of taking those substances might be. Attempts to allay those concerns with persuasive arguments are often difficult and even ineffective. Thus, Mindsets 1 and 2 may see the same study results, and Mindset 1 may remain unchanged in their interpretation of the results. But, if the trusted authority of Mindset 2 were significantly influenced by negative reports, then this group's interpretation of the study results would be different from that of Mindset 1. As a result, the two group's definitions of science might conflict.

How the two mindsets obtain the news or reports may further contribute to a disagreement on the meaning of science. According to Pew Research Center (2021), about 86% of American adults get news from a smartphone, computer, or tablet "sometimes" or "often." When using a digital platform, about 69% of U.S. adults are likely to get their news from websites or apps "sometimes" or "often," except for Gen Z (42% for those aged 18–29), who turn to social media for their news.

The results of the Grunfeld and Belger study indicate that members of Gen Z belong to Mindset 2 more often than they

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Cannabis Corner

GMPs for Cannabis-Infused Foods

Food safety oversight of cannabis products only occurs at the state level. When will we see national adoption of GMPs for these foods?

BY **JESSE STANIFORTH**

For food production professionals, Good Manufacturing Practices (GMPs) start on day one—they're the set of all programs, policies, and procedures that aren't directed at controlling specific hazards. As a matter of federal law, GMPs are laid out in the human food rule of the Food Safety Modernization Act (FSMA), but, in practice, they define the food safety culture of an organization from the first training newly onboarded employees receive. FDA, likewise, prioritizes GMP inspections.

However, the moment a food producer infuses their food with cannabinoids—which the U.S. Drug Enforcement Agency continues to classify as a Schedule 1 drug—all federal law ceases to apply to that food product, meaning that national GMPs for cannabis foods do not exist in the United States.

"Cannabis edibles do not meet the federal definition of a dietary supplement," says Kathy Knutson, PhD, a food safety consultant. "So, cannabis edibles are neither food nor dietary supplements, and they are not regulated at the federal

level. The FDA has been very clear about how even edibles with CBD are not legal."

Food that isn't legal is no longer subject to inspection by FDA, nor is its production subject to the GMP standards laid out in FSMA's Final Rule for Preventive Controls for Human Food. Instead, what little food safety oversight cannabis products may encounter occurs at the state level—and in many cases it's minimal.

David Vaillencourt, CEO of Denver's GMP Collective, says, "People unfortunately get this false sense of security that because they went to a dispensary that's licensed by the state, it must be safe, just like if you went to Target or Walmart. But all they're doing is making sure that you track the physical plant from every stage of the life cycle. They took a few milligrams of the product and verified that, and it passed. Is that a representative as a whole batch? Were there preventive controls put in along the line? Does anybody do any environmental swabbing? I don't know."

There's little argument that the cannabis-infused food industry would benefit from the standardization of GMPs, even if they're not dictated by a federal body like FDA. However, because every state that has legalized cannabis has done so in its own manner and has been left to develop its own oversight for cannabis edibles in the absence of federal regulation, the path to national adoption of GMPs for cannabis food and beverages is not an easy one.

The Issue

As is the case with many of the complexities of American cannabis legalization, the problem begins with the division between the many states in which citizens have voted to legalize cannabis and the federal government's firm stance on keeping cannabis criminal. When states began to legalize, beginning with Colorado in 2012, they had no federal guidelines for regulating infused food safety. "They had no support, and they had no direction," says Vaillencourt. "The states regulate restaurants and the food service industry—they don't regulate Nabisco and ConAgra and Pepsi; they've never had to deal with that, so why would you expect them to know about GMPs? They weren't even aware."

Lezli Engelking is president and founder of the Foundation of Cannabis Unified Standards, based in Scottsdale, Ariz. She notes that, while states have legislated cannabis out of an overabundance of caution, which led to fairly onerous regulations, those regulations tended to ignore food safety experience or training as well as the implementation of quality management systems.

> The industry has developed without an understanding of basic food safety principles, or the importance of organizational culture in effectively implementing a food safety management system.
>
> *—Lezli Engelking*

Some states required dispensary employees to take a ServSafe course, Engelking says, but "no specific food safety guidance or regulations were required for the production, manufacturing, or processing of cannabis. This is one of the many challenges of enacting state cannabis programs without any federal guidance and oversight."

In particular, Engelking notes that the absence of federal GMP guidelines means that because the cannabis industry was built state by state, this important guidance was not developed. "The industry has developed without an understanding of basic food safety principles, or the importance of organizational culture in effectively implementing a food safety management system," she adds.

GMPs for Cannabis

Developing GMPs for cannabis requires a clear understanding of how cannabis is produced and refined into edible products, which sometimes occurs all in the same location. Dr. Knutson gives the example of a facility with which she works that has vertically integrated its site. In the same production plant, the company cultivates cannabis, extracts cannabinoids from the plants they've cultivated, and bakes them into edibles in an area they call the "cannabis kitchen." Each zone must be protected in different ways, sometimes from different pathogens.

"The flower is going into extraction, and the concentrate is then going into the edibles, all within these four walls," Dr. Knutson says. "In terms of GMPs, starting at cultivation, there is the importance of having separate air handling. The cannabis kitchen has its own roof-mounted HVAC unit, and it has its own dehumidifier so the two sides of air have been physically separated from each other." She goes on to detail the various concerns for developing GMPs in a vertically integrated site, which include everything from dedicated footwear and uniforms to considering where freight carriers like forklifts and handtrucks have been prior to entering the facility to deliver ingredients.

Yet from a macro perspective, says Vaillencourt, the process of applying GMPs to cannabis-infused foods shouldn't be significantly more complicated than it is with traditional foods. He counsels producers to consider the demands of the ISO 9001 quality management and risk assessment system. "Start with a basic quality management system," he says. "Are you making infused products? Does that mean it's orally ingested? What are the risks and what controls do I put in place to address the risks? Logically, that should lead you to food GMPs, preventive controls, sanitation, environmental monitoring, and allergens. Just apply logic; let's not reinvent the wheel."

Change Is Happening Already

Because legalization has occurred one state at a time, the process of developing food safety for cannabis products has likewise happened state by state. Vaillencourt notes that New York is beginning to require GMPs for CBD-infused products, while Florida was the first state to demand GMP certification in its cannabis laws.

"Then of course people called them to ask, 'What does that mean? It's a federal thing. Nobody can give me a federal GMP certification.' And the state was like, 'I don't know,' and they literally wouldn't answer anybody. You can't just flip a light switch and tell a billion-dollar market, 'You have to be GMP tomorrow.'"

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But states have to do something, and they're trying. Vaillencourt says that Michigan is toying with provisions for GMP, while in his home state, the Colorado Marijuana Enforcement Division has taken notice. "Within the last 18 months," he says, "we went from 'What the heck are GMPs?' to 'Everybody's on board with this, we want to get to a GMP system. How do we do that?'"

The answer isn't easy. Engelking says she's been happy to see state programs evolving to include more food safety requirements, but she laments that, too often, they're just box-checking compliance demands. "As a result, little or no emphasis is placed on doing the hard work of changing the organizational culture and behaviors, which are the backbone of any effective management system," she says. "Industry executives must make a commitment to implement and maintain GMP standards, even if not yet required by regulation. For this to happen, the C-suite must understand how standards and good manufacturing practices can benefit their bottom line."

Educating everyone in the company—not just about what the GMPs are but also why they exist—is fundamental to Engelking's approach. "A company's values must be integrated into all activities, including daily team meetings, operating procedures, internal and external communications, etc. All members of the team—employees, managers, and executives—should receive training on good manufacturing practices as well as the importance of organizational culture. There really isn't a cannabis business that can afford not to implement GMP standards."

However, she says, there are plenty that won't, and will wait until they're forced to do so by law, which is inevitable. "Regulations will continue to evolve, and will eventually mandate GMP, at both the state and federal level. States will begin to require it just as they now require ISO 17025 accreditation for analytical testing laboratories."

What's Changing

The good news is that all over the U.S., independent organizations are working to develop standards. Last year, the 200-year-old nonprofit U.S. Pharmacopeia published a standard of quality attributes for cannabis flower products in their *Journal of Natural Products*. "I think it's now in the top 5% of citations in the history of the *Journal of Natural Products*, which for an article that's only 14 months old, that's big," says Vaillencourt.

The good news is that all over the U.S., independent organizations are working to develop standards.

At the same time, standardization body ASTM International has approved more than 20 standards, thanks in part to the work of thousands of volunteers across 30 countries.

Most importantly, Vaillencourt says that a coalition of state groups and representatives from the federal department of agriculture, working in conjunction with the National Institute for Standards and Technology (NIST), are finalizing a food safety guide for cannabis edibles production.

But it remains to be seen what sort of final shape cannabis GMPs might take. Vaillencourt suggests that producers adhere to the Global Food Safety Initiative and Safe Quality Food Program. And then there's ISO 22000: the food safety management systems. Hopefully we don't go down the GFSI road; between SQF, BRC... there are so many groups in there it's so complicated to have 10 different systems to harmonize. I hope we can just have one system."

The Final Picture

Vaillencourt cautiously predicts it will take between two and five years before the U.S. sees anything like a nationally coherent set of GMPs for infused foods, but Engelking isn't willing to make a ballpark prediction. "With any luck, the continued advancement of state programs and the changing perceptions of Americans around cannabis will expedite this process," she says. "The global cannabis industry is hampered by the lack of American federal regulatory development, just like the domestic industry. Most of the world would prefer to follow U.S. standards and regulatory leadership, especially with respect to quality and safety, as well as compliance with international treaties."

Cannabis standards have not emerged from the federal level, but rather from the 36 states that have legalized it so far, and Vaillencourt thinks those states will be hesitant to accept advice from the federal government, which left them to work their standards out alone. Dr. Knutson agrees. "I don't think there's any consensus anywhere," she says, adding that she sees the clearest path to food safety for infused foods in either rescheduling cannabis on the DEA list or descheduling it completely. "As many little steps as we can take forward, I think there's going to be greater progress in the long run, even though it's painful at every little step."

Engelking argues that cannabis's Schedule 1 status—reserved for drugs with no medical potential and high likelihood of abuse—has created the vacuum for guidance and oversight at the federal level. She thinks Schedule 1 status is both the biggest obstacle to the development of the U.S. cannabis industry as a whole, and also the biggest stumbling block on the path to implementing GMP nationwide standards.

"Until those things change," says Engelking, "inconsistent and disjointed state regulations will continue to emphasize third-party testing as the primary means for controlling the quality and safety of cannabis-infused beverages and foods, and operators will continue to be forced to build individual operational practices and procedures based on differing state regulations, both of which can lead to inconsistent, unsafe products being found in the marketplace." ■

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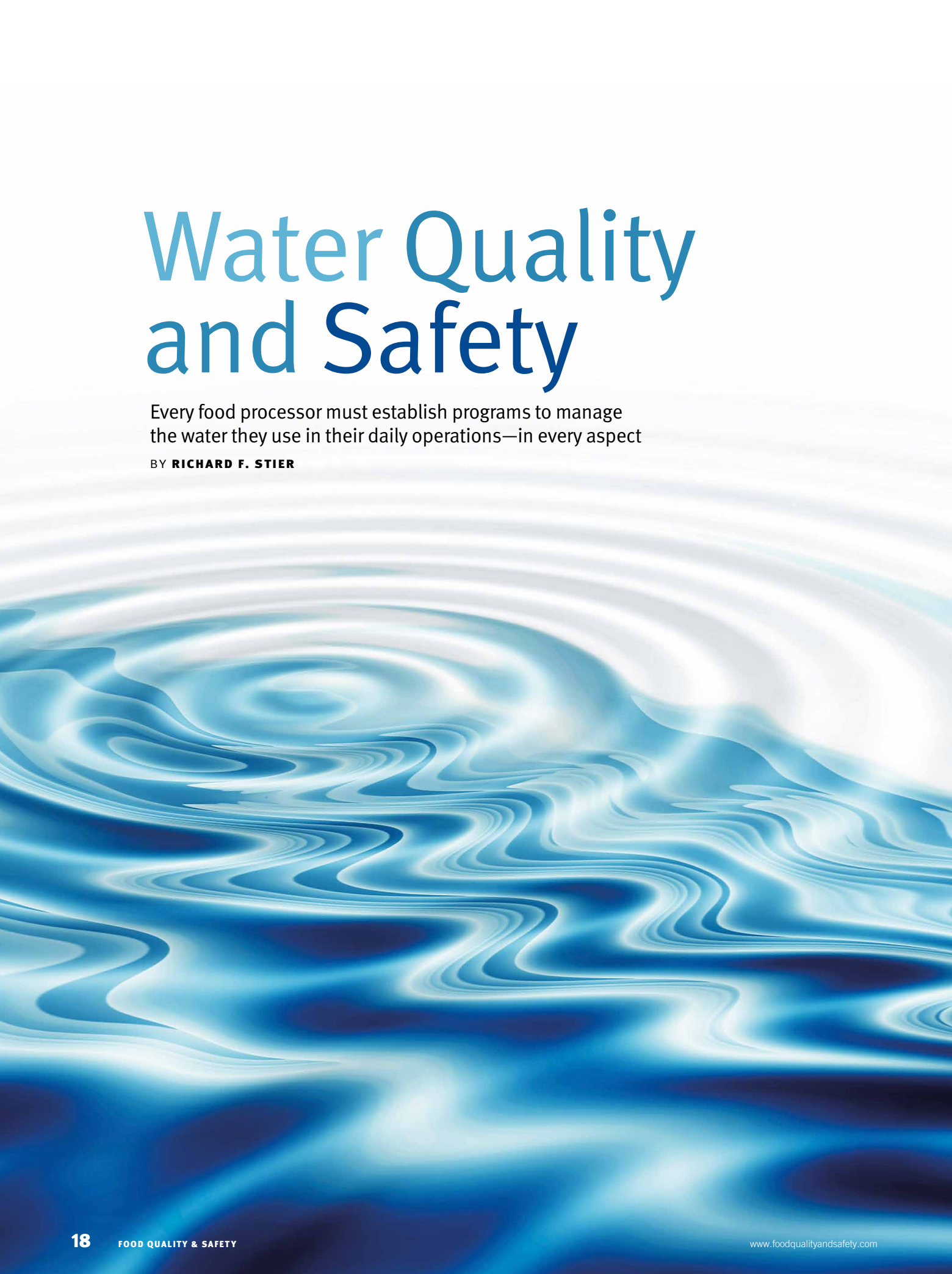
TAKE YOUR PICK!

