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APRIL / MAY 2024

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Letters should be no longer than 350 words.

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From The Editor

New Beginnings

It's springtime! A time of new beginnings, a fresh start after the long days of relentless grayness that is winter. Here in Florida, that just means it's time to start mowing the grass every three or four days, but that's a small price to pay compared to those who are shoveling snow for months on end. Regardless of your location, spring will come and with it, the inevitable spring cleaning chores.

This spring has a different feel, a feeling that it's not just a change in the weather but a sense that it is truly a new beginning in food safety. With the pandemic really behind us (knock on wood), travel is back. My favorite meetings are once again in my calendar, and I look forward to seeing old friends again. My thoughts have also turned to those projects that were interrupted by the isolation of the pandemic. The sense of possibility is also back—the idea that we can have a positive impact on food safety with new ideas that no longer have to be prefaced with "when this is over."

Along with this renewed sense of purpose comes the reality that we'll also see more activity from our regulatory partners. FDA has a new structure, and with it, a new leadership team ready to usher in a new era of food safety.

Early indications are that there will be additional focus on chemical hazards as the massive changes in FSMA are assessed during inspections. Speaking of inspections, we should not forget that FSMA also included new requirements for FDA. Chief among those are the requirements for a minimum number of inspections based on product risk. Based on early inspection data, pre-pandemic, most facilities had failed to identify all of the hazards applicable to their products. With that in mind, FDA revised and updated their guidance document to reflect the need for this information. I'm happy to see that it was finally released early this year, so I would encourage everyone to review their food safety plan's hazard analysis against FDA's latest guidance document.

FDA also released a new regulatory dashboard designed to help industry prepare for upcoming regulatory changes. Its release implies FDA is encouraging everyone to improve their preparation activities for imminent regulations, and this new tool should make this an easy task for most.

Yes, spring is here—in Florida anyway—and it's time to get to that spring cleaning!

Patrica A. Wester
Executive Industry Editor

Food Quality & Safety
FARM TO FORK SAFETY

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NEWS & NOTES

FDA: PFAS No Longer Used in U.S. Food Packaging

FDA has announced that grease-proofing materials containing per- and polyfluoroalkyl substances (PFAS) are no longer being sold for use in food packaging in the U.S. This means the major source of dietary exposure to PFAS from food packaging like fast-food wrappers, microwave popcorn bags, take-out paperboard containers, and pet food bags has been eliminated.

PFAS, also known as "forever chemicals," are a diverse group of thousands of chemicals that resist grease, oil, water, and heat. FDA has authorized certain of these substances for limited use in cookware, food packaging, and food processing equipment. Exposure to some types of PFAS have been linked to serious health effects.

The announcement marks the fulfillment of a voluntary commitment by manufacturers to not sell food contact substances containing certain PFAS intended for use as grease-proofing agents in the U.S. "This FDA-led effort represents a positive step forward as we continue to reevaluate chemicals authorized for use with, and in, food," said Jim Jones, deputy commissioner for human foods, in a statement. In 2020, the FDA engaged companies to cease sales of grease-proofing substances that contain certain types of PFAS following a post-market safety assessment conducted by the agency.

FDA says it will continue to conduct research and update its evaluations using the most up-to-date science to ensure that its risk determinations continue to be accurate and based on current science. ■

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DOL Seeks Injunction Against Sanitation Company Over Allegations of Child Labor

The U.S. Department of Labor has asked a federal court to issue a nationwide temporary restraining order and injunction against Fayette Janitorial Service to stop the Tennessee-based company from illegally employing children while the department continues investigations into the company's labor practices. The company provides contract sanitation and cleaning services for meat and poultry processing facilities in approximately 30 states and employs more than 600 workers.

The request for a restraining order was prompted by investigations that found Fayette employed minors to clean and sanitize spaces and equipment during overnight shifts to fulfill sanitation contracts at a Perdue Farms plant in Accomac, Va., and at Seaboard Triumph Foods in Sioux City, Iowa. The Fair Labor Standards Act bans children younger than age 18 from working in dangerous occupations, including most jobs in meat and poultry slaughtering, processing, rendering, and packing establishments.

In its filing, the department alleges that Fayette employed 15 children, hired as young as 13 years old, in Virginia and at least nine children in Iowa on its overnight sanitation shifts. Minors were used to clean dangerous kill floor equipment such as head splitters, jaw pullers, meat bandsaws, and neck clippers. At least one 14-year-old at the Virginia facility suffered severe injuries while employed by Fayette.

A spokesperson for Fayette told the Associated Press in an email that the company is fully cooperating with the investigation. Further, the Fayette says it has made policy and staffing changes, including hiring a new CEO and using third-party legal representation for vetting potential employees. "Fayette has always had a zero-tolerance policy for minor labor in the workforce, and we have continued to work diligently to ensure that something like this cannot occur," the statement read.

The allegations come after an April 2023 letter from USDA Secretary Thomas Vilsack to members of the meat and poultry industry, asking companies to take precautionary steps to deter illegal child labor in their supply chains.

The Department of Labor says its investigations into Fayette are ongoing. ■

California Bill Would Ban Foods Containing Some Synthetic Dyes in Public Schools

A California assembly member has introduced legislation that would prohibit the state's public schools from serving foods that contain certain additives. In particular, Assembly Bill (AB) 2316, introduced by Jesse Gabriel (D-Encino), would prohibit schools from serving foods containing six synthetic food dyes—Red 40, Yellow 5, Yellow 6, Blue 1, Blue 2, and Green 3.

Currently, products containing these dyes are required by the EU to carry a warning label.

The introduction of AB 2316 follows the 2023 passage California Food Safety Act – which banned the use of four chemicals from foods sold in California. Like the California Food Safety Act, AB 2316 would not ban any specific foods or products; rather, Gabriel says it would encourage companies to make modifications to products sold in the state.