Water Quality and Safety

Every food processor must establish programs to manage the water they use in their daily operations—in every aspect

BY **RICHARD F. STIER**



Water is one thing that most of us take for granted. You turn on the tap and get clean, fresh water. This is not, however, something that applies around the world. There are places where clean water is a rarity and waterborne diseases such as cholera are common. But, even in a nation like the United States where clean water is the norm, problems do crop up. Look at the lead problems in Flint, Michigan from a few years back. And in 1993, we had the following outbreak, as reported in *Morbidity and Mortality Weekly* (1994, Vol. 43:36):

In March and April 1993, an outbreak of cryptosporidiosis in Milwaukee resulted in diarrheal illness in an estimated 403,000 persons. Following that outbreak, testing for Cryptosporidium *in persons with diarrhea increased substantially in some areas of Wisconsin; by August 1, 1993, three of six clinical laboratories in Dane County were testing routinely for* Cryptosporidium *as part of ova and parasite examinations. In late August 1993, the Madison Department of Public Health and the Dane County Public Health Division identified two clusters of persons with laboratory-confirmed* Cryptosporidium *infection in Dane County (approximately 80 miles west of Milwaukee).*

This particular incident has had a lasting effect on how FDA expects food processors to assess risk; that is, there is an expectation that *Cryptosporidium* parvum will be evaluated as part of a company's hazard analysis of water. This parasite is resistant to chlorine; a combination of chlorine and microfiltration is needed to ensure the safety of water. The Wisconsin systems lacked the latter.

So, each and every food processor must establish programs to manage the water that they utilize in their daily operations. Think about all the different ways water may be used in a food processing facility. Potential applications include but aren't limited to the following:

- Ingredient;
- Cleaning and sanitizing;
- Steam generation or heating (with direct product contact);
- Ice;
- Cooling;
- Transport of foods;
- Waste disposal; and
- Drinking.

Water as a HACCP Prerequisite

FDA's HACCP regulations for both the juice and seafood industries include eight areas where processors must have documented programs to assure good sanitation. One of these emphasizes the safety of water and ice used in food processing. The following has been drawn from the FDA HACCP regulation for the juice industry found in 21 CFR Part 120:

§120.6 (a) Sanitation controls. Each processor shall have and implement a sanitation standard operating procedure (SSOP) that addresses sanitation conditions and practices before, during, and after processing. The SSOP shall address: (1) Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice.

As part of any inspection, FDA will examine the programs that the regulated industries have established to ensure the safety of water.

USFDA's Current Good Manufacturing Practice Hazard Analysis and Risk Based Preventive

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Controls for Human Food regulation (21 CFR Part 117) expands on this and emphasizes the importance of water in a food processing facility as follows:

§ 117.37 (a) Water supply. The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) Plumbing. Plumbing must be of adequate size and design and adequately installed and maintained to:

1. Carry adequate quantities of water to required locations throughout the plant.

2. Properly convey sewage and liquid disposable waste from the plant.

3. Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

4. Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

5. Provide that there is not backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing.

Let's look at what the regulation is mandating. The water supply must be adequate for all uses of the operation and must be derived from an adequate source. This can be interpreted as follows: Not only must there be enough water to meet all the needs of the processing facility, but the plumbing system must be able to handle all wastewater and sewage that is reasonably likely to occur.

Years ago, I observed a poorly designed system in a cannery. When all retorts were running and in the cooling cycle, the volume of wastewater going into the drains was so great that the toilets backed up and flooded the rest rooms. The system definitely did not "properly convey sewage and disposable liquid from the plant."

All food processing facilities should also have complete and accurate diagrams of their plumbing systems. These diagrams should include freshwater lines, sanitation chemical lines, wastewater lines, and the sewage system and clearly demonstrate that there are no cross-connections between these systems. Ideally, they should also provide the company with insights as to whether there are any dead legs or dead ends in the system. Dead ends or dead spots can adversely affect product quality and safety and are extremely hard to properly clean and/or flush. They may even harbor spoilage organisms or microorganisms of public health significance. This may be a challenge for processors in old buildings or in structures that have been adopted for use in food processing.

Water Supply

Processors need to understand the source or sources of their water. Many processors draw water from city water supplies or from public or private wells. Processors may also obtain water from multiple sources, and the water from these sources may have different chemistries. The assumption is that these are safe sources, but this needs to be verified periodically by the processor. There are also many operations around the world that draw from reservoirs, rivers, or other open water sources and must treat water on site to assure its sanitary quality. In the United States, for example, salmon canneries in remote locations of Alaska operate in this manner. Treatment plants must, therefore, be an integral part of these facilities. In the early 1980s, two outbreaks of botulism that were traced to canned salmon processors underscored the need for both good sanitation and good water quality in these operations. The cause was determined to be post-process contamination by *Clostridium botulinum* type E, which gained access to the containers through a container defect. Several operations installed reservoirs for chlorinating can cooling water to minimize the potential for a reoccurrence. Using information developed by the National Food Processors Association in 1990, the waters were treated to achieve a five-log reduction of spores of *C. botulinum* in an effort to reduce the potential *C. botulinum* type E hazard from water.

All food processors should test water from each and every water source and in the plant from different outlets at least once a year, and preferably more often. Operators should collect water samples from the farthest outlet from main entering the facility. This should be done even if water is obtained from a city water system. The water quality as it leaves a treatment plant and its condition when it gets to your plant may vary. This is especially true in cities where pipelines are old. If the pipes are iron, water can pick up that metal quite easily from the lines. High iron water, whether from old pipes or a natural source, is quite easy to detect. All one needs do is look for iron stains wherever there are leaks or drips. Now, iron might not be a safety risk, but iron in the water can affect product quality and may be an indicator of other potential

All food processors should test water from each and every water source and in the plant from different outlets at least once a year, and preferably more often.

problems. Along these lines, processors should always request that the city provide them with water test results on a regular basis.

If a company uses water from multiple sources, such as wells, city, or other places, they must be sure that samples from each source are tested on a regular basis for both microbiological and chemical parameters. Keep in mind that these analyses may be used to do more than just assure the safety of your food and ingredients. Knowing the chemistry of the water coming into the plant will help in other areas, as will be discussed below. If there are concerns that the water may have been contaminated with runoff from fields or elsewhere, the processor should not only look for pathogens or parasites but should also run a series of chemical tests, including pH, water hardness, heavy metals, pesticides, radiological hazards, iron, and nitrates.

Some U.S. states require pesticide testing of well water. Water samples for complete microbiological and chemical analyses should also be collected at least once a year and submitted to a recognized water testing laboratory. Testing the microbiological quality of the water should be done more frequently and, if the source is a well, every quarter at a minimum.

Processors must establish documented programs for water sampling and testing. These protocols should include how to sample, how often to sample, where to sample, and how samples should be stored or shipped. These procedures should also include what tests should be done, methods for doing the work, and what to do if a sample fails to meet established specifications. Records and testing procedures should be maintained in a separate file or binder so that test results may be quickly and easily accessed. Of course, many operators are now maintaining records electronically. The key is easy access.

Installing sample ports on water lines is a good idea, provided they are installed properly, which means do not leave a large dead-leg. It is also a good idea to allow the sample port to "run" for a short period to flush the port before collecting a sample. If water samples are being collected for microbiological testing and the water is chlorinated, be sure that the sampling program includes a step to neutralize any residual chlorine. Sample bags that include a sodium thiosulfate tablet will meet this need. Since these bags are plastic, they're safe to use in any kind of processing environment.

Water as an Ingredient

Water is used as an ingredient in many products. The quality—that is, the chemistry of the water—required depends on the product being manufactured. For example, baked goods do not contain large amounts of water, but the chemistry of the water can affect doughs or batters, and eventually the finished baked good. Water also acts as a solvent for salt, leavening chemicals, sugars, and emulsifiers.

Water may also contain dissolved minerals, organic matter, gases, and microbial contaminants. The degree of hardness is generally expressed as hard, soft, saline, or alkaline. The specific composition is expressed in parts per million (ppm) of the dissolved hardness-causing minerals, which are mainly calcium and magnesium salts.

Here are examples of how hard water may adversely affect the quality of baked goods:

- Calcium and magnesium may precipitate from hard waters in steam lines and can then be carried by the steam used in bakery ovens, which may cause spotting on the top crust of breads and rolls.
- Calcium sulfate is the primary component of scale formed on boilers and is generally considered undesirable. Calcium sulfate in a dough system stimulates yeast activity and has a strengthening effect on gluten structure. The salt is often added if the water is soft.
- Calcium and magnesium bicarbonates create highly alkaline water, increasing the buffering capacity of the water and potentially resisting the ability of acids to lower the pH of the product. Yeast and enzymatic activity may be compromised in doughs made with alkaline water, as the pH remains above the optimum range. Water treatments or formula adjustments can be made to compensate for this condition.

Water quality is extremely important in beverage operations. Soft drink and bottled water producers using city or spring water may subject water to the following steps: sand filter for foreign material control, charcoal filter to remove chlorine and volatile organic compounds, reverse osmosis to remove minerals, and ultraviolet light and ozonation to control pathogens. In bottled water, ozone levels must be greater than 0.2 ppm and not exceed 0.4 ppm.

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Fortunately, a bottled water operator that exceeds the upper limit for ozone can hold product and allow excess ozone to dissipate. Whenever ultraviolet light is utilized as a sterilant, the company must incorporate the UV light into the preventive maintenance program to ensure that efficacy of the light treatment remains high.

Processors must establish specifications for water that is used as an ingredient and monitor water quality on a regular basis.

Water for Sanitation

Water is considered to be the universal solvent. The first step in most cleaning procedures is flushing to remove gross soil. Cleaning compounds are used with water to enhance the cleaning ability of the water. Water carries detergents to the soil to be removed, carries detergents and soils away from the surface, and can be used to sanitize a surface. Surfaces may be sanitized using hot water or a sanitizer that has been diluted in water.

The chemistry of the water, particularly water hardness and pH, affects the performance of cleaning chemicals. Water hardness affects detergent consumption and may cause the formation of films, scale, or precipitates on equipment surfaces. As an example, a cleaner designed for use in soft water may end up redepositing soil on the surface of the equipment if used in hard water (see Table 1, right). Failure to properly understand water chemistry can cost an operator money in both how much detergent is used and the time required for cleaning.

When working with a supplier of cleaning compounds, be honest with them as they work with you to develop your cleaning program. It is especially important to let them know if water is being drawn from multiple sources. The water chemistry of waters from each source must be fully understood. A reputable sanitation service/chemical supplier should do a water analysis for you before selecting chemicals.

Water chemistry can also affect sanitizer performance. Chlorine is more effective at lower pH levels. The lower the pH of the system, the more hypochlorous ion in the system and, hence, the greater the antimicrobial activity. For example, if the pH of your water is 8.5, the efficacy of chlorination will be significantly reduced and lethality to bacteria decreases.

If the water used is very hard, the processor may need to treat it. Water softening may be necessary for both processing and cleaning applications.

Water as a Transport Medium

Water is employed in many operations as a means to move products through the process. This is especially common with fruits and vegetables. The water used for this application often performs multiple functions. It cleans product, removing dirt and other soil, such as in tomato processing. Tomato processors unload gondola trucks into flumes, which convey the tomatoes into the plant and clean them in the process. These lines are usually built with collectors to remove mud and stones. The tomatoes are carried into the plant on conveyors and rinsed with water sprays in which chlorine levels are boosted. This operation is immediately upstream of the peelers, which usually use steam to loosen and remove the skin.

The water used to move and wash fresh-cut produce is an integral element for this industry. Water used for fluming fresh cut produce must include an effective antimicrobial, such as chlorine or peracetic acid, to prevent cross-contamination. In many operations, the processor sets up automatic monitoring systems that check pH and antimicrobial levels and will automatically signal meters to make adjustments to these two parameters.

Table 1. Hardness Classification

Class	ppm	gpg*
Soft	0–60	0–3.5
Moderately Hard	60–120	3.5–7.0
Hard	120–180	7.0–10.5
Very Hard	>180	>10.5

**gpg: grains per gallon 17.2 ppm; $CaCO^3$ = 1 gpg*

One of the great myths in the industry is that adding antimicrobial to flume waters and maintaining that level makes fluming a "kill step." Fluming or washing may reduce the counts on the product by one to two log cycles, but this reduction is due in large part to the physical action of the water in the washer or flume. The addition of antimicrobial maintains the microbiological quality of the water so this step in the process does not adversely affect the microbiological quality of the produce. A 2017 paper published in the *Journal of Food Protection* by Gombas and colleagues recommends three options for validating antimicrobial in wash water as a preventive control for leafy greens:

1. Use a surrogate for the microbial hazard and demonstrate that cross-contamination is prevented.

2. Use antimicrobial sensors and demonstrate that a critical antimicrobial level is maintained during worst-case operating procedures.

3. Validate the placement of antimicrobial sensors in the processing equipment with the demonstration that a critical antimicrobial level is maintained at all locations regardless of operating conditions.

Unfortunately, as noted in that publication and still true as of this writing, there are neither validated surrogates nor knowledge of critical levels for any commercially used wash water antimicrobials, so validating the effectiveness of these antimicrobials in a commercial operation remains an elusive goal.

Water is an integral element for most food processors. It is used for many different operations within each plant. Processors must have the infrastructure to properly ensure the safety and quality of all water in the plant, which includes the plumbing system. Specifications for each potential use must be developed and documented, and programs must be established to ensure that these are monitored and maintained. If routine monitoring indicates that the system is "out of control," the procedures must document the necessary corrective actions and records to be kept. As has been shown, federal regulations mandate that these protocols must be developed and implemented. ■

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Dry Cleaning in the Food Industry

Part 1: Rationale and challenges

BY **DEBRA SMITH** AND **PURNENDU C. VASAVADA, PHD**

Editors' note: *This is part 1 of a two-part series on dry cleaning. Part 1 looks at the rationale for dry cleaning, and the challenges that can accompany the process. Part 2, which will publish in the October/November 2021 issue of* Food Quality & Safety, *will focus on solutions to these challenges.*

We tend to think of dry cleaning in the food industry as being related only to those food plants that undertake dry/low water activity (a_w) food and ingredient processing. But, dry cleaning and sanitization can be a valuable option in the control of microbial hazards for any processing plant. In this series of articles, we look at the rationale, challenges, and solutions related to microbial control through controlled use of water, dry cleaning, and other sanitization techniques.

Rationale

The production of dehydrated foods and food ingredients with low a_w, such as cereals, chocolate, cocoa powder, dried fruits and vegetables, dried meats, egg powder, herbs, spices, condiments, milk powder, whey protein powders, pasta, powdered infant formula (PIF), grains, and seeds is popular, due to their long shelf life and less stringent holding and storage condition requirements.

Low-moisture and low a_w foods also have advantages in that they are less prone to spoilage. Although low a_w foods seem to have clear advantages with respect to controlling the growth of microorganisms, there are, nevertheless, major concerns regarding the survival of pathogenic microorganisms, and outbreaks linked to low a_w foods and dry ingredients have been reported. Major foodborne pathogens of concern include *Salmonella* spp., *Bacillus cereus*, *Cronobacter saka zakii*, *Clostridium* spp., *E. coli* O157:H7, and *Staphylococcus aureus*.

Many food processors and consumers mistakenly believe that dried foods are sterile or that microorganisms do not survive in dried food due to their low moisture content. However, many microorganisms, including pathogens, are able to survive

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drying processes and, while they may not grow, vegetative cells and spores may remain viable for several months or even years. Microorganisms are known to persist longer in dried foods and dry food processing environments than in foods and environments with higher moisture content and low a_w. It's also important to note that foodborne pathogens in low a_w foods and environments may have an increased tolerance to heat and other treatments that are lethal to cells in high a_w environments, making them very difficult to eliminate in many dry foods or dry food ingredients without compromising the quality of the food product.

Potential sources of microbial contamination in dried foods include incoming raw materials and ingredients, the external environment (surroundings, water, air, pests), inadequate cleaning and sanitation, inadequate processing, and post-processing contamination, mainly through the food plant environment. Primary strategies for reducing microbial pathogens include:

- Supplying specifications segregating hygiene areas to separate dry and wet processing areas;
- Controlling human and material movement in the plant to avoid cross-contamination,
- Implementing effective dry-cleaning and wet-cleaning practices; and
- Employing an effective environmental pathogen monitoring program, particularly in a facility producing ready-to-eat (RTE) foods.

The Food Safety Modernization Act (FSMA), signed into law in January 2011, represents a paradigm shift from reaction-based systems to prevention-based systems and clearly places the burden of assuring food safety on the food manufacturer. The "Current Good Manufacturing Practice Hazard Analysis and Risk-Based Preventive Controls for Human Food," or the Preventive Controls for Human Food (PCHF) rule, requires food processors to identify "known or foreseeable" hazards in foods, using a risk-based hazard analysis, and identify preventive control(s) to mitigate the hazard identified. In addition, management components such as monitoring; procedures for corrective action, verification, and record keeping; supply chain programs; and recall plans are also required. The FSMA PCHF is based on the modified cGMPs and includes sanitation controls. The PCHF regulation emphasizes environmental monitoring programs, as well as targeted sampling and testing, as appropriate ways to control microbial hazards in RTE foods.

Other FSMA regulations, including Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) and the Sanitary Food Transportation Act (SFTA) may also apply to dry food manufacturers.

Controlling the potential for dry/low a_w food contamination with foodborne pathogens should therefore focus on preventing this problem through implementation of efficient cleaning and sanitation procedures in the food processing environment. Food processing environments in which dried foods are handled must be maintained at low humidity and kept dry, a requirement that gives rise to the need for specific cleaning and sanitizing procedures. The challenges of cleaning and sanitation in dry food plants and specific approaches to accomplishing efficient and effective sanitation and hygiene are discussed below.

Challenges

Dry cleaning is hard work. Let's face it: Cleaning with water is easy, fast, and effective. There also seems to be something in our psyche that makes us enjoy using water. By contrast, dry cleaning is hard work, tedious, and awkward. It

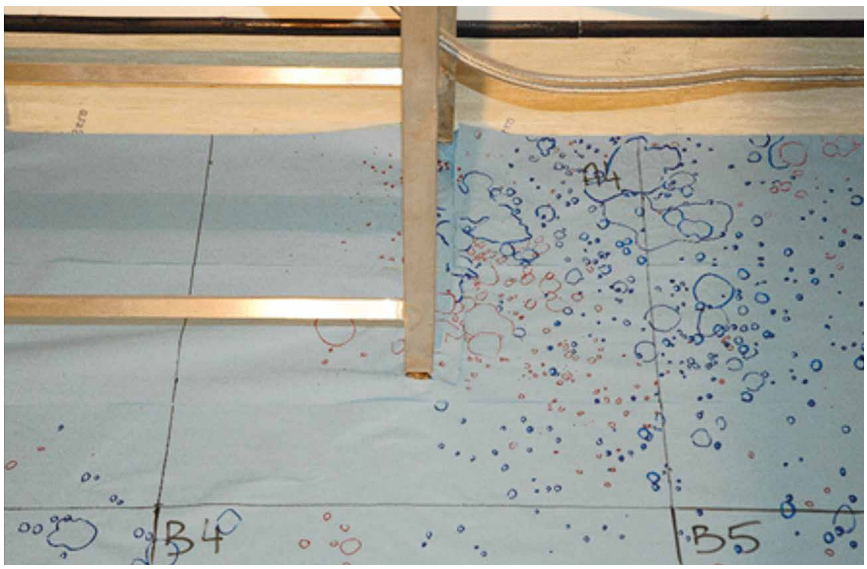

Figure 1. Water droplets on the floor surrounding a hand wash sink.

COURTESY OF CAMPDENBRI.

A1 7	A2 149	A3 175	A4 73	A5 45	A6
B1 61	B2 146	B3	B4	B5	B6
C1 152	C2	C3	C4 11	C5	C6
D1	D2	D3	D4	D5	D6
E1	E2	E3	E4	E5	E6

Figure 2. CFUs developed on agar plates arranged on the floor around a handwash sink.

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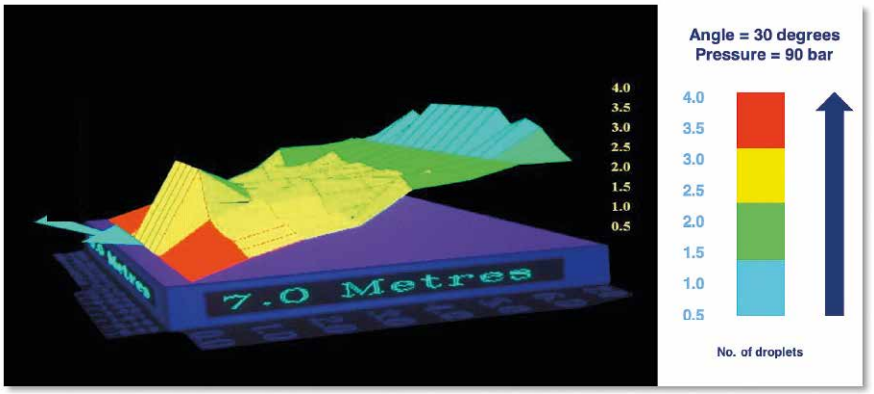

COURTESY OF CAMPDENBRI.

Figure 3. Water droplet spread by a high-pressure hose.

often takes considerably longer to do than cleaning with water, and adds pressure on an already beleaguered hygiene team to minimize cleaning windows in favor of production.

So, why should we dry clean? Well unfortunately, for all of its benefits, water also comes with some serious downsides, especially when it comes to its use in the food industry.

Water promotes microbial growth and spread. We know that some microbes can survive in dry environments, but most require five things to grow: nutrients, water, the right temperature, the right atmosphere, and time. Once established, microbes can spread throughout an environment via vectors, namely on surfaces (hands, equipment, packaging), through the air (particles), and via water (droplets, aerosols, splashes, standing water). The presence of water significantly increases the risk of both microbial growth and spread.

In a food factory, access to nutrients will rarely be a problem. Similarly, working temperatures and atmospheres must be kept at levels people can tolerate—levels that tend to also favor most microbes. Consequently, within a dry/low a_w food factory, there are generally only two things we can control—time and water. We deal with time through the use of cleaning windows that remove contamination at a frequency that limits microbial growth. But how do we clean without water?

Water spreads contamination. We know from various studies that water, in the form of droplets, aerosols, and standing water, can significantly aid the spread of contamination. Research conducted at CampdenBRI demonstrated that "contamination" on a wet boot can be transferred over 24 m on a dry floor. However,

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Food Safety in Dry, Low-Moisture, and Low-Water-Activity Foods

Part 2: Strategies for controlling emerging pathogens

BY **PURNENDU C. VASAVADA, PHD,** AND **ALVIN LEE, PHD**

Editors' note: *This is part 2 of a two-part series on emerging pathogens in dry, low-moisture, and low-water-activity foods. Part 1, which published in the June/July 2021 issue of* Food Quality & Safety *(p. 16), focused on which pathogens pose the most risk in these foods. Part 2, here, looks at technologies and strategies for their control.*

Food dehydration is one of the oldest methods of food preservation. It involves simultaneous heat and mass transfer to remove moisture for reduction of the water content and water activity to increase the shelf life of the food. Aside from preservation, dehydration reduces the weight and bulk of the food, lowering transportation and packaging costs. In conventional food dehydration, air is used to heat the food and carry moisture vapor away from the material subjected to drying.

A typical drying process involves several stages. An initial period of warming up is followed by a constant rate period in which water is removed from the surface of the food at a uniform rate and the water inside the material moves to the surface by diffusion to replenish the moisture removed. The rate of drying is controlled by this diffusion of moisture to the surface after the surface moisture pool has been evaporated. As the drying progresses, the surface moisture pool becomes depleted and water can no longer diffuse to the surface to maintain the constant rate of removal. This is when the falling rate period begins. The moisture content when the constant rate changes to the falling rate is called the critical moisture content. As more and more water evaporates from the surface, less water from inside the product migrates to the outer surface as the rate of diffusion slows and the rate of moisture loss is reduced. In a typical drying process of 40 to 44 hours, the constant rate period is about six to eight hours, and the falling rate period is approximately 34 to 36 hours. Additionally, the initial warming phase may not occur in all cases.

The quality of a dried product depends on a variety of factors related to the drying conditions (i.e., factors affecting heat and mass transfer and moisture diffusion) and product (i.e., size, shape, and thickness; composition, structure, and porosity; and the initial moisture content and surface area available for moisture loss). Careful attention must be paid to drying conditions to minimize—if not prevent altogether—quality and functionality problems with the dried product.

Drying Technologies

As early as 2000 B.C., sun drying was used to reduce moisture in foodstuffs. To avoid dependence on weather and to reduce drying time while obtaining acceptable quality, air drying was introduced.

Convective air drying. This is the most common technology employed to dry fruits, vegetables, herbs, and spices. In convective air drying, a flow of heated air is passed over or through the material and water is removed by evaporation. A typical drying process follows constant rate and falling rate periods, which can be extended or absent depending on the food material, moisture content, and drying conditions. Convective air drying can be carried out at an atmospheric pressure between 40°C and 80°C, using several types of dryers such as tray dryers, cabinet dryers, tunnel dryers, and conveyor belt and fluidized bed dryers.

Spray drying. This popular process, which has been used in the food industry for more than 150 years, involves drying concentrated liquid products into dried powders to obtain some key ingredients. The process involves spraying concentrated liquid/slurry in a finely atomized form into a spray drying chamber where the liquid feed material in atomized (mist) form comes in contact with the stream of hot air and loses moisture instantly. The dry powder is then separated from the drying air using a cyclone separator and/

or a filter bag. Often, the spray drying process is combined with a fluidized bed dryer and/or agglomeration and instantization to improve reconstitution of the dried product. The spray drying produces fairly uniform particle sizes and is considered suitable for heat-sensitive products such as milk powder, instant coffee, powdered flavors, and other ingredients.

Drum drying and roller drying. In drum or roller drying, a liquid feedstock is applied as a relatively thin layer on the heated surface of a rotating drum or a roller that is heated internally with steam. As the material is sprayed onto the drums, it sticks and dries to the surface. The dried material is then peeled from the drums using a knife system. Sheets of drum-dried product are milled to a finished flake or powder form. Drum drying yields a larger particle size than spray drying and is considered suitable for drying high-viscosity materials that may not be easily spray dried. Drum drying is generally used in the production of instant mashed potatoes, pre-cooked cereals, soup mixtures, bakery goods, and low-grade milk powder.

Vacuum drying. In vacuum drying, the objects to be dried are placed in an enclosed container to vent air and create a vacuum with a vacuum pump to reduce pressure. The vacuum and the reduced pressure allows the removal of water at a lower temperature, as the boiling point of water decreases with a decrease in pressure. Therefore, vacuum drying is considered particularly suitable for drying oxygen and heat-sensitive compounds and microorganisms such as commercial starter cultures and enzymes.

Freeze drying. In freeze drying, a completely frozen product is placed under a vacuum to remove water by process of sublimation, i.e., directly from a solid (ice) to a vapor without passing through a liquid phase. This process requires minimal heat input. Freeze drying is more expensive than other drying technologies, however; it is considered ideal for the long-term preservation of high-value ingredients and products with the same color, shape, flavor, and nutrients of a fresh product.

Over the years, drying technology research and development has focused on improving the efficiency of the drying process, energy efficiency, and product quality and functionality. Studies on the survivability of microorganisms during drying have been rare and, as such, most studies dealt with the preservation of microbial cultures. In recent years, outbreaks linked to dried and low moisture (LM), and low-water-activity (a_w) foods contaminated with *Salmonella* spp., *Bacillus cereus*, *Cronobacter sakazakii*, *Clostridium* spp., and other microorganisms, have raised new concerns about how to control foodborne pathogens in dried and LM/low a_w foods and the food plant environment.

There is a lack of information concerning the survivability of pathogens during the drying of complex matrices such as foods. Recently, research has focused on the development of novel inactivation methods as alternatives to mitigate the risks associated with the survival of bacterial pathogens in dried, LM, and low a_w foods. Some of these technologies suitable for use on these foods include nonthermal inactivation methods and other novel methods discussed below.

Novel Methods

A number of novel technologies suitable for processing certain foods, methods that result in unique qualities and improved shelf life, have become available to the food industry (see Table 1, p. 28).

High-pressure processing (HPP). This technology consists of applying pressures at 600 MPa (up to 900 MPa or 135,000 lb/in²) to food products to extend shelf life by causing microbial inactivation. HPP technology has been used for the preservation of high-moisture foods such as meat, but limited research has been conducted on the use of HPP in low-moisture foods (LMFs). The mode of action of HPP against microorganisms has shown that high pressures can affect gene expression, inhibit protein synthesis, and disrupt cell membranes, resulting in the leakage of cellular compounds, including amino acids and metal cations. Much higher pressures of approximately 1,000 MPa are necessary to inactivate bacterial spores. Additionally, high pressure can have a protective effect on some bacterial endospores, and the inactivation of some microorganisms is lower at lower a_w values. The HPP for inactivating microorganisms in LMFs typically requires very high pressures and costly equipment. Thus, HPP at lower pressures, combined with other inactivation methods such as CO_2 extractions, has been applied to solid foods with lower a_w.

Nonthermal plasma. This promising novel technology can be applied to LM/low a_w foods (La_wF) without the addition of water to the system prior to treatment and can usually be applied to food prior to packaging. Nonthermal plasma uses a gas (air, nitrogen, or a mixture of noble gases) with a neutral total charge that is either completely or partially ionized by an energy source (electricity or microwave) to generate photons, ions, and free electrons to treat food products by "showering" the LM/La_wF as they pass the plasma beam. Several foodborne microorganisms, including bacteria, yeasts, spores, fungi, biofilms, and aflatoxins, have been inactivated by nonthermal plasma.