AB 2316 now heads to the Assembly Education Committee, where it is expected to be heard in the coming weeks. ■

USDA Finalizes "Product of USA" Label Rule

USDA has finalized a rule to align the voluntary "Product of USA" label claim with consumer understanding of what the statement means. Tom Vilsack, USDA agriculture secretary, also says the agency is awarding $9.5 million to 42 projects through the Local Meat Capacity grant program to expand processing options for the meat and poultry industry and new actions to ensure transparency and a fair and competitive market in the U.S. seed industry.

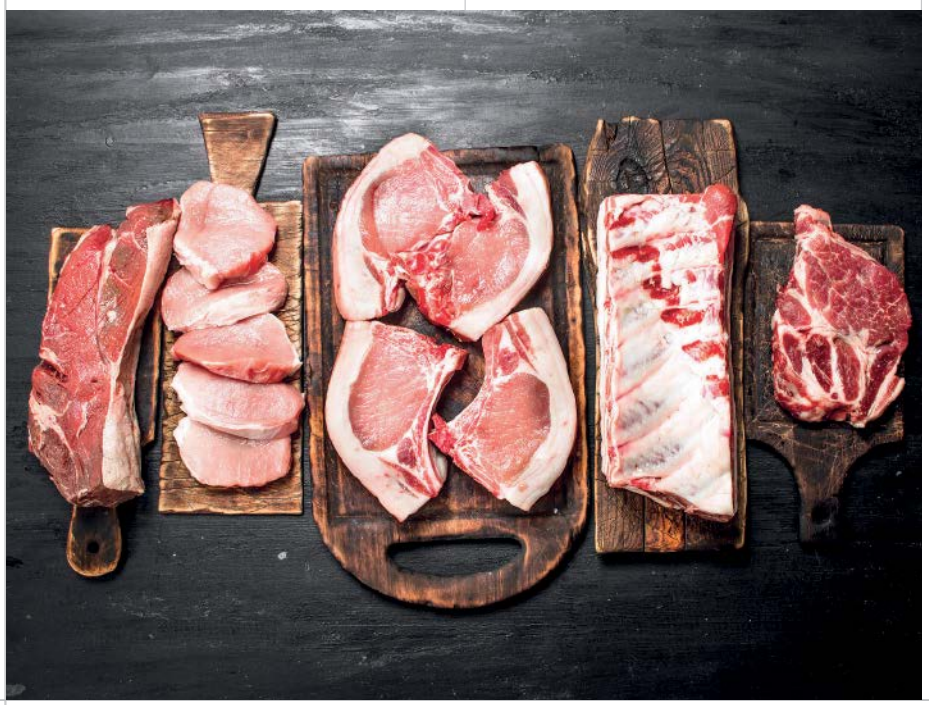
These actions build on President Biden's Executive Order on Promoting Competition in the American Economy and the Biden-Harris Administration's Action Plan for a Fairer, More Competitive, and More Resilient Meat and Poultry Supply Chain, the agency says, adding that they are intended to help increase competition in agricultural markets, create a fairer playing field for small- and mid-size farmers, lower grocery costs for consumers, and strengthen local and regional food systems.

The final rule allows the voluntary "Product of USA" or "Made in the USA" label claim to be used on meat, poultry and egg products only when they are derived from animals born, raised, slaughtered and processed in the United States. The rule will prohibit misleading U.S. origin labeling in the market and help ensure that the information that consumers receive about where their food comes from is truthful.

Under the rule, the label claim will continue to be voluntary. It will also remain eligible for generic label approval, meaning it would not need to be pre-approved by USDA's Food Safety and Inspection Service (FSIS) before it can be used on regulated product but would require the establishment to maintain documentation on file to support the claim. The final rule also allows the use of other voluntary U.S. origin claims on meat, poultry, and egg products sold in the marketplace. These claims will need to include a description on the package of the preparation and processing steps that occurred in the United States upon which the claim is made.

USDA has also published an updated labeling guidance on the use of voluntary U.S.-origin label claims to provide examples of claims and the types of documentation that establishments may maintain to support use of the claims. The guidance will be open for public comment for 60 days after publishing in the Federal Register. Public comments can be submitted at www.regulations.gov.

Establishments voluntarily using a claim subject to the final rule will need to comply with the new regulatory requirements by January 1, 2026.



Study: Standard Test for Raw Organic Milk Not Sufficient

By Keith Loria

A group of food scientists from Cornell University in New York have concluded that a standard quality test often used for raw organic milk is not sufficient for differentiating between specific groups of bacteria and should be updated. The research appeared in January in the *Journal of Dairy Science* (doi: 10.3168/jds.2023-24330).

Nicole Martin, PhD, senior author of the study and assistant research professor in dairy foods microbiology and the associate director of the Milk Quality Improvement Program in the Department of Food Science at the institution, says that the present test, known as the laboratory pasteurization count (LPC), searches for thermoduric bacteria, but doesn't distinguish whether bacteria form spores or not.

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She notes that when dairies deliver organic milk to processors, the milk is sometimes tested for thermoduric bacteria using LPC. Under current standards, if thermoduric bacterial counts are high, the milk can be downgraded or even rejected by the processor. "We saw firsthand the struggle that some dairy farmers had with controlling and troubleshooting the LPC in their raw milk, which selects for thermoduric bacteria, or bacteria that can survive temperatures considerably above their maximum growth temperature," Dr. Martin tells *Food Quality & Safety*. "This can lead to loss of premiums and, ultimately, even loss of contracts if the LPC is not brought back into compliance."

With that in mind, the researchers noted that the criteria for determining milk quality at processing plants is no longer valid and a new way for producers to address milk-production hygiene is necessary.

The researchers went into the study looking to answer a few questions about the LPC that they hear frequently from farmers and other stakeholders, including, "Can milk be frozen prior to LPC testing?" "What are the types of organisms making up the thermoduric population in organic raw milk?" and "Can a rapid identification method used primarily for mastitis organisms be used to identify thermoduric bacteria?"