Ultraviolet light and pulsed light. These can be applied to foods in a way that is similar to the use of nonthermal plasma, and they have been used in the pharmaceutical and water purification industries for the inactivation of microorganisms. Depending on the amount of power generated, the penetration power can be limited by the packaging and opacity of the food. These technologies rely on the photochemical reaction triggered by the absorption of light by pyrimidine bases, which leads to the formation of chemical dimers and genetic material damage and stops cell replication. Most vegetative bacteria and some bacterial spores and viruses are sensitive to UV light. These technologies can generate heat due to prolonged exposure and the proximity of the

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food to the light source. Therefore, during validation, the factors that could influence inactivation need to be carefully considered during experimental design and execution stages. The advantage of this technology is the relatively low ongoing cost and maintenance, aside from one-time costs involved in equipment setup.

Irradiation. Typically refering to ionizing irradiation such as gamma-rays, irradiation is a well-established technology that can be applied as an alternative to thermal processing and has been FDA and USDA approved to eliminate foodborne pathogens and undesirable spoilage microorganisms, control insects, extend shelf life, and slow ripening and sprouting. Irradiation applied in high doses can be used to achieve sterilization and has in fact been used to sterilize pharmaceutical and scientific equipment and consumables. The mode of action of irradiation is triggered by the generation of the ions H+ and OH-, which result from the hydrolysis of water molecules (radiolysis), followed by the generation of reactive oxygen species, such as hydroxyl radicals (HO·), as well as hydrogen radicals (H·), leading to the disruption of microbial metabolic and structural functions and, ultimately, cell death.

The application of irradiation to LM/La_wF is well documented, especially in the spice industry, for the inactivation of *Salmonella* spp., *B. cereus*, *C. perfringens*, molds, and mycotoxins, in particular for products that need to stay dry for optimal product quality and are often difficult to treat with other technologies. Irradiation technologies, particularly gamma-rays, have good penetration and are easily scalable to treat large quantities of pre-packaged food. Although commonly used for spices, irradiation may meet some consumer resistance to its use in certain foods.

Other emerging technologies include dielectric drying, i.e., radiofrequencies (RF) and microwave (MW) drying, infrared drying, osmotic drying, low-pressure superheated steam drying (SSD), and supercritical carbon dioxide ($scCO_2$) drying. In SSD, superheated steam is used as the drying medium instead of hot air. The $scCO_2$ drying process is an extraction process. Water is not removed by vaporization or sublimation but is dissolved in the

Table 1. Novel Technologies and Mechanisms of Action for the Treatment of Foods.

Technology	Mechanism of Action	Advantages	Limitations
High-Pressure Processing	Disruption of protein synthesis, hydrophobic and ionic bonds, protein denaturation.	Well studied for its effect on microorganisms in high-moisture foods; can be applied to in-package, solid, or liquid products; retains taste and texture; extends shelf life.	Use of very high pressures and costly equipment; affects the texture and appearance of certain foods; bacterial spores are resistant.
Nonthermal Plasma	Mechanism not well understood; could target the cell membrane through lipid oxidation; formation of antimicrobial products, e.g., reactive oxygen species.	Can be adapted for continuous process; chemical- and water-free processing.	Requires a carrier gas; types of foods treated may result in shadowing.
UV Light and Pulse Light	Disruption of genomic material and possible protein destabilization.	No use of heat during treatment; little change to food product quality and characteristics; continuous process. Can yield 4–6 times better inactivation than traditional UV-C.	Prolonged exposure can lead to surface heating; equipment operators may require exposure monitoring.
Irradiation	Disruption of linkages in DNA or RNA; may disrupt other structures of bacteria.	No heat used and a precise and controllable process; effective on various foods with various moisture levels; few changes to food texture, taste, and nutrition; no radioactive waste (electron beam)	Public acceptance of processes; oxidation of fats in products; high disposal costs for irradiation source; electron beam irradiation mayhave limited penetration depth; equipment operators need to be trained and their exposure monitored.
Radiofrequency and Microwave Heating	Thermal/heat inactivation.	Rapid heating with various degrees of penetration; retention of food qualities and characteristics; can be applied to various foods to achieve either extended shelf life or shelf stability.	Relatively new process; food composition can affect efficacy; aw can affect microbial inactivation.

Adapted from *Ann Rev Food Sci Technol.* 2018;9:105–127.

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Figure 1. Pathogen Control Equation.

$scCO_2$. The emerging drying technologies have been shown to reduce microbial populations; however, the number of studies is still low.

The application of oxidizers in gaseous form could be another non-thermal inactivation method, using oxidizing agents including ozone and hydrogen peroxide in a gaseous state within a treatment chamber, while others such as peroxyacetic acid and chlorine-base disinfectants may be sprayed onto food products. The emerging drying technologies have been reviewed elsewhere.

It should be noted that the efficacy, food matrix characteristics, and suitability of use need to be appropriately assessed and validated for any new technologies before they are used for the preservation of food. Therefore, risk assessments conducted for the product may provide information on whether a selected technology will adequately inactivate the pertinent microorganism of concern in a particular food matrix. It is also important to know that the data for thermal susceptibility of microorganisms may not necessarily transfer to a new technology that uses a different inactivation strategy, e.g., HPP of spore formers. Similarly, understanding the limitations of novel technologies is important. The emerging drying technologies have been reviewed elsewhere.

Controlling Emerging Pathogens

The control of emerging pathogens in dried foods, LMFs, and La_wF presents an important and significant challenge. The pathogens are widely distributed in nature and could contaminate raw materials during harvest and storage at farms and production facilities, as well as in processing environments. Controlling pathogens requires control of pests and dust, stringent compliance with GAP and GMPs, and high standards of hygiene. Additionally, pathogens may be present in processing plant environments, and the post-processing contamination of ingredients and products may occur through cross contamination.

Earlier, a food industry task force convened by the Grocery Manufacturers Association reviewed industry programs and practices and published information on controlling *Salmonella* and developed industry-wide guidance on controlling this pathogen in dried and LMFs.

The general strategy for controlling pathogens in foods and ingredients includes:

- Preventing entry or contamination;
- Inactivating them using a kill step in the manufacturing process;
- Preventing post-processing contamination and cross-contamination; and
- Controlling growth of surviving microorganisms.

Because the presence of pathogens is often linked to poor sanitation practices, facility and equipment design, and poor operational and manufacturing practices, the proper process control and control of cross-contamination to minimize the potential for post-process contamination are important. Potential sources of pathogen contamination include incoming raw materials, the external environment (e.g., pests, water, and air), inadequate hygienic facility and equipment design, inadequate sanitation practices, and lack of process control. Thus, strategies for controlling pathogenic contamination include sourcing raw material and ingredients, controlling cross-contamination from harvest through post-process, controlling the entry of water into dry processing areas, and employing effective dry cleaning and sanitation processes.

The food industry has implemented the GMPs and the Hazard Analysis Critical Control Point (HACCP) system to ensure the safety of processed foods since the 1960s. The system deals with identifying hazards (biological, chemical, and physical) and identifying points during the production process at which a product may be subject to pathogenic contamination and where identified hazards can be controlled or eliminated. While implementation of GMPs and HACCP has reduced the likelihood of pathogenic contamination and improved food safety, post-processing contamination or cross-contamination from the processing plant environment can still occur. In the wake of *Salmonella* contamination in dried foods and almonds, the industry has developed guidance to control Salmonella in processing facilities and enhance the microbial safety of dried and La_wF. These guidance documents emphasize monitoring the process plant environment as a key element in controlling pathogens.

Additionally, the Food Safety Modernization Act (FSMA) Preventive Controls for Human Food was signed into law in January 2011. This law places the responsibility of producing safe food squarely on the industry and requires "all food facilities to have a written food safety plan in place that includes an analysis of hazards and risk-based preventive controls to minimize or prevent the identified hazards." FSMA stresses that good agricultural, manufacturing, and hygienic practices should be employed at every step in the processing/manufacturing chain. Controlling pathogens in dry product plants includes establishing segregated hygiene areas in the processing facility based on the need for moisture control and exposure of the product to the environment, hygienic principles of equipment design and installation to address the need for water control, dry and wet cleaning, and an environmental monitoring program.

Key approaches for controlling pathogens in dried, LMFs, and La_wF include:

- Moisture control;
- GMPs and plant traffic patterns;
- Proper sanitary design of facilities and equipment;
- Cleaning, sanitation, and hygienic zoning; and
- Environmental pathogen monitoring.

The main approaches for controlling pathogens in dried foods, LMFs, and La_wF can be summarized in the so-called Pathogen Control Equation (see Figure 1, above).

Deficiencies in any of the elements of the equation may lead to growth niches and harborage sites for pathogens and increase the chances for the cross-contamination

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Understanding ISO 22000

A U.S. perspective on certification requirements

BY **RICHARD F. STIER** AND **JAMES S. DICKSON, PHD**

The ISO 22000:2018 food safety management system is a set of requirements for any organization in the food chain that describes what a processor must do to show that it can control food safety issues and assure that the food produced is safe. It can be applied to organizations of any size and at any place in the food production or processing chain. The basic approach contained in this document to developing and implementing a food safety management system is based on risk analysis, which includes the probability of the occurrence of a hazard and the severity of the outcome of the hazard if it occurs. The ISO document includes a cross reference section to the Codex Alimentarius Hazard Analysis and Critical Control Points (HACCP) document, which further emphasizes the need for hazard (risk) analysis.

To understand ISO 22000, it is helpful to recognize how the International Organization for Standardization (ISO) is structured and how the United States interacts with it. ISO is a global organization established in 1947 that provides standards for many different operations and manufacturing processes. It is a non-governmental organization that is linked to national standards institutes of member countries. There are approximately 165 member countries, and the U.S. representative is the American National Standards Institute (ANSI).

ISO is managed by a central secretariat, located in Geneva, Switzerland. The secretariat handles the operations and management of the organization. The general assembly is the final authority of the organization for statutory decisions, and all member nations and ISO officers participate in it. ISO is governed by a council that consists of six permanent members and 14 rotating members who address strategic, financial, commercial, and external relations issues. ANSI is one of the six permanent members, and the council reports directly to the general assembly. As the U.S. representative, ANSI also has a vote in the general assembly. The management of the preparation and revision of standards is addressed by the technical management board, which reports to the governing council. This board oversees the technical committees that develop and revise the standards.

ISO has a standardized procedure for the development of a new standard. To initiate a new standard, a preliminary work item may be developed for the initial study of a subject before starting actual standards development, but this is not required. A formal proposal (a new work item) is developed for ISO members to vote on, and, if approved, actual standards development begins on a working draft. If the proposed project does not appear to relate to an existing committee, the technical management board will assign the project to an existing committee, or a new committee will be created. The committee will then develop a working draft to be issued eventually as a draft international standard for formal voting, after which it may be issued as a final draft international standard. The final draft will undergo further review and approval by ISO members. Once approved, the new or revised international standard is published.

The United States has many technical advisory groups (TAGs) to represent the U.S. position on various ISO standards. These TAGs address all aspects of the ISO process, from the development of new work to determining the U.S. position on draft international standards. The TAGs are managed by a U.S. administrator who

Table 1. Organizational Structure of ISO 22000:2018

Element	Components
Organization	Needs and expectations, scope
Leadership	Leadership commitment, establishing and communicating the policy; roles and responsibilities
Planning	Risks, opportunities, objectives; plans
Support	Resources, competence, awareness, communication, documentation
Operation	Prerequisite programs, traceability, hazard analysis, monitoring, verification, corrective actions, validation
Evaluation	Internal audits
Improvement	Continuous improvement

serves a similar function to a standards development committee secretary by managing the day-to-day administrative activities of the groups.

The management of the food safety activities of ISO is addressed by the ISO Technical Committee 34, Sub-committee 17. The scope of this committee is defined as "standardization in the field of food safety management systems, covering the food supply chain from primary production to consumption, human and animal foodstuffs, as well as animal and vegetable propagation materials."

This subcommittee, coordinated by the American Society of Agricultural and Biological Engineers, consists of approximately 30 members from the food industry, government agencies, and academia. It provides a U.S. perspective on matters related to food safety, primarily ISO 22000.

The ISO 22000 standard was finalized in 2005, hence the original designation ISO 22000:2005. The standard was the result of the labors of Technical Committee 34. The first meetings of the committee were hosted by the Danish Standards Association in Charlottenlund, Denmark. Among the driving forces behind the establishment of the group that was convened for the development of this standard was the desire for certification of HACCP programs, which required the establishment of an auditable international standard for food safety management systems. Another element was a desire to harmonize the current national food safety management standards. For example, there were and are currently many private food safety standards that have been established globally. ISO 22000 became a global standard. Now, there is the Codex Committee on Food Hygiene document that defines the basic HACCP principles and prerequisite programs. Although this document, along with ISO 9000, served as a reference in developing the ISO 22000 standard, it's not an auditable standard by itself.

ISO 22000:2018

The latest version of ISO 22000 was published in 2018. ISO 22000:2018 is organized by sections, with the first being the "context" of a food processing organization. This means that the organization should consider all of the potential areas that could affect food safety, both within the company and outside of it. These could include the role of raw material suppliers in the manufacturing process and process variation within the operations, as well as the end use of the product by the consumer—whether the consumer is another business or an individual.

The next sections focus on leadership, planning, and support within the company, followed by operations, performance, and improvement. One of the strengths of the ISO 22000 standard is its focus on leadership. The plant manager, CEO, or whoever is ultimately responsible for managing the processor is also ultimately responsible for the food safety management system. This includes setting policies, assigning responsibilities, managing continual improvement through management review meetings, and handling internal and external communication. The standard presents a logical approach to developing and implementing a food safety plan, and the concepts are fully compatible with both HACCP and the preventive controls described within the Food Safety Modernization Act. All of these programs focus on risk management by mitigation at appropriate steps in the process.

As with all ISO standards, ISO 22000 is periodically reviewed to assure that it represents the current thought processes for food safety. One of the reasons behind the revision of the standard was to bring the standard into line with other ISO standards by incorporating elements of the high-level structure (HLS). This ensured that language and standard format were uniform. Among the changes incorporated into ISO 22000:2018 is wording that more closely conforms to the Codex HACCP document and also emphasizes the difference between operational risk (i.e., traditional HACCP) and overall organizational risk (i.e., management decisions to avoid risk). In addition, the 2018 version introduces the concept of operational prerequisite programs and requires that a company demonstrate that it is effectively using the results from monitoring and verification activities. A summary of the organizational structure of ISO 22000:2018 is given in Table 1.

The most recent development for ISO 22000 was the publication of a document entitled "ISO 22000:2018–Food Safety Management Systems–A Practical Guide," which was published jointly by ISO and the United Nations Industrial Development Organization. As the name implies, this publication provides practical information about and examples of how to implement ISO 22000:2018 and is a valuable addition not only for those who are interested in implementing 22000, but also for those who are currently certified. Other recent developments include the establishment of a committee draft on the requirements for bodies providing audits of food safety management system elements, ISO/CD 22003, parts 1 and 2. These will be an update of the existing ISO/TS 22003:2013 Food Safety Management Systems–Requirements for bodies providing audit and certification of food safety management systems.