"So, it's not necessarily that the LPC is insufficient, but that the LPC alone can only give us so much information, and for farmers who are actively trying to reduce LPC, it may be beneficial to understand the types of bacteria leading to the elevated LPC," Dr. Martin adds. "This would also for more targeted troubleshooting efforts."

The research showed that there are two different groups of bacteria making up the thermoduric population in organic raw milk—sporeformers and non-sporeformers—and an individual milk sample with a high LPC may have one or the other, or both, of these types. "Once we know what type of bacteria is driving the elevated LPC, it then allows for more targeted troubleshooting since these groups of bacteria are likely to originate from different sources on the farm," she says. "We're giving organic farmers the knowledge they need to make high-quality raw milk and for it to be economically viable; it will make a better dairy product in the end." ■

(Continued on p. 35)

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Washington Report

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The "New" FDA

What we should expect to see, and when we might see it

BY **PATRICIA A. WESTER**

The infant formula crisis was the headline event that triggered a restructuring of FDA's operational framework. Much of the new framework is based on a report presented by the Reagan Udall Foundation in December 2022, which also included findings from an internal agency review that was published in September 2022. Steven M. Solomon, DVM, MPH, director for FDA's Center for Veterinary Medicine, handled the internal review and notes in the forward of the findings:

"On May 25, 2022, in the wake of an ongoing investigation of *Cronobacter* and revelations of a whistle blower complaint regarding Abbott Nutrition's infant formula manufacturing plant in Sturgis, Mich., FDA Commissioner Robert M. Califf, MD, requested that I undertake an internal agency review of the situation. My charge was to identify the challenges encountered in addressing the circumstances that eventually led to a shortage in supply of infant formulas that serve as the sole source of nutrition for many infants and for people with certain metabolic conditions that require specialty formulas. Dr. Califf also tasked me with framing out recommendations to address the findings from the internal review."

The findings and recommendations detailed in the report are the result of dozens of interviews with FDA staff and leadership directly involved with the events that transpired.

The information that came out of these internal interviews allowed us to identify five critical elements central to the core functions of the agency.

Five Major Areas of Need

1. Modern information technology that allows for the access and exchange of data in real time to all the people involved in response.
2. Sufficient staffing, training, equipment, and regulatory authorities to fulfill FDA's mission.
3. Updated emergency response systems capable of handling multiple public health emergencies occurring simultaneously.
4. Increased scientific understanding about *Cronobacter*, its prevalence and natural habitat, and how this translates into appropriate control measures and oversight.
5. Assessment of the infant formula industry, its preventive controls, food safety culture, and preparedness to respond to events.

There is no single action to explain the events that occurred; rather, the report identifies a confluence of systemic vulnerabilities that demonstrate the need to focus on continued modernization and investment in the expertise and tools needed to better anticipate and address future public health challenges in this area.

This analysis also illustrates the importance for the agency to continuously reassess conditions and make necessary adjustments to keep pace with the constantly evolving public health challenges the agency tackles.

The Triggering Event

Between September 2021 and January 2022, FDA received information about four cases of illness or death in infants who consumed powdered infant formula. After learning that each of these infants consumed powdered infant formula products manufactured by Abbott Nutrition in Sturgis, Mich., and initiating an investigation at the facility that revealed unsanitary conditions, the agency warned consumers not to use certain products manufactured at this facility.

On February 17, 2022, Abbott Nutrition issued a voluntary recall of certain infant formula products manufactured at its Sturgis plant and temporarily ceased production. While necessary to safeguard public health, the recall and pause in production further stressed a supply chain already strained by the COVID-19 pandemic. A shortage of these products created hardships for parents and caregivers who rely on infant and specialty formulas to feed their babies, as well as loved ones with certain metabolic disorders.

FDA's responsibility to respond to foodborne illness and contamination is a critical programmatic activity, and one the agency takes seriously. This incident involved unique circumstances, requiring the agency to address a relatively poorly understood pathogen, *Cronobacter sakazakii*, in a critical sole source of nutrition for vulnerable populations. While infant formulas—and specialty and metabolic formulas in particular—are regulated by FDA as food, they are in many ways comparable to life-saving medications. Therefore, FDA's foods program had to balance considerations of product safety and product availability in a way it has never had to do before.

This event demonstrated the need for an integrated, multidisciplinary agency approach that included scientific, clinical, nutritional, analytical, and inspectional expertise; legal processes; supply chain and policy considerations; and the resources to support this multidisciplinary work.

Given the unique circumstances and far-ranging consequences of the shortage, as well as the technology, process, policy, and resource challenges that became apparent during the management of the incident, FDA initiated a comprehensive evaluation of the events leading up to, during, and after the recall initiation until June 4, 2022. The evaluation team, led by Dr. Solomon, conducted 43 interviews with a total of 61 employees.

The interviewees identified several actions FDA centers and offices had already initiated in response to challenges encountered during the incident. For example, improvements regarding how consumer complaints and whistle blower complaints are triaged and escalated have already been implemented in the Office of Operations, ORA, and CFSAN. CFSAN, in collaboration with ORA and OFPR, also developed a powdered infant formula prevention strategy to provide targeted root cause analysis guidance to industry.

Another review conducted by the third-party Reagan Udall Foundation added additional insights into the core attributes a successful government agency should consider. This report was published in December 2022 including an outline of the basic functions of FDA, and its mission and goals in the public health space.

The analysis illustrates the importance for the agency to continuously reassess conditions and make necessary adjustments to keep pace with the constantly evolving public health challenges the agency tackles.