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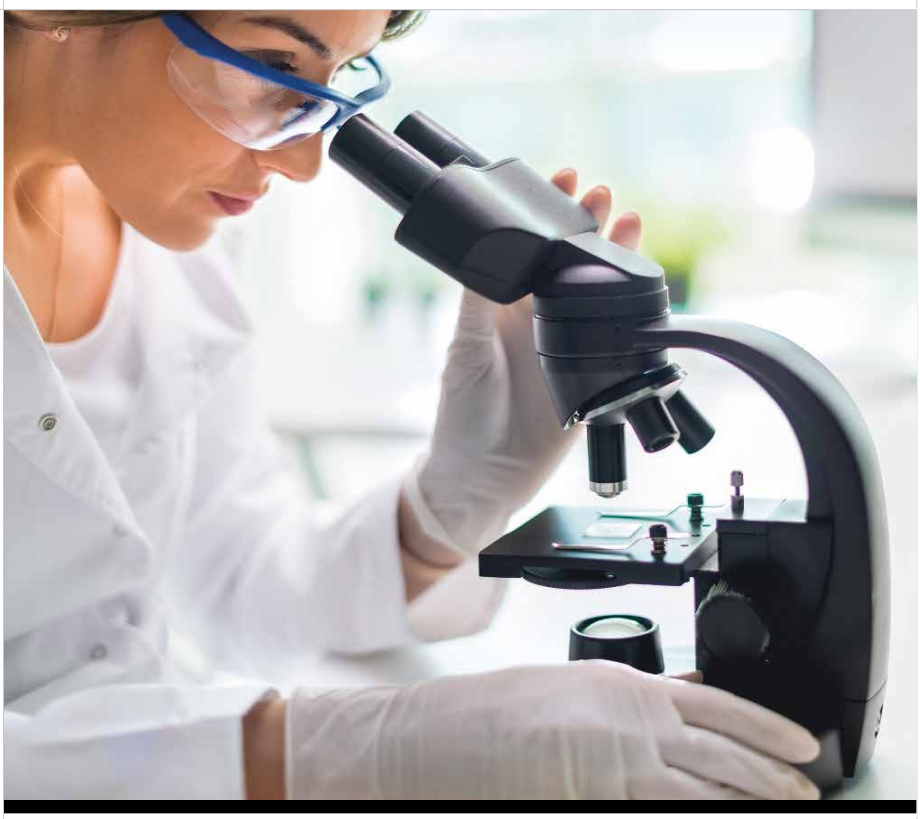
Testing



Gluten Detection Methods

Current testing methods—and their limits

BY **MARY BETH NIERENGARTEN**

An estimated 5% of the world's population is currently affected by gluten-related disorders, and the prevalence of these conditions continues to grow. Along with celiac disease (CD), other gluten-related disorders that make gluten-free products attractive and necessary for many consumers include dermatitis herpetiformis, gluten ataxia, wheat allergy, and non-celiac gluten sensitivity. When looking at CD alone, evidence shows a significantly increased incidence over the past few decades in industrialized counties, particularly in females and children.

Specifically for people with CD, ensuring a gluten-free diet is the only safeguard to ward off disease progression. As such, food processors and manufacturers are under strict regulations regarding which products can be labeled gluten free to ensure their safety for consumers.

One challenge for food manufacturers is how labeling requirements vary globally. Food producers in the U.S. must comply with FDA regulations that, following an international regulation set by the Codex Alimentarius Commission, set a limit of 20 mg/kg gluten as the amount a product can contain and still be labeled "gluten free." The Codex Alimentarius Commission also allows food products to be labeled "very low gluten" if they contain 20 mg/kg to100 mg/kg of gluten. Ensuring products meet this standard for appropriate labeling is critical and is accomplished by rigorous adherence to and understanding of current testing methods.

This is not a new issue for food producers, but it's one that will continue to drive the need for improved methods of detection given the high stakes for a growing consumer population.

Current Testing Methods

Current testing methods loosely fall into three categories, all of which have advantages and disadvantages (see "Table 1," p. 33), according to Sachin Rustgi, PhD, assistant professor of molecular breeding in the department of plant and environmental sciences at the College of Agriculture, Forestry and Life Sciences at Clemson University Pee Dee Research and Education Center in Florence, S.C.

Two of these methods, both immunological, are currently approved by the Prolamin Working Group of the Codex Alimentarius Commission and supported by the FDA: the R5 antibody raised against omega-secalin from rye (rye gluten compliment) and the G12 antibody developed against the wheat alpha 2-gliadin 33 amino acid peptide (highly immunogenic peptide). Dr. Rustgi described these methods along with the others listed above in a 2019 review article of gluten detection methods published in *Nutrients*.

"Immunoassays are currently the primary methods used by the food industry," says Steve Taylor, PhD, professor emeritus in the department of food science and technology, and retired founding director of the Food Allergy Research and Resource Program at the University of Nebraska in Lincoln. Available in both quantitative and qualitative (lateral flow devices) formats, the most popular quantitative gluten methods are excellent, according to Dr. Taylor. "Based on either R5 or G12 monoclonal antibodies, [these tests] are so very specific, and [there's] not much of a chance of a false positive," he says, adding that qualitative methods based on the same antibodies are quite good.

He cautions that methods based on older Skerritt antibodies are not as highly recommended because they can miss barley. Along with R5 and G12, Skerritt is a monoclonal antibody used for gluten

Table 1. Current Gluten Testing Methods

	Description	Advantages	Disadvantages
Genomic	PCR-based methods that can detect trace quantities of wheat contamination in a sample below the allowed limit of 20 mg gluten per kg of food.	Excellent sensitivity as demonstrated by qPCR-based tests for SARS-CoV-2 detection.	Need optimization of DNA/RNA extractions and PCR conditions, and need precise standards for relative quantification. Difficult to adopt widely given the need for special equipment.
Proteomic	Uses molecular mass and ionization patterns of molecules to directly identify contaminants.	Most precise method.	Relies on the establishment of standards and expensive specialized equipment, so not feasible for use in low/medium income countries.
Immunologic	Target specific antibodies (proteins) or aptamers (nucleic acid).	Once developed, can be converted into relatively cheap portable assays and do not require specific conditions for storage and use. Reasonably sensitive and could be widely adopted.	Processing conditions affect the detection efficiency of these antibodies. Do not act well on hydrolyzed samples as partially hydrolyzed proteins can escape detection. Certain processing conditions might expose antibody binding sites buried in the protein structure, bringing them to its surface and leading to over-quantification or a false positive. Using several antibodies/aptamers targeting different areas on one or several of the various gluten proteins might avoid escape, and using a combination of methods may reduce the over-prediction problem.

testing. He also says that issues sometimes found with the food matrix are less problematic with gluten methods, especially when Mendez cocktail is used.

Dr. Taylor doesn't see many gaps in these immunoassay methods but cites three large issues that remain important in improving detection: how to manage particulate contamination in a product, questions around testing used frying oil, and detection of gluten residues in fermented and hydrolyzed foods.

Calling it the proverbial needle in the haystack problem, Dr. Taylor says that the problem with particulate contaminant is that if a particle containing gluten is found in a food sample, the test will be positive, but if you miss the particle, then the test may not be positive. "This issue is magnified with gluten testing because the sample size for the immunoassay is 0.25 mg, which is rather small [and, by contrast] most allergen immunoassays have a sample size of 5 g, or 20 times larger," he says. "With the small sample size, you could easily miss the presence of particles, and much depends on the homogeneity of distribution of gluten particles in the overall sample." For powders, the particulate issue is not as serious as it could be with larger particles such as crumbs, he adds.

Like all sampling issues, you can mitigate the problem by taking multiple samples or, sometimes, by the effective use of composite samples.

Detecting gluten in used frying oil is more challenging. "To do gluten analysis on used frying oil, you must first try to extract the gluten with ethanol/water solvent, but you probably won't get all of the gluten into the extract so you will underestimate the gluten level in oil," says Dr. Taylor. Since consumers never eat oil except for the amount absorbed in the food product, such as fries, he doesn't recommend trying to test used frying oil. "I recommend testing the product that is fried in the used oil, which is a more relevant sample in any case and probably more amenable to analysis," he adds.

Detecting gluten in hydrolyzed or fermented foods also remains a problem, he adds, referring to the recent FDA 2020 final rule on the recommended approach to mitigating this problem by testing the food matrix before fermentation or hydrolysis.

Effective as of October 13, 2020, the FDA final rule establishes compliance requirements for labeling "gluten-free" fermented and hydrolyzed foods or foods containing fermented or hydrolyzed ingredients. "Because gluten proteins in hydrolyzed and fermented foods are no longer intact and, currently, cannot be adequately detected and quantified through testing, the FDA will determine compliance based on records kept by the manufacturer to

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show that their foods are gluten free before fermentation or hydrolysis," says an FDA spokesperson, who underscores that the ruling doesn't change FDA's definition of "gluten free," established in 2013. "[This] means that hydrolyzed and fermented foods bearing the gluten-free claim would still need to meet the requirements of the gluten-free final rule," the spokesperson adds.

Manufacturers are required to comply with the rule by August 13, 2021.

In-House versus Third-Party Testing?

One decision that manufacturers will have to make is whether to conduct gluten testing in house or employ a third-party lab. Charles McGuill, product manager for allergens at Hygiena in New Braunfels, Texas, says that food companies normally don't conduct just one type of testing, but will perform multiple tests. "They may use rapid technology where they can get a pass or fail test that gives them an idea if they have an allergen in their product, in their environment, or in the incoming raw ingredients they are using in their production facility, and then may use a third-party laboratory to send the finished product to make sure it is truly free of allergens," he says, adding that some customers will require a certification of analysis from a third-party lab.

Most food production companies that want to test in house will use the lateral flow technology (pass/fail) test, he says, given how easy it is to use. Tests provided to food companies are calibrated to detect gluten at the restricted level of 20 mg/kg to 100 mg/kg. Hygiena also offers a lateral flow test that can be adjusted to detect levels above or below this, which, says McGuill, offers customers the flexibility of testing a finished product or ingredient that, for example, might be a microingredient used in the product.

McGuill also underscored the usefulness of current testing with the antibody assays as a screening tool but noted that they are limited when it comes to products that are highly processed, such as fermented or hydrolyzed products. "Customers should be aware that when they are testing complicated products, they should make sure to do their proper research and make sure the method they are using can properly identify the target," he adds. "Do your homework."

Dr. Rustgi underscored the need for food production companies to ensure their products are gluten-free; he would like to see a more concerted international effort among countries to comply with a single standard or set of regulations given free trade and tourism. "Similar standards and detection methods need to be adopted across industry and throughout the globe," he says. ■

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Food Safety in Dry, Low-Moisture ...

(Continued from p. 29)

and/or survival of environmental pathogens. The equation and an environmental pathogen monitoring program can help provide effective pathogen control.

Dried foods and ingredients are increasingly used in both product development and processing of a wide variety of foods, including frozen desserts, processed meat, cereal products, snack foods, and beverages. Dried foods and ingredients are LM, low a_w ($a_w < 0.7$), and shelf stable; however, they are not sterile and are not necessarily inherently safe from pathogenic bacteria, as evidenced by numerous dried and La_wF implicated in outbreaks of foodborne illnesses and recalls.

Food dehydration is one of the oldest methods of food preservation, involving simultaneous heat and mass transfer to remove moisture for the reduction of water content and water activity to increase the shelf life of a food. Over the years, many drying technologies have been developed to improve the efficiency of drying without damaging the quality of the products and/or to improve the energy efficiency of the drying process. Thus, research and development into drying technologies have focused on improving the efficiency of the drying process, improving energy efficiency, and improving product quality and functionality. Research on the effects of drying and the survivability of microorganisms during drying has been rare and primarily deals with the preservation of microbial starter cultures used in fermentation processes.

In recent years, outbreaks linked to dried and LM/La_wF contaminated with *Salmonella* spp., *B. cereus*, *C. sakazakii*, *Clostridium* spp., and other microorganisms, have raised new concerns about controlling foodborne pathogens in these foods and in the food plant environment. Recently, research has focused on the development of novel inactivation methods, including nonthermal inactivation, as alternatives to mitigate the risks associated with the survival of bacterial pathogens in these foods.

Controlling pathogenic contamination requires an understanding of the microbial load of raw material and ingredients, along with stringent compliance with GMPs and hygiene, including cleaning, sanitation, hygienic zoning, and environmental pathogen monitoring, preventing post-processing contamination during packaging, and handling, storage, and transportation contamination. Additionally, consumers can use dried, LM, and La_wF and ingredients without cooking or store them at ambient temperature after rehydration. So, cooking instructions and other pertinent information must be included on the label, and any foreseeable consumer use as well as abuse should be considered by those designing a food safety plan for these foods.

References are included in the online version of this story, which is available at foodqualityandsafety.com. ■

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In The Lab

Mycotoxin Testing

When high-throughput screening makes a difference

BY **WES SHADOW**

Mycotoxin testing is one of the most prevalent necessities for stakeholders in the grain, grain processing, and grain-based food and feed industry. Because these toxic compounds can grow on numerous food ingredients, either before or after harvest and during storage, there are countless opportunities for mycotoxin contamination throughout the food growing and production stages. In fact, studies show that more than 68% of grains test positive for molds, which can create serious health issues for both humans and animals. Because of the dangers of mycotoxin contamination, it is imperative that stakeholders have highly sensitive testing systems for accurate analysis of mycotoxins at all phases.

When stakeholders are testing a small number of commodities for only a few mycotoxins and contamination incidence is low, they can easily turn to lateral flow test strips for testing needs. Lateral flow test strips are relatively inexpensive, simple to use, and accurate for testing at required levels. However, when mycotoxin incidence is high or when a user needs to test multiple types of commodities for many different mycotoxins—perhaps even in complex matrices such as finished feeds or pet foods—scaling up lateral flow testing may not be the best option. Instead, stakeholders should consider automated, high-throughput ELISA testing for fast, accurate, and cost-effective results.

So, how do you know when to make the move to ELISA testing?

> Because requests may change in an instant, contract labs need versatile testing options that can handle a variety of needs.

When You're a Large Grain Processing Plant with Years of Outbreaks

Large grain processing plants may be more likely to come across mycotoxin outbreaks due to the sheer amount of grain they're testing on a daily basis. When you're dealing with large volumes of contamination, speed and accuracy are an absolute necessity. Finding testing solutions that enable you to automate as many steps as possible can cut down on human error and free up time for testing professionals to work on additional tasks.

During years of high mycotoxin levels, testing requirements ramp up quickly and dramatically. These automated and simplified solutions help large processors meet their increasing needs while providing the flexibility to scale up or down as the demand fluctuates.

When You're a Corporate Lab That Serves as a Hub for Testing

Corporate or regional labs that support mycotoxin testing for multiple plants face specific challenges. If the plants are in different regions, even the same commodity may require testing for different mycotoxins. The lab may support different types of traders or processors as well, so the base-matrix may vary. The new automated

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ELISA solutions provide the flexibility to address each incoming sample separately and distinctly, be it corn for aflatoxin or wheat for deoxynivalenol.

When You're a Corporate Lab That Tests Complex Matrices

Testing complex matrices, such as pet foods, compound feeds, or other finished products, comes with its own set of challenges. Mycotoxins can be found in items such as cereals, animal feed, or pet food, but the addition of spices or an unknown composition (as in the case of animal feed) can make analysis extremely challenging. Previously, testing options for complex matrices were extremely limited or required certain sacrifices around convenience or speed, but technology is ever changing, and testing technology developers are continuing to develop new, automated options for these types of challenges.

Some new testing options on the market enable labs to test for specific mycotoxins within these complex matrices—some by using just a single sample, which can greatly increase testing throughput and save time. Hands-free sample dilution and distribution can help corporate labs reduce cross-contamination, and valuable integrations with software solutions can optimize result recording and analysis.

When You're a Contract Lab with Samples That Change Day to Day

As a contract lab, the samples you're testing can change daily. You may be asked to test grains or grain-based ingredients for a single mycotoxin or multiple mycotoxins, you may need to run tests on complex matrices, or you may deal with large disparities in testing volume. Because requests may change in an instant, contract labs need versatile testing options that can handle a variety of needs.

ELISA testing is comparable to other testing methods, but it comes with a few key advantages. It's high precision, and handling the tests is simple and requires less training than other options. ELISA testing also has strong standardization potential, meaning that testers can cut down on the number of steps to get to results. One of the most important advantages of ELISA testing is the ability to obtain quick and accurate results, which are amplified when using high throughput options for large quantities of samples.

The Bottom Line

Technology around mycotoxin testing is always evolving, so it's imperative to stay up to date on the latest options that best suit your needs. For those with special use circumstances or specific needs, finding a service provider that can explain all the best options can make a world of difference. Make sure you're considering all possible options, and look for solutions that can make your testing processes even easier. Making the leap to a new system may not only save you time and money, but may also improve the health and well-being of consumers and livestock around the world. ■

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Detecting Phthalates in Food Contact Materials

Using gas chromatography–mass spectrometry to conduct contamination analysis

BY **EBERHARDT KUHN, PHD**

Commercially available foods and beverages are exposed to a variety of substances during production and storage processes. The materials in contact with foods leach into the products and could have an impact on consumer health. Leaching is exacerbated when the plastic is exposed to heat. Increasing concern about food contact materials has led to a heightened need for manufacturers and processors to conduct contamination analysis.

This article first presents a method to detect polyethylene terephthalate (PET) and, next, a technique to identify phthalate esters. Each is a chemical used to manufacture plastics commonly found in food and beverage packaging materials. By using these analytical procedures, it is possible to identify the source of contamination and take appropriate countermeasures.

To identify PET, we demonstrate qualitative analysis of assumed resins in a food packaging material by using a pyrolysis-GC/MS method, including analysis of trace contaminants and contaminants in multilayer films, which are difficult to analyze using a Fourier transform infrared (FTIR) spectrometer.

Then, we demonstrate how to identify specific phthalate esters by confirming their molecular weight using the solvent mediated chemical ionization (SMCI) method. This technique is an effective alternative to using electron ionization, in which mass spectra are similar, which makes identification difficult.

Analyzing Resins in Food Packaging Material Using Pyrolysis-GC/MS

The FTIR and energy dispersive X-ray fluorescence (EDXRF) spectrometers are commonly used in identifying contaminants by instrumental analysis. However, these methods have limitations when analyzing trace impurities and contaminants in multilayer films. A different approach that enables the qualitative analysis of resin materials and additives contained in trace organic contaminants involves thermal methods: pyrolysis-GC/MS and thermal extraction-GC/MS.

Here we present an analysis of the resins in a food packaging material using the pyrolysis-GC/MS method, assuming food contamination. A Shimadzu OPTIC-4 multimode inlet for GC/MS was used in the analysis by pyrolysis-GC/MS. Because the OPTIC-4 enables high-speed heating (60°C/s) to a maximum temperature of 600°C, diverse sample injection modes are available and simple pyrolysis was possible.

Sample and analysis conditions. A commercially available food packaging material was used as the real sample material. The sample material was cut with a knife to obtain a sample weighing approximately 0.2 mg, which was inserted into the difficult matrix introduction (DMI) microvial of the OPTIC-4 and then set in the DMI insert liner.

Qualitative analysis of resin material. Figure 1 shows the obtained pyrogram (total ion chromatogram obtained by pyrolysis-GC/MS). According to a reference containing pyrolysis data on resins, this is a

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Table 1. Capability of Confirmation of Molecular Derived Ions by the EI Method and SMCI Method

Compound Name	MW	SMCI	EI
Dimethyl phthalate	194	Yes	Yes
Diethyl Phthalate	222	Yes	Yes
Diisobutyl phthalate	278	Yes	No
Di-n-butyl phthalate	278	Yes	Yes
Bis(2-methoxyethyl) phthalate	282	Yes	No
Bis(4-methyl-2-pentyl) phthalate	334	Yes	No
Bis(2-ethoxyethyl) phthalate	310	Yes	No
Dipentyl phthalate	306	Yes	Yes
Di-n-hexyl phthalate	334	Yes	Yes
Benzyl butyl phthalate	312	Yes	Yes
Bis(2-n-butoxyethyl) phthalate	366	Yes	No
Dicyclohexyl phthalate	330	Yes	No
Bis(2-ethylhexyl) phthalate	390	Yes	No
Di-n-octyl phthalate	390	Yes	No
Di-nonyl phthalate	418	Yes	No

(Continued from p. 37)

distinctive pyrogram of polyethylene (PE), in which hydrocarbon species are arranged at equal intervals. Therefore, it could be inferred that the foreign matter in this experiment contains PE as the base material.

In addition to the peaks seen in the pyrogram of PE, three distinctive peaks—(a) to (c) —are also detected in the pyrogram of the real sample. Compound identification of these peaks was carried out using the NIST Research Library and the above-mentioned reference. As a result, it was found that (b) is caprolactam, a compound characteristically seen as a pyrolysis product of polyamide (PA), and (a) and (c) were identified respectively as 4-(vinyloxycarbonyl) benzoic acid and benzoic acid, which are compounds characteristically seen as pyrolysis products of PET.

Based on these results, the foreign matter measured in this experiment was estimated to be a composite resin containing polyamide (PA) and PET in addition to PE.

To identify contaminants in food products, the resins contained in an assumed foreign matter sample were analyzed by the pyrolysis-GC/MS method in an OPTIC-4 multimode inlet. As a result, qualitative analysis of the composite resin was possible from the pyrogram and pyrolysis products. Thus, this experiment demonstrates the possibility of qualitative analysis of resin materials using the pyrolysis-GC/MS method, including analysis of trace contaminants and contaminants in multilayer films, which are difficult to analyze using FTIR. This analysis technique makes it possible to identify the source of contamination and take appropriate countermeasures.

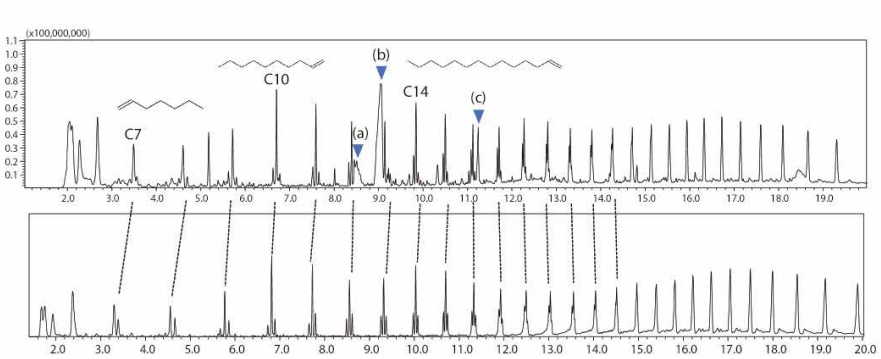


Figure 1. Top: Pyrogram of Analyzed Foreign Matter; Bottom: Pyrogram of PE

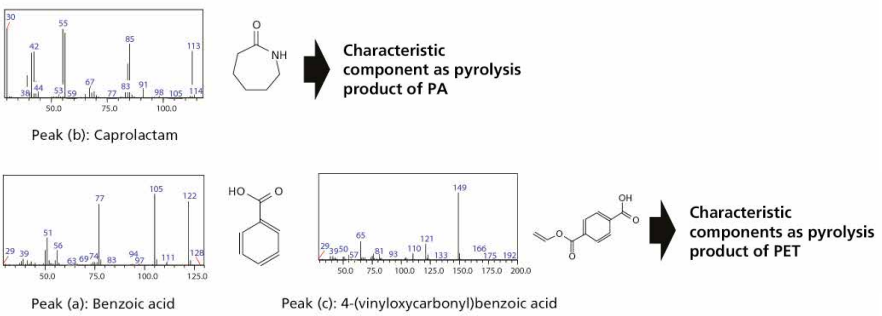


Figure 2: Mass Spectra of Peaks (a) to (c) and Identified Compounds

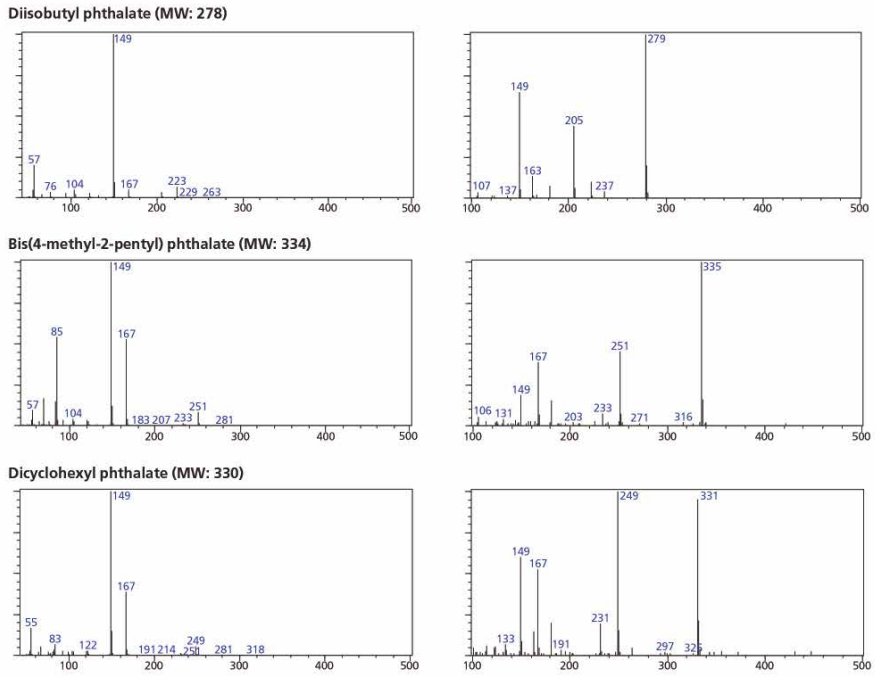


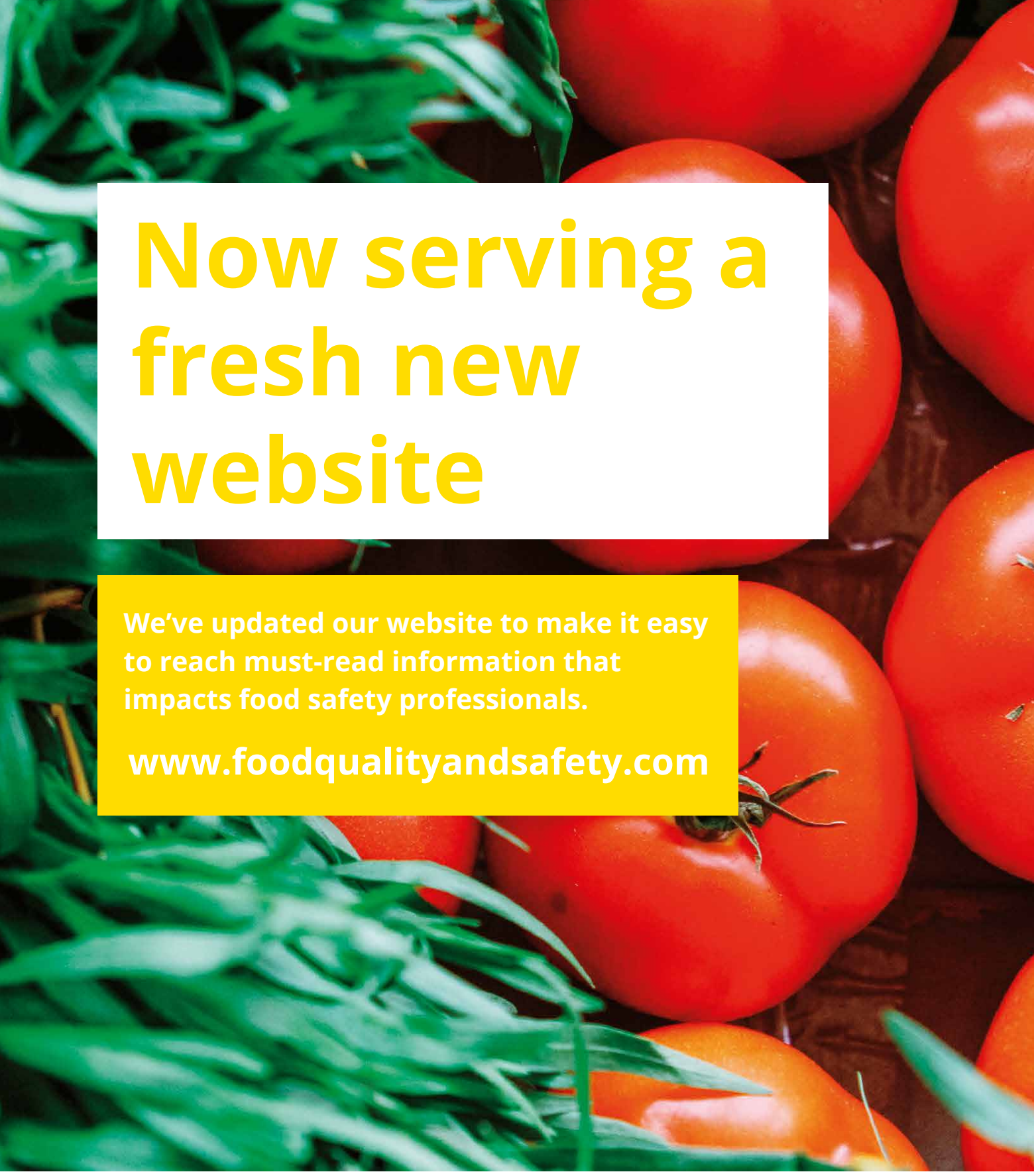
Figure 3: Mass Spectra for Phthalate Esters (Left: EI, Right: SMCI)

Identification of Phthalate Esters Using the SMCI Method

During production and storage processes, commercially available foods and beverages come into contact with a variety of substances, such as phthalate esters, which are used as plasticizers for polyvinyl chloride. Phthalate esters present a health concern because of their connection with endocrine disruption effects, developmental toxicity, reproductive toxicity, and tissue damage.