Primary Function of FDA Human Foods

According to the Office of the Commissioner, the current FDA Foods Regulatory Program has nine primary functions:

1. Standards setting and policy development for food safety, nutrition, labels, regulatory program frameworks, food defense, and other requirements, including development of regulatory methods.
2. Education, outreach, and training in collaboration with stakeholders in food production, processing, distribution, retail, and regulation related to food safety, as well as public outreach and education on FDA-led nutrition efforts.
3. Premarket notification and petition review on issues as varied as food and color additive petitions, infant formula, and food packaging, amongst others.
4. Surveillance activities, including inspections, reviews, and sample testing of the domestic and imported food production and food supply for compliance with standards, including surveillance of public nutrition status.
5. Response actions when standards are not met or when food safety problems occur, including shortages and outbreaks.
6. Enforcement, including civil actions and, at times, criminal investigations, to protect the public and maintain standards.
7. Inter- and intra-governmental relations and cooperation with other government entities involved in food production and regulation, including state, territorial, local, tribal, federal, and international.
8. Information management, including compiling, validating, analyzing, and maintaining information related to regulated food entities and products, and their compliance status.
9. Cross-cutting support activities, such as governance, planning and strategy development, human resource management, and budgets.

Attributes of an Agile and Effective Regulator

As the panel evaluated and considered programmatic recommendations for the FDA Human Foods Program, it also considered the attributes of a high-performing organization (in this case, an agile and effective regulator). The National Academy of Public Administration, an independent, nonpartisan organization charted by Congress in 1984 to advance the field of public administration, identified guiding principles for an agile and effective government.

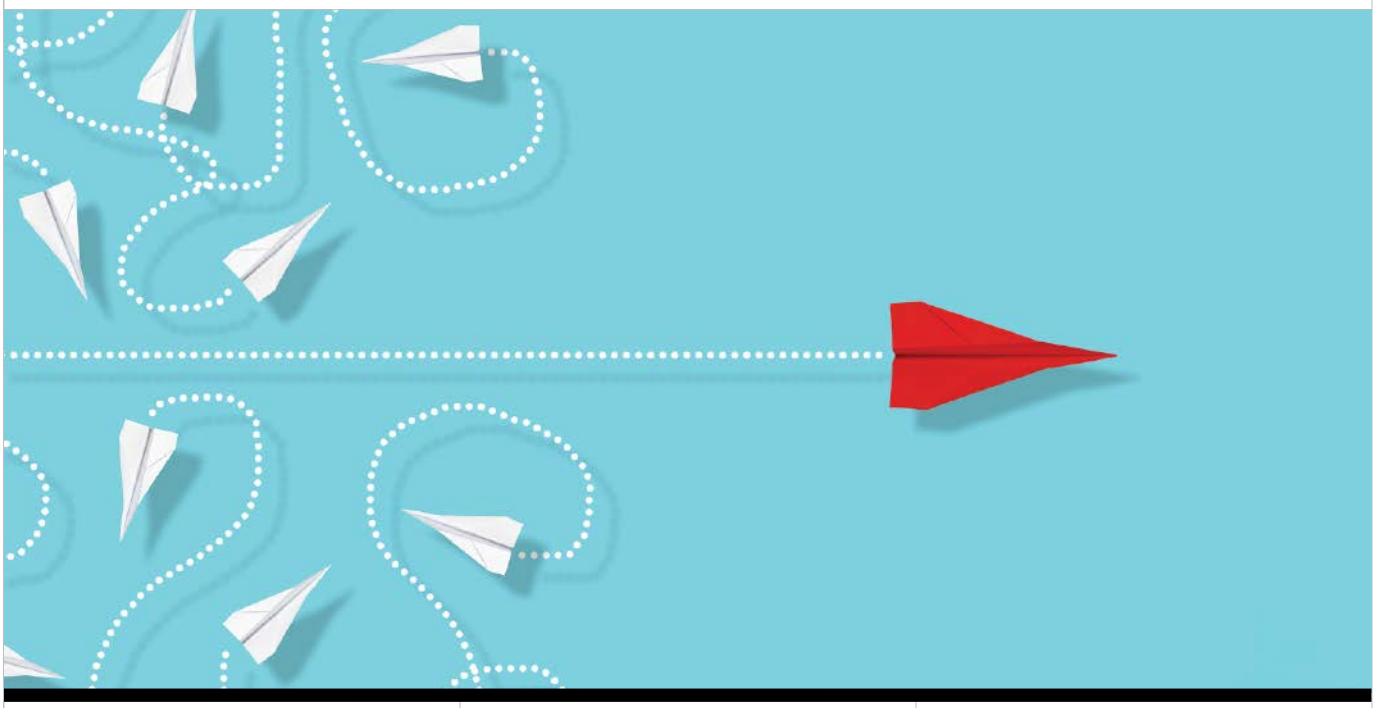
These included:

- A laser-focused, crystal clear, easily understood and communicated mission.
- Mission-focused, outcome-based, widely agreed upon, and simple to track metrics.
- Stakeholder behavior and input are critical to any program design, and the stakeholder journey should be embedded in an organization's culture.
- Work environments and culture that celebrate speed, persistence, innovation, and evidence-based solutions.
- Optimized internal teams that are empowered, highly skilled and cross-functional.
- External relationships and networks require attention and affirmation that they are critical to mission success.
- Effective leaders who eliminate roadblocks, aggregate, and assume risks, empower teams, hold people accountable, and reward accomplishments.

These reports provide valuable insights into what the "new" FDA will look like. The actual changes will become publicly known later in 2024. In the meantime, it's important to review the data they considered as an objective measure of how well they meet the challenges of a maturing government agency. ■

Wester is Executive Industry Editor of *Food Quality & Safety*. Reach her at fqseditor@pawesta.com.

Career Development



Leading the Charge

Effective leadership qualities for food safety professionals

BY **KEITH LORIA**

Food safety leaders encounter numerous obstacles in their field. They shoulder the weighty burden of safeguarding public health, juggle substantial workloads, and are expected to possess knowledge in various areas. While many excel in technical proficiency, some overlook the importance of interpersonal skills crucial for effective team leadership, influence, and strategic planning. Consequently, food safety leaders aren't always seen as vital collaborators who actively enhance systems, structures, and organizational culture to align with business objectives.