Phthalate esters share the same basic structure, and their mass spectra are similar when the electron ionization (EI) method is used, which can make the identification of target phthalate esters difficult. Conventionally, in such cases, the molecular weight is confirmed via the positive chemical ionization (PCI) method, using methane, isobutane, and other flammable, high pressure gases. In contrast, if the use

(Continued on p. 43)



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Ammonia Refrigeration System Testing in the Food Industry

Where to test, how often, and what to look for | BY JIM KOVARIK

Rooftop ammonia refrigeration system at a food manufacturer.

Compliance for industrial refrigeration system owners is generally defined for all industries that process highly hazardous chemicals by the Occupational Safety and Health Administration (OSHA) Process Safety Management (PSM) standard and the Environmental Protection Agency (EPA) Risk Management Plan (RMP) Rule.

The majority of food and beverage manufacturing plants, and the distribution centers in their supply chain, use the highly hazardous chemical anhydrous ammonia in their industrial refrigeration systems. The system owner is responsible for complying with all governing regulations and ensuring all measures are taken to mitigate the risk of release to its employees and the general public.

The International Institute of Ammonia Refrigeration (IIAR) develops standards to advise the food and beverage and cold storage industries on the management of these systems to support safety and compliance with OSHA and EPA. On April 16, 2019, the American National Standards Institute (ANSI) approved ANSI/IIAR 6-2019, Standard for Inspection, Testing, and Maintenance of Closed-Circuit Ammonia Refrigeration Systems (IIAR 6). The publication of this standard further defines compliance qualifications for the use of anhydrous ammonia as an industrial refrigerant.

The standard captures previously employed IIAR Bulletins, normative and informative information, timetables, and guidelines for recordkeeping. Tony Lundell, senior director of standards and safety at IIAR, clarifies, saying, "IIAR 6 is intended to be part of a mechanical integrity program, as the minimum requirements for inspection, testing, and maintenance, or ITM."

A significant development in IIAR6 is the need to regularly test piping, vessels, and system components in addition to the traditional practice of visual inspection. For decades, many companies have relied solely on an annual visual inspection of their refrigeration system. While generally effective, this visual inspection is not reliable in all scenarios; 46% of ammonia releases in food and beverage and cold storage facilities occur as a result of equipment failure. Testing, an effective early detection practice that will reveal system degradation and defects that visual inspection cannot detect, helps mitigate this problem.

The Burden on the System Owner

OSHA's Standard 1910.119, Process safety management of highly hazardous chemicals, section (j)(4) states:

1. Inspections and tests shall be performed on process equipment.
2. Inspection and testing procedures shall follow recognized and generally accepted good engineering practices.
3. The frequency of inspections and tests of process equipment shall be consistent with applicable manufacturers' recommendations and good engineering practices, and more frequently if determined to be necessary by prior operating experience.

ANSI/IIAR Standard 6-2019 states testing should be performed:

1. When the state of a component cannot be determined by visual inspection.
2. At minimal timeframe intervals independent of visual inspection.

These documents serve as a foundation, as both define only the mimimum requirements for refrigeration system owners and reasonably don't accept responsibility for system failure if only the minimum requirements are met. The system owner bears the burden of:

1. The responsibility for preventing or minimizing the consequences of catastrophic release.
2. Establishing, documenting, and executing processes and procedures related to testing, frequency, acceptable operating threshholds, further action, and more.

Knowing where to test, how often, and what to look for are common challenges system owners must address. Practice,

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education, peer best practices, and years of analysis help provide some answers.

Testing

Testing should be performed on all components and equipment in the refrigeration system. Instructions and frequency for testing are straightforward for equipment such as compressors, condensers, evaporators, and alarms. This is, in part, due to the manufacturer manuals that accompany these parts. However, components such as piping, vessels, and valves are mercurial and must be evaluated with non-destructive testing (NDT) to determine their operable state.

NDT involves the use of technology to examine an object or material's structure, imperfections, composition, or properties without destroying or compromising the object or material's future use. NDT provides information about the state of material that one cannot capture visually or that would otherwise require a great deal of manual effort.

All piping in an ammonia refrigeration system—including long and short runs, vertical, nested, and suspended piping—is subject to degradation and should be tested at the following areas:

- Periodically along long runs of pipe;
- The intersection of the pipe segment and major pieces of equipment;
- Before and after direction changes (e.g., elbows, tees, reducers);
- Wall and roof penetrations;
- Insulation terminations (e.g., valve groups, end caps);
- Low or "sagging" areas of a line segment; and
- Areas of concern or those identified as suspect during a visual inspection.

For all pressure vessels that are at least 10 years old and/or show external evidence of corrosion or degradation, testing should be performed on areas where water is most likely to infiltrate and corrode the shell or heads. Uninsulated vessels should be tested on areas where the most corrosive activity is present.

When possible, owners should employ NDT that does not require the removal of secure, intact jacketing and insulation. Cutting holes in or stripping the insulation breaches the vapor barrier and threatens the mechanical integrity of the insulated component.

Corrosion under insulation (CUI), or pipe and vessel external corrosion, is the primary damage mechanism that affects the integrity of ammonia piping and vessels. Moisture enters the insulation and becomes trapped against the pipe, vessel wall, or valve, and corrosion forms on the surface wall. If unaddressed, the corrosion will persist over time, eating away at the exterior wall and thinning the metal to the point of failure. Due to the variables present, progression time from moisture entering the insulation to the point of failure varies. Using testing to obtain accurate wall thickness values for your piping and vessels is critical.

Ensure that the chosen NDT technique uses technology that does not require direct contact with the component wall (specifically piping and vessels). Or, if contact is necessary, confirm that valid thickness readings are collected by using suitable couplants that will not freeze.

Damaged insulation jacketing, biological growth on the jacketing or insulation, and excessive ice build-up are all visual indications that moisture is or is likely to be trapped in the insulation; however, not all trapped moisture is revealed visually. On average, 30% of a system is compromised by moisture trapped in insulation, and the majority is not evident visually.

Testing for ammonia refrigeration piping and vessels, at a minimum, must be capable of collecting and reporting on the following data points at the aforementioned areas on insulated and uninsulated piping:

1. Location and volume measure of moisture in insulation;
2. Location and measurement of corrosion; and
3. Pipe wall thickness (on the top and bottom of the pipe).

Additional information can be captured during testing that is helpful with decision making and PSM compliance. Some testing can (but is not required to) locate and measure pipe size and schedule, welds, blockage, liquid levels, and other components, including valves and reducers.

A facility's entire system should be tested every five years. Many companies with larger systems test different sections over the course of five years, resulting in a comprehensive test for each cycle. Exceptions to this rule occur in the event of a release, when areas of the system are rapidly degrading and it's determined that testing should be employed more frequently for monitoring, or on areas that have been flagged as suspect and whose state cannot be determined.

Implementing regular testing, adopting the minimum requirements in ANSI/IIAR 6-2019, and establishing corporate-specific directives in PSM programs, especially in today's landscape, are paramount.

Compliance and Safety

EPA's Risk Management Plan Rule (40 CFR 68, defined by Section 112(r) of the Clean Air Act Amendments) adopted the OSHA PSM standard as its prevention program for processes in Program [Level] 3. Compliance and safety continue to be high priorities for EPA. In 2016, the agency announced a series of national enforcement initiatives focused on improving safety in a variety of high hazard industries. Among these initiatives was an effort entitled, "Reducing Accidental Releases at Industrial and Chemical Facilities," which has subsequently been renamed a National Compliance Initiative (NCI).

Originally scheduled to run 2017 to 2019, during which time plant inspections increased (638 were performed) and 62 cases were filed against facilities for CAA §112(r) non-compliance, the initiative has since been extended through 2023. Lowell Randel, Senior Vice President of Government and Legal Affairs at Global Cold Chain Alliance, has stated, "EPA has placed specific emphasis on ammonia facilities as part of the initiative."

It's also important to note that, while COVID-19 has impacted the industry, OSHA and EPA have not suspended maintenance and compliance responsibilities related to ammonia refrigeration systems. Reduction in resources and/or contractor personnel could easily lead to an ammonia release. EPA supports the concept of self-reporting compliance issues. Should a system owner find themselves in a situation where compliance is impossible, they must contact their local compliance officials as soon as possible. ■

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Follow the Science! (Continued from p. 13)

belong to Mindset 1. They select their trusted authority and then form attitudes and share them with friends, family, and followers using social media. Those thoughts and sentiments are further shared with others in their own respective social networks.

Social Media

It is important to note that users of social media generally follow other users with the same attitudes and beliefs that they have on a topic. The final opinions that people form are an amalgamation of all of the factors that make them who they are—what they read, think, see, believe, and feel. They are influenced by their emotions, those factors beyond what they read. Thus, one group may define science strictly as the results of studies or experiments on a topic, but another group may define science as the interpretation of their trusted authority, who may be a contributor on the social media platform to which they subscribe. For example, about 67% of Gen Z and 71% of Millennials have expressed the opinion on social media that climate should be top priority to ensure a sustainable planet for future generations, a significantly higher percentage than the Baby Boomers and older people (57%). Gen Z (76%) and Millennials (81%) also shared posts on social media stating that the U.S. should prioritize alternative energy development. Because Gen Z and the Millennials comprise the largest segments of the U.S. population, they are the arbiters of the major preferences in the U.S. Future consumer behavior seems to be formed through social media.

Is Science Still Dependable?

Science is "some claim or line of reasoning or piece of research" that is "done in a way that is intended to imply some kind of merit or special kind of reliability," according to *What Is this Thing Called Science?* Scientific studies use scientific procedures and methodologies, then present a discussion of the results. Conclusions are written, and the entire report is reviewed and published. It is through this scientific process of sharing experiments or scientific studies with the community that the reliability, or repeatability, of the studies is determined and confirmed. Challenge studies may result and, often, additional questions are raised and answered. This is a normal occurrence because scientific information is not infallible.

Scientific information may change with technology, available information, and even interpretation by experts. It is through science that knowledge is improved. We must continue the discourse even in the presence of difficult discord. Disagreement with the information presented by those who subscribe to beliefs or behavior different from ours is not necessarily misinformation or lies. Science will help determine the credibility of these seemingly opposing ideas or thoughts.

Science is dependable. But we need to be committed to continuing an intelligent discussion of our differences in order to improve our knowledge—about anything. ■

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Dry Cleaning in the Food Industry (Continued from p. 25)

if that floor is wet, the transfer distance increases to more than 35 m. If the boot is contaminated with microbes, a few can be detected on a dry floor for up to four steps, but they can be found for more than 15 steps on a wet floor.

Unfortunately, some of the measures we take to reduce the spread of contamination may actually increase it. Take handwashing, for example, which forms a fundamental part of any food production site's personal hygiene policy. This action is aimed at the removal of contamination from peoples' hands and, consequently, minimizing the risk of contamination transfer to the food product. However, the act of handwashing itself can lead to the spread of contamination.

Studies conducted by CampdenBRI have demonstrated that a significant number of water droplets (circled in pen in Figure 1 on p. 24), many of them carrying microbial contamination (as indicated by the number of colony-forming units developed on agar plates arranged on the floor around the handwash sink in Figure 2, p. 24), fall onto the surrounding floor during handwashing. Imagine the amount of water and contamination that could accumulate in this area at the start of a shift and, subsequently, be transferred by footwear into the production area.

It's not just the floor that can become contaminated during handwashing. CampdenBRI studies have shown that the protective clothing worn by food production area workers can also be affected.

Additionally, if a worker's hands are dried using high velocity air, the risk of cross-contamination from water droplets to both the floor and the protective clothing worn can be increased and any microbes remaining on hands that are not dried thoroughly after washing are more easily transferred to any surface subsequently touched.

Even in a wet-cleaned food production area, the use of some wet-cleaning activities can significantly increase the risk of contamination spread. The model in Figure 3 (p. 25) illustrates the spread of water droplets generated when a high-pressure hose is used to clean a slot drain. In this case, the droplets spread a minimum distance of 7 m and at a height of up to 3.5 m, meaning that they could potentially settle on food contact surfaces.

Consequently, the way we use water for cleaning, even in wet food production environments, needs to be considered carefully.

In part 2 of this article, we'll look at the solutions to these challenges, including ways in which we can reduce the risk of microbial growth and spread through use of modified personnel hygiene and entry systems. We'll also cover dry cleaning and sanitization techniques. ■

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Understanding ISO 22000 (Continued from p. 31)

ISO 22000 versus FSSC 22000

The Global Food Safety Initiative (GFSI) has been in place for more than 20 years, and many of the major food retailers are requiring that processors be GFSI certified. In this context, there has been some discussion about the difference between ISO 22000 and FSSC 22000, as sometimes these terms are used interchangeably. FSSC 22000 incorporates ISO 22000, 22002, and 22003, as well as other technical specifications. The primary difference is that FSSC 22000 has more extensive requirements for infrastructure and prerequisite programs than ISO 22000. Of importance to many is the fact that FSSC 22000 is one of the GFSI-recognized food safety management systems, while ISO 22000, by itself, is not. The FSSC 22000 audit scheme, which includes prerequisite guidelines described in TS 22002-1:2009 (formerly PAS 220), incorporates the ISO 22000 standard. The feeling at GFSI was that the ISO 22000 standard did not specifically address prerequisite programs in sufficient detail, hence the development of PAS (Publicly Available Standard) by the British Standards Institute (BSI), which eventually became Technical Standard (TS) 22002-1:2009.

The ISO 22000 standard has been very well received and has been adopted globally, especially in Europe and Asia, with more than 25,000 companies certified worldwide. However, these figures do not reflect companies that have adopted FSSC 22000 principles and would probably meet the necessary audit requirements. These companies are, for all intents and purposes, following ISO 22000 to the letter. In the future, ISO 22000 may continue to grow, although there have been some growing pains associated with the revised standard. As noted, the overall data show greater acceptance of the ISO 22000 standard in Europe and Asia, but many multi-nationals based in the United States have elected to adopt the FSSC 22000 audit scheme. Among their reasons are the lack of prescription and an emphasis that is not just on whether a processor has established a procedure, but also on whether the protocol is truly effective. This is the ultimate goal of third-party audits. Another benefit that has been seen by companies of all sizes is that the adoption of FSSC 22000 has provided a management system that allows the company to grow and improve.

> One of the strengths of the ISO 22000 standard is its focus on leadership. The plant manager, CEO, or whoever is ultimately responsible for managing the processor is also ultimately responsible for the food safety management system.