David Acheson, MD, founder and CEO of The Acheson Group, has more than three decades of experience as a leader in the medical industry and in food safety, including serving as FDA's associate commissioner for foods from 2002 to 2009. "A food safety leader must understand the science of food safety and the business pressures to run a business with a profit," he says. "A leader in food safety must also know where the next risk is coming from by staying well connected with the scientific and regulatory changes that drive food safety."

Mitzi Baum, CEO of Stop Foodborne Illness, knows that when food safety leaders do things correctly, it will help reduce illnesses and deaths associated with foodborne pathogens. But there are issues that get in the way of that mission, chief among them the fact that leadership isn't always recognized as an essential job. "The perception is the work that they do doesn't have any ROI," she says. "That's a misnomer, because the work that food safety professionals do every day protects the brand and protects the consumers. They keep food businesses in business because of what they do every day."

Hal King, PhD, managing partner of Active Food Safety, says that food safety leadership is very different in a food industry business role when compared with work in other organizations such as government, academia, trade groups, and vendors. In these organizations, he adds, there is a mandate to develop new food safety knowledge or products. "The same knowledge of food safety hazards and their controls is needed in all of these organizations of course, but in order for a food safety business leader to be successful, they must know the food business they are in very well, and be able to work with the other business function leaders and employees (e.g., supply chain, procurement, retail operations, regulatory compliance, legal liability, and facility design) to influence and lead others to execute food safety management and culture throughout the business," he says.

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An Effective Leader

Food safety management is non-negotiable, Dr. King says, and must be supported by the business via a commitment to resource the business function, or the food safety business leader will be hampered in their effectiveness. "From my experience, when supported by the business, the ability to communicate food safety knowledge and align it to the other business functions within a food enterprise is the most important trait of an effective leader," adds Dr. King, who spent 11 years as food safety director for Chick-fil-A.

He adds that the most successful food safety business leaders continuously learn new skills and food safety management methods, help others in the business learn and execute important food safety controls, facilitate food safety culture, and share what they have learned with the industry, so the industry at large gets better at preventing foodborne diseases.

An ideal food safety leader, in Baum's opinion, would be someone who could tell the food safety story and influence the C-suite, someone open to suggestions and ideas for improvement, knowledgeable but not afraid to be curious and ask questions, and motivated to get better and make more of an impact.

Managing Regulatory Requirements

Regulatory and other requirements come from sources such as laws and regulations. Government-issued guidance documents, industry best practices, third parties, and suppliers can offer more product/process-specific support. This is a collection of entities that is often difficult to manage. "Food companies are often asked to comply with regulatory requirements from multiple agencies—such as FDA, USDA, and local jurisdictions—with similar intentions but with slight nuances that make it challenging to navigate," says Jill Stuber, co-founder of Catalyst LLC, a coaching and leadership development company for people in food.

Understanding what must be done, what is a best practice, and what an organization will do based on its risk tolerance, takes resources. "Ways to keep up include attending conferences, listening to webinars, and talking to outside experts to help [leaders] understand how new regulations impact their operations," Dr. Acheson says.

Steven Mandernach, executive director of the Association of Food and Drug Officials, says that right now, the regulatory climate is challenging, and keeping current is hard. The courts often have not kept up with the science or technology in food safety practices, and the process to amend codes often takes years. "Sometimes people don't understand government is a process of negotiation, and so is regulation, and so are laws, and you have to keep that in the back of your mind," he adds. "Think of where you want to get to eventually and the path to get there, though it may not happen right away."

When it comes to regulatory requirements, Baum focuses on pathogens, bacteria, and viruses. "Sometimes things change pretty quickly, or state by state even, but at the federal level, it takes some time to see change," she says. "Part of the work we do is to identify where there are gaps."

A Sound Food Safety Culture

Every food company already has a food safety culture. The bigger question is whether the food safety culture is supporting the business outcomes needed to empower team members, protect consumers, and protect the brand. Implementing a savvy food safety culture among staff is a vital requirement for any strong food safety leader, and nurturing that element is essential.

Dr. Acheson says that food safety leaders must juggle many different hats to perform their job well, often managing downward to their QA team and managing upward to business units who may not fully understand food safety. "A good idea is to set up programs to help line workers and others in the plant such as maintenance understand food safety culture and why it matters," he says. "Simple examples are when the QA lead takes a line worker and walks the plant looking for foreign material that can help that line worker understand that the culture is about food safety being everyone's job, not someone else's job."

While a sound food safety culture comes from the top, Baum says that everyone on staff needs to buy into it—from sanitation workers in the facility all the way up. "Engaging everyone regardless of their position in the organization to talk about food safety and how they impact food safety is vital," she adds. "Encouraging the conversation and encouraging people to take action, is imperative. When your decisions are food safety-motivated, it creates a completely different culture within your organization and the people you employ respond to that."

> A food safety leader must understand the science of food safety and the business pres-sures to run a business with a profit.
>
> —DAVID ACHESON, MD

Advice for Future Leaders

For those hoping to succeed as food safety leaders someday, Dr. Acheson recommends finding a mentor to help navigate the role. "Learn how to keep up with change and risks and new regulations," he says. "Build a network of outside support you can rely on to help you both scientifically, regulator[ily], and in understanding risks. Be a listener and develop a strong relationship both up to senior management and down to the line workers."

Baum agrees that learning from others is a great idea and also counts listening skills as an important trait to work on. "Everyone approaches a problem from a different perspective and understanding that all the stakeholders that can help you create a solution are all going to do so differently," she says. "No one can solve a problem by themselves; it needs to be a collaborative effort. Listening, learning, and thinking broadly for creative solutions helps to create a new leader." ■

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The Age of Delivery

While demand for meal kits and food delivery services rises, guidance on ensuring food safety during transport lags

BY **KAREN APPOLD**

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In the last quarter of 2023, 77% of U.S. consumers used a food delivery service over a one-month period, according to a 2023 report from DoorDash (doordash.com). "Meal kit services have grown in tandem with the overall trend toward food delivery and consumption at home," says Paul Bradley, senior director of product marketing at TraceGains, a supply chain solutions company in Broomfield, Colo.

Social distancing measures initiated during the COVID-19 pandemic accelerated the adoption of meal kit and food delivery services as consumers aimed to reduce their exposure to crowded places such as grocery stores and restaurants. After the pandemic, meal kits remained popular in light of busy lifestyles, a preference for convenience, and a desire for a wide range of recipes that cater to various dietary preferences and restrictions, says Rachel Fogle, PhD, associate professor of biological sciences, program lead for environmental science and sustainability, and director of aquaponics and hydroponics initiatives at Harrisburg University of Science and Technology in Harrisburg, Penn.

Meal kit and food delivery services also offer a convenient solution for many urban dwellers, especially in food deserts, considering transportation constraints and the proximity of grocery stores with healthy, fresh produce, Dr. Fogle says. Smartphones and mobile apps have simplified the process of ordering food and meal kits.

With the popularity of food delivery services and meal kits growing so quickly, however, food safety regulators have given little guidance regarding best practices for direct-to-consumer (DTC) or third-party delivery (TPD) services. In food delivery, this "last mile," the means by which food is transported from a producer and packager to an actual consumer, presents unique challenges for maintaining food safety.

"Whether food is being carried by a delivery driver or conveyed by a package delivery service or other means, situations can arise in which food can be handled unsafely," Bradley says. "In particular, concerns exist around perishable food items that must be held within safe temperature ranges, as many delivery methods don't account for temperature verification and other traditional food safety process controls."

Addressing these concerns mandates collaboration among meal kit companies, food delivery services, regulatory bodies, and consumers to establish and enforce strict standards and protocols for the safe handling, packaging, and delivery of food.

—RACHEL FOGLE, PHD

Regarding meal kits, issues can surface when using non-traditional delivery channels such as mail or package delivery systems, which typically aren't designed to provide the kinds of checks and controls required by safe food handling guidelines, Bradley says.

Greatest Safety Concerns

Due to limited regulations for DTC and TPD, as well as a lack of understanding of risks posed by these services, concerns have mounted. When food is placed in a box for shipment, it's no longer under that establishment's control, and delivery companies such as the U.S. Postal Service, UPS, FedEx, aren't regulated by food safety agencies, says Donald W. Schaffner, PhD, distinguished professor, extension specialist, and current chair of the department of food science at Rutgers University in New Brunswick, N.J. Even if these companies do guarantee delivery times, they use unrefrigerated vehicles and therefore don't have the capacity or ability to guarantee delivery temperatures.

Temperature control of perishable goods is a top concern, says Martin Bucknavage, MS, MBA, senior food safety extension specialist in the department of food science at Penn State University in University Park, because it can result in quality issues related to spoilage and contamination by organisms such as *Listeria* and *Staphylococcus aureus*, along with the spore-forming pathogens *Clostridium botulinum*, *Clostridium perfringens*, and *Bacillus cereus*.

Temperature abuse becomes problematic when a shipped product doesn't get to a consumer in a timely fashion, which could occur to a shipment being mailed to the wrong address or a consumer not being present when a product is delivered. Even if coolants are used, in some cases they may not compensate for delivery delays, Bucknavage says.

"There may be sporadic cases of foodborne illnesses from food delivery services due to one-off bad actors, but with meal kit delivery, the possibility of large outbreaks exists," says Mitzi D. Baum, MSc, CEO of Stop Foodborne Illness in Chicago. "Studies have shown that the ingredients in meal kits don't always stay at a safe temperature. Harmful bacteria can grow quickly in meats and seafood if left sitting on a porch, and consumers may not realize it. Refrigerated items can only be left out at temperatures above 40°F for a maximum two hours, which includes transport time."

Tampering with food during the delivery process is another concern, Dr. Schaffner says. The platform-to-consumer delivery method introduces increased opportunities for food tampering and contamination due to additional touchpoints in the delivery process. To address this concern, more restaurants have implemented tamper-evident closures; however, studies show that using tamper-evident seals might send the wrong message to consumers (*Int J Hospital Manag*. doi: 10.1016/j.ijhm.2022.103315). "When consumers see these seals, it might send a signal raising the possibility that tampering could occur," he says.

Personal hygiene of the individuals preparing and handling the food, as well as those delivering the food, is another concern. Most states require all restaurant workers to have a food handler's license; however, delivery companies don't explic-

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itly state on their websites that any kind of food handling experience or license is required, Baum says.

In fact, some reports have highlighted concerns regarding food safety knowledge and practices among food handlers and delivery workers (*PLoS One*. 18(10): e0293004). "Proper hygiene practices, including hand washing and sanitization, are essential to mitigate the risk of foodborne illness," Dr. Fogle says.

Ensuring the cleanliness of delivery vehicles is yet another aspect to address because spills and food residue can cause contamination, Dr. Fogle says. Regular cleaning can reduce this risk.

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"Clearly, many companies have mastered the home delivery channel—showing that it can be done safely with great success," Bucknavage says. "But because of lower barriers to entering the delivered meal space, some providers of home delivery meals can fly under the radar, away from inspection or other oversight. It's up to regulators to constantly search for these less-than-compliant operations."

Ignorance can also play a role. Some start-up businesses that have a good meal kit idea simply may not know about state, federal, and local laws and how to meet their standards, says Benjamin Chapman, PhD, department head, professor, and food safety specialist in the department of agricultural and human sciences at North Carolina State University in Raleigh.

"Addressing these concerns mandates collaboration among meal kit companies, food delivery services, regulatory bodies, and consumers to establish and enforce strict standards and protocols for the safe handling, packaging, and delivery of food," Dr. Fogle says.

Guidance Document Contains Best Practices

Although few regulations regarding DTC and TPD exist, in 2022 a Conference for Food Protection committee drafted a voluntary guidance document on best practices for food safety for these service lines. It includes advice pertaining to preventive controls, mechanisms to assess risk, recommendations for proper packaging, temperature controls, physical and chemical contamination controls, and allergen controls. The document was drafted by the Conference for Food Protection Direct to Consumer Delivery Committee, chaired by Dr. Schaffner. Committee members included representation from grocery stores, restaurants, food processors, delivery companies involved in these new delivery models, consumer and academic representatives, and state and local public health officials. Following is some insight on each practice.