ISO 22000:2018 certification is a well-defined process. The company applies to an ISO certification organization and defines the overall scope of the certification. There is an initial review that verifies that the basic components are in place, followed by a certification audit. After all non-conformities are resolved, the company is certified, subject to surveillance audits and re-certification every three years. As part of the preparation for the certification process, the company should follow the standard and be sure that they have all of the components of the food safety management program established, documented, and up to date.

Future revisions of ISO 22000 may focus on closing the gap between FSSC and ISO 22000 and, perhaps, ultimately eliminating the need for two separate programs. ■

The authors gratefully acknowledge the comments and suggestions of Steve Cornish at the American National Standards Institute.

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Detecting Phthalates in Food Contact Materials (Continued from p. 38)

of flammable, high pressure gases is problematic, the molecular weight can be confirmed via the SMCI method using organic solvents.

Here, we present the results of an analysis of phthalate esters using the SMCI method.

Samples and analytical conditions. A standard solution of phthalate esters was prepared to a concentration of 1.0 ng/mL. The solution was measured using the EI and SMCI methods.

EI and SMCI mass spectra. When a similarity search was performed from the EI mass spectrum for Di-n-octyl phthalate, phthalate esters with different molecular weights but with a high degree of similarity were identified. Because compound identification using only the EI mass spectrum was difficult, the number of candidate compounds was narrowed down by confirming the molecular weights using the SMCI mass spectrum.

Additionally, Figure 3 shows the mass spectra for typical phthalate esters using the EI method and SMCI method, respectively, and Table 1 shows the capability of confirmation of molecular derived ions.

The molecular ions for many of the phthalate esters cannot be confirmed using the EI method. In contrast, using the SMCI method, the protonated molecular ions for all the phthalate esters can be confirmed, which provides strong support for compound identification.

For many phthalate esters, confirmation of molecular weight from the EI mass spectrum is difficult. However, pseudo molecular ions can be confirmed using the SMCI method. Accordingly, even if the use of a flammable, high pressure gas is problematic, it is evident that the SMCI method is effective for the confirmation of molecular weights. ■

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NEW PRODUCTS

Centrifugal Compressor

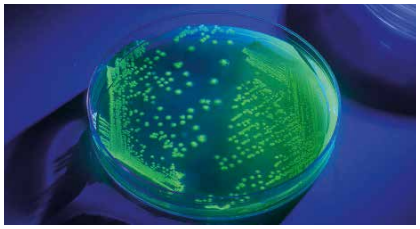
Ingersoll Rand has released the MSG TURBO-AIR NX 5000, an oil-free air and nitrogen compressor for instrument and process applications in the food and beverage industry. The compressor is rated for powers from 600 kW to 1,050 kW (800–1,400 hp) with flows from 125 to 210 m3/min (4,500–7,500 CFM) and pressures from 2.5 to 14.5 barg (35–210 psig). With a 35% turndown range, the compressor can be used in various demand scenarios to compress air or nitrogen for the process. During periods of low or fluctuating demand, the operator can engage the wide turndown range to adjust the compressor's production without the need to shut it down or deploy energy-wasting blow-off. **Ingersoll Rand, ingersollrand.com.**

Washing Compound and Defoamer for Egg Processing

Birko has launched an all-in-one washing compound and defoamer for egg processing facilities. The solution, called Egg-Shellent, combines surfactants, alkalinity, and dispersion agents to maximize shell-egg cleaning. It's formulated with substances either considered GRAS or regulated for food associated use. The solution is suitable for use in accordance with the provisions of 9CFR 416.4c and 21CRF 110.35b. **Birko, birkocorp.com, tmicle@birkocorp.com.**

Microbial Control Strains

Microbiologics has expanded their UV-BioTAG line of microbial control strains containing green fluorescent protein (GFP) markers. Designed for food microbiology testing, these control cultures visibly fluoresce under ultraviolet (UV) light, making them easily distinguishable from naturally occurring microflora and true contamination. UV-BioTAG is available in two formats: The UV-BioTAG Vial Kit includes six individual vials containing a single lyophilized microorganism pellet in each, which are rehydrated in a sterile fluid, such as saline, and then plated on culture media. **Microbiologics, microbiologics.com/UV-biotag.**



Clean-In-Place System

HRS Heat Exchangers is now offering clean-in-place (CIP) and sterilization-in-place (SIP) systems for cleaning and disinfection for the food industry. The single- and multi-tank CIP/SIP systems are supplied with a control system to enable automated cleaning cycles. They are fully skid mounted and have modular designs for quick and easy site installation. The single-tank system is designed for simple cleaning applications where recovery of the cleaning fluid is not required, while multi-tank systems are suitable for more complex situations. For small, portable applications, the tank can be heated to 185°F using electric heating elements, but steam heating using an HRS K Series multi-tube heat exchanger is also available. Units start at 132-gallon capacity, and single tank systems are available up to 660 gallons. **HRS Heat Exchangers, hrs-heatexchangers.com, info@us.hrs-he.com.**

Metal Detection System

Mettler-Toledo Product Inspection has launched a series of washdown-resistant combination product inspection systems, integrating checkweighing and metal detection technologies. The CM33 Washdown and CM35 Washdown combination systems are aimed at manufacturers of packaged food products, including dairy and meat products. The systems are capable of mid-range frequency operation and throughput of up to 250ppm, with weighing accuracy of up to +/- 0.2g. Customers can choose one of three stainless steel Mettler-Toledo Profile metal detectors: one for small, packaged products, one for bulk, dry product applications, and one that delivers maximum sensitivity in challenging applications. **Mettler-Toledo, mt.com/pi.**

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Events

AUGUST 2021

15-21
Conference for Food Protection
Virtual Event

Visit foodprotect.org.

25-26
NAMI Meat Industry Food Safety Conference
Chicago, Ill.

Visit meatinstitute.org.

August 27-September 2
AOAC Annual Meeting and Exposition
Boston, Mass.

Visit aoac.org
or email aoac@aoac.org.

SEPTEMBER 2021

1
International Conference on Food Safety & Health
Virtual Event

Visit foodsafety.nutritionalconference.com.

22-24
Petfood Forum
Kansas City, Mo.

Visit petfoodforumevents.com.

28-29
North American Food Safety & Quality
Chicago, Ill.

Visit foodsafetyna.com.

OCTOBER 2021

18-19
European Food Sure Summit
Milan, Italy

Visit foodsureeurope.com.

27-28
China International Food Safety & Quality Conference
Beijing, China

Visit chinafoodsafety.com.

NOVEMBER 2021

2-5
Process Expo
Chicago, Ill.

Visit myprocessexpo.com.

3-5
Dairy Practices Council Annual Conference
Pittsburgh, Penn.

Visit dairypc.org
or email dairypc@daritypc.org.

JANUARY 2022

25-27
International Production & Processing Expo (IPPE)
Atlanta, Ga.

Visit ippexpo.org.

MARCH 2022

5-9
Pittcon
Atlanta, Ga.

Visit pittcon.org.

MAY 2022

9-12
Food Safety Summit
Rosemont, Ill.

Visit food-safety.com/food-safety-summit.

JULY 2022

10-13
IFT
Chicago, Ill.

Visit ift.org/events.

July 31-August 3
IAFP
Pittsburgh, Penn.

Visit foodprotection.org
or email info@foodprotection.org.

OCTOBER 2022

23-26
Pack Expo International
Chicago, Ill.

Visit packexpointernational.com.

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SCIENTIFIC FINDINGS

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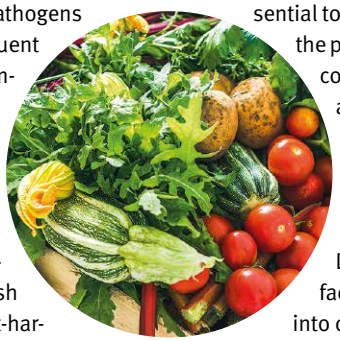
Malting Barley Improvement for Craft Brewers

American craft brewers are targeting barley malt as a novel source of flavor and as a means of differentiation. However, fundamental tools have only recently emerged to aid barley breeders in supporting this effort, such as the hot steep malt sensory method, a wort preparation method recently approved by the American Society of Brewing Chemists for evaluation of extractable malt flavor. The primary objective of this study was to determine whether insights into beer liking and sensory attributes can be gained through hot steep malt sensory using an untrained panel of craft beer consumers. The authors evaluated consumer acceptance of hot steep and beer samples of different barley genotypes using a nine-point hedonic scale, check-all-that-apply (CATA), and open comment during separate sensory panels. Beers brewed with Washington State University breeding lines, selected for all-malt craft brewing, generally had higher consumer acceptance than the industry-standard control variety. Genotype had a significant influence on the consumer acceptance of beer aroma, appearance, taste/flavor, sweetness, and overall liking, but only on hot steep appearance. Significant differences between genotypes were found for 18% (fruity and other) and 46% (chemical, citrus, earthy, fruity, stale, and sweet aromatic) of CATA attributes for the hot steep and beer panels, respectively. Hot steep and beer liking and sensory attributes had low correlation coefficients. This study demonstrates that untrained craft beer consumers can better differentiate among genotypes using beers than hot steep samples. ***Journal of Food Science*. Published online ahead of print on June 30, 2021. DOI: 10.1111/1750-3841.15786.**

In-Storage Interventions to Control Foodborne Pathogens on Fresh Produce

Although tremendous efforts have been made to ensure fresh produce safety, various foodborne outbreaks and recalls occur annually. Most of the current intervention strategies are evaluated within a short timeframe (less than one hour), leaving the behavior of the remaining pathogens unknown during subsequent storages. This review summarizes outbreak and recall surveillance data from 2009 to 2018, obtained from government agencies in the United States, to identify major safety concerns associated with fresh produce, discusses the post-harvest handling of fresh produce and the limitations of current antimicrobial interventions, and reviews intervention strategies that have the potential to be applied in each storage stage at the commercial scale. One long-term (up to 12 months) pre-packing storage (apples, pears, citrus among others) and three short-term (up to 3 months) post-packing storages were identified. During the pre-packing storage, continuous application of gaseous ozone at low doses is a feasible option. Proper concentration, adequate circulation, and excess gas destruction and ventilation systems are essential to commercial application. At the post-packing storage stages, continuous inhibition can be achieved through controlled release of gaseous chlorine dioxide in packaging, antimicrobial edible coatings, and biocontrol agents. During commercialization, factors that need to be taken into consideration include physicochemical properties of antimicrobials, impacts on fresh produce quality and sensory attributes, recontamination and cross-contamination, cost, and feasibility of large-scale production. ***Comprehensive Reviews in Food Science and Food Safety*. Published online ahead of print on June 30, 2021. DOI: 10.1111/1541-4337.12786.**



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Cold Plasma as an Emerging Nonthermal Technology for Milk

Plasma, the fourth state of matter, is under wide evaluation for the preservation of highly perishable foods, including milk and milk products. Cold plasma (CP) techniques have been promoted as a novel nonthermal technology for the preservation of milk and milk products. Apart from maintaining the nutritive value, CP also inactivates microorganisms without any chances of developing resistance. CP was also found to deactivate enzymes that are responsible for browning (color change) reactions and off-flavor generation. This review describes the action of CP and its effect on the nutritional quality of milk and milk products. ***International Journal of Dairy Technology*. Published March 23, 2021. doi: 10.1111/1471-0307.12771.**

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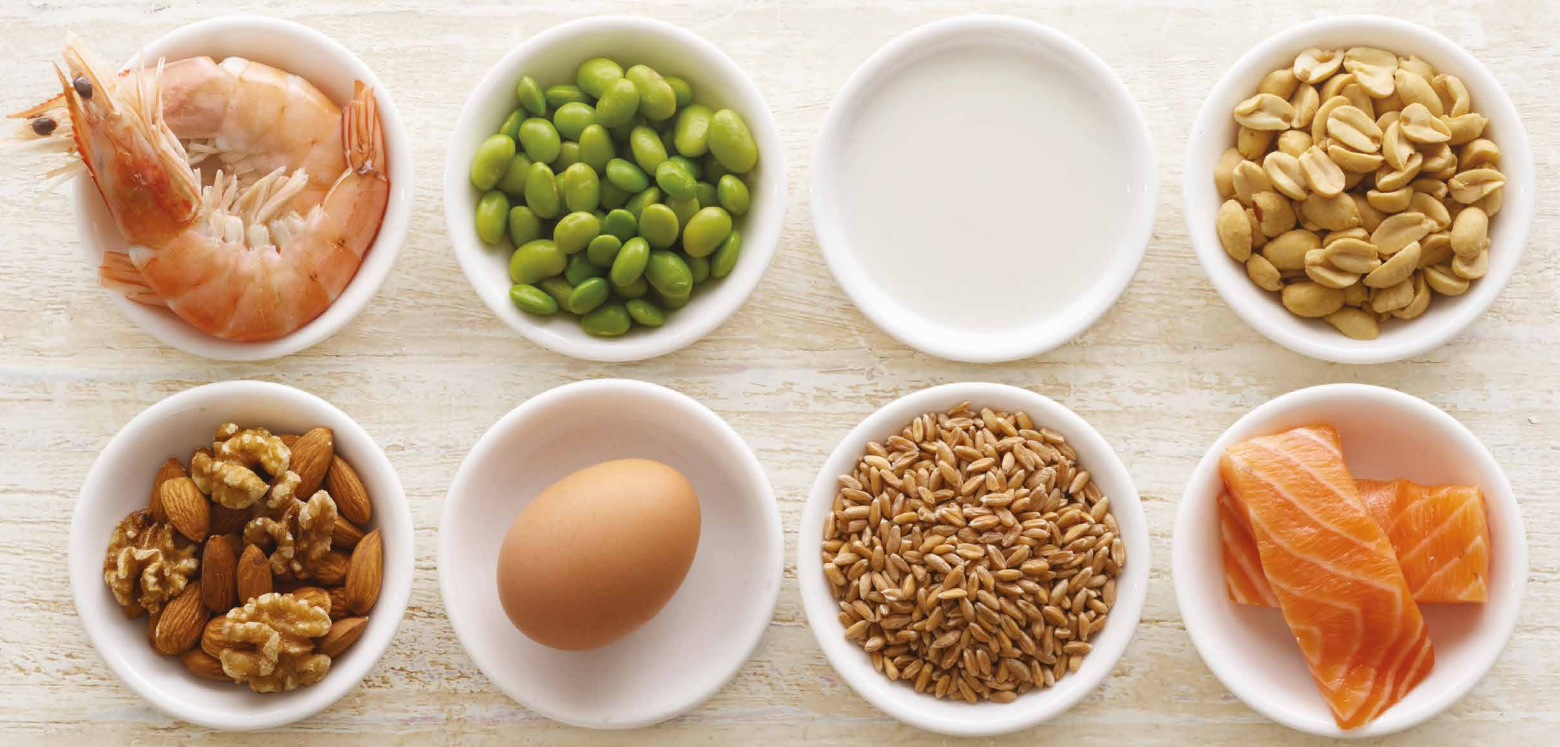

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