Preventive controls. Food companies that include "last mile delivery," whether DTC or TPD, should conduct thorough hazard analyses to identify potential food safety hazards at each stage of the delivery process, Dr. Fogle says. Regular verification activities, including inspections, testing, and recordkeeping, are essential to ensure the adequacy and effectiveness of preventive controls. It's important to establish procedures for taking corrective action in response to deviations from established controls. Proper training of employees and delivery personnel are crucial for ensuring compliance with preventive control regulations and maintaining food safety standards.

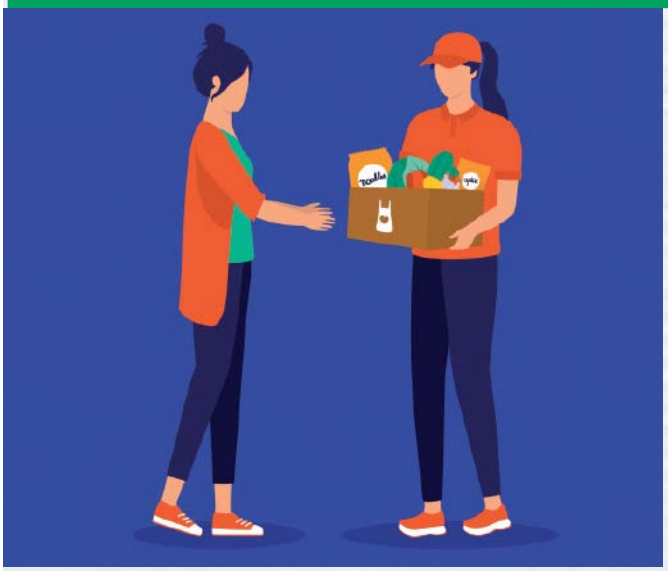
Mechanisms to assess risk. Managing food safety risks requires leveraging both internal and external resources. Internal resources include self-assessment, flexibility, and response capabilities, Dr. Fogle says. Regular internal assessments—conducted through daily checklists, shift-based logs, internal reviews, and the use of third-party auditing firms for independent audits—enable companies to proactively identify and mitigate food safety risks.

Third-party auditing firms can conduct independent audits to ensure safe food practices. External experts offer impartiality during assessments, providing unbiased insights and recommendations to improve food safety practices, Dr. Fogle says. These professionals often possess specialized training in inspection techniques and root-cause investigations, facilitating thorough assessments of food safety risks. Additionally, external resources can supplement internal teams by aiding in program design, updating educational materials, and developing standard operating procedures, thereby strengthening overall food safety protocols.

Recommendations for proper packaging. Attention to each layer of packaging—outer packaging, coolant selection, and dunnage—is vital for ensuring food safety and quality during transit and delivery, Dr. Fogle says.

Outer packaging serves as insulation to maintain temperature control and prevent contamination. Companies must ensure its integrity, conduct crush tests, and provide handling instruc-

Incorrect Temperatures Pose the Greatest Threat to the Safety of Delivered Foods



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Temperature mismanagement is indeed the greatest food safety concern regarding food delivery, says Sara Bratager, senior food safety and traceability scientist at the Institute of Food Technologists in Chicago. Research on meal kit delivery services found that surface temperatures of 76% of high-risk items such as meat, poultry, and seafood in meal kits exceed the recommended threshold of 40°F. These temperatures were observed after just eight hours, well within the typical 12-hour delivery window.

Similarly, another study found that more than 75% of food packages shipped using standard carriers such as FedEx contained at least one product that exceeded 40°F upon opening, underscoring the prevalence of temperature inconsistencies in food delivery.

Despite efforts from organizations such as the Centers for Disease Control and Protection to educate consumers on safe food delivery and receipt practices, Bratager says a gap remains in guidance from food companies themselves. Few companies provide explicit instructions recommending that high-risk food products be received at temperatures below 40°F or advocate for visual inspection of food products upon receipt, leaving consumers vulnerable to potential foodborne illnesses.

Although restaurant delivery and online grocery operations don't regularly face challenges with extended delivery times, they still grapple with maintaining product safety and quality during the crucial "last mile" of delivery. Many restaurants aim to keep the delivery period within 40 minutes, falling in line with FDA's recommendation that delivery windows remain fewer than two hours for cold foods (<90°F) or fewer than one hour for hot foods (>90°F) for categories that operate without supplementary packaging to minimize temperature abuse.

Enforcing this time frame proves challenging, Bratager says, and limited visibility into actual delivery durations exists. With fluctuating and unpredictable delivery demand, online grocery services are similarly challenged as they aim to standardize delivery periods.—*KA*

tions. Reusable packaging requires defined collection logistics and proper cleaning procedures.

Coolants, such as ice packs or dry ice, are chosen based on scientific principles and data, considering factors like transit time and temperature fluctuations. Dunnage fills voids, aids insulation, and protects contents during transportation. It shouldn't insulate food from coolant and must maintain sanitary quality.

Temperature control. Perishable ingredients like meats, dairy, and certain vegetables must be stored at specific temperatures to prevent bacterial growth, Dr. Fogle says. During transportation, inadequate refrigeration or insulation can lead to excessive temperature fluctuation, risking food safety.

According to the guidance document, "A DTC delivery company should identify the temperature requirements throughout transport and delivery based on regulatory requirements as well as the company's evaluation of its products, including their unique characteristics and uses ... a company should account for all possible variables that may compromise temperature control. With respect to transportation and delivery, for example, some businesses conduct same day or overnight delivery and can control the longest possible delivery time (e.g., by restricting delivery ZIP codes). Companies with less control over delivery times should account for this variability."

Physical and chemical contamination control. Materials used for packaging shouldn't introduce contamination and should be stored in a way that maintains cleanliness. Measures should prevent leakage and cross-contamination, particularly for packages containing raw meats. Food delivery companies must be cautious when delivering non-food items alongside food items and acknowledge allergens as chemical hazards, Dr. Fogle says.

Allergen control. Providing mechanisms for consumers to identify allergies during ordering is essential. Precautions should ensure that unpackaged food items remain free from potential allergen contact throughout packaging and delivery, Dr. Fogle says. Resources such as the FDA model Food Code offer additional information on allergens and associated risks, including appendices on food allergen labeling and food allergens as food safety hazards.

More to Chew On

Additional guidance on transporting food safely can be found in FDA's New Era of Smarter Food Safety blueprint, an initiative that focuses on leveraging technology, data analytics, and collaboration across the food industry to enhance food safety practices. This includes addressing challenges specific to meal kit and food delivery services, such as traceability, transportation, supply chain transparency, and real-time monitoring of temperature and sanitation, Dr. Chapman says.

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FDA is clearly aware of food safety issues with respect to these novel delivery mechanisms," Dr. Schaffner continues. "But to a certain extent, its hands are tied because they must operate under the current regulatory structure, which has some gaps with respect to these innovations."

—DONALD W. SCHAFFNER, PHD

A key component of New Era is FDA's final rule on requirements for traceability, often referred to as FSMA 204, because it implements section 204(d) of FDA's Food Safety Modernization Act (FSMA). "The essence of FSMA 204, which becomes effective in 2026, is to enact strong requirements for both forward and backward traceability for certain food items, with a goal of enabling much faster outbreak response if a serious food safety event occurs," Bradley says.

Alongside existing FDA and USDA guidance on recalls, this regulation establishes an expectation that meal kit and delivery services should maintain a trace-forward capability inclusive of last-mile consumer delivery. "Put simply, the job of meal kit providers doesn't end when a product is handed off to a carrier or delivery driver, which has meaningful implications for record keeping and process management going forward," Bradley says. "The industry will have some work to do in order to create the kind of transparent supply network required to meet it."

Furthermore, the third of four core elements in the New Era blueprint, "New Business Models and Retail Modernization," focuses on tech-enabled traceability and recognizes an evolution in the way food is produced and delivered to consumers. "FDA seeks to protect foods from contamination amid the expansion of e-commerce and other new business models," says Sara Bratager, senior food safety and traceability scientist at the Institute of Food Technologists in Chicago.

To achieve this, FDA outlines several key initiatives in the blueprint, such as collaborating with regulatory partners, and educating delivery services and consumers on proper food handling practices, and promoting the adoption of technology to monitor risk factors and drive safe product innovation.

Shortly after the release of the New Era blueprint, FDA held a summit on e-commerce to gain insight into how foods are sold through business-to-consumer e-commerce models in the United States and worldwide. Continued efforts are illustrated through the Core Element 3 web page.

In October 2021, FDA convened an e-commerce summit. "It represented a snapshot of current understanding and best practices," Dr. Schaffner says. "It's still a useful resource for companies looking to quickly get up to speed with this area of the food system."

"FDA is clearly aware of food safety issues with respect to these novel delivery mechanisms," Dr. Schaffner continues. "But, to a certain extent, its hands are tied because they must operate under the current regulatory structure, which has some gaps with respect to these innovations."

The Beef Industry Food Safety Council has also established best practices for DTC sales. "It's recognized that risk is influenced by the type of product being considered and suggests that re-evaluating risk should occur each time a product profile changes," Dr. Fogle says. "Expectations of packaging and distribution need to consider temperature control, allergens, and traceability."

Thoughts on Proceeding

Looking ahead, Bratager has identified several areas to focus on to improve the safety of food delivered by DTC and TPD services. Existing regulations for registering food businesses often categorize e-commerce alongside traditional brick-and-mortar retail establishments. "While this classification may be suitable for some businesses, it fails to address the nuances of all e-commerce actors," she says. "Operations such as meal kit fulfillment centers, which involve more handling and processing akin to manufacturing facilities, may fall through regulatory gaps," she says.

Additionally, point-of-sale labeling requirements designed for in-store operations don't adequately address the responsibility of online-to-consumer businesses to provide essential information to consumers at the point of sale, Bratager says. Clarification and guidance are needed to bridge these regulatory gaps and safeguard public health.

Furthermore, current foodborne illness tracking systems largely overlook business to consumer e-commerce categories, which limits the understanding of the risks posed by DTC and TPD services, Bratager says. For instance, the CDC's National Outbreak Reporting System dashboard includes some restaurant settings but omits crucial categories such as "restaurant delivery" and "online grocery." "Integrating these significant categories into foodborne illness reporting practices is essential for accurately assessing their risks and informing risk-based regulatory measures," she concludes. ■

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Standard Operating Procedures

Generating appropriate SOPs can drive improvement in food quality and safety behaviors among staff, and vice versa

BY **BOB LIJANA**

Many food manufacturing companies presume—and hope—that the safe quality foods (SQF) process will certify that their food is safe and of high quality. Hence, a very common approach is to follow the SQF code line by line to generate appropriate standard operating procedures (SOPs) and to generate document templates to match these SOPs. These documents are then filled out by employees in real time to prove that the food must, therefore, be safe. To clarify for those new to this arena: The SQF process is just one of many different certified processes to satisfy the food safety requirements of the Global Food Safety Initiative (GFSI).

Although these steps are necessary, they are woefully insufficient without a systematic approach to achieving consistent and self-improving food safety behaviors in the plant. Said another way, the goal is to improve food safety behaviors—continuously and organically. Hence, the SQF process is not an end in and of itself—especially not just getting an SQF score. Rather, it is a means to an end. Sustainable behaviors that ensure safe food drive cross-functional goals and training, and that allows even better food safety behaviors to become habits. Documentation provides the bookends to these behaviors. Even without complete and thorough documentation, improved behaviors are still the right thing to do to keep food safe.

A Common SQF Approach

I have seen the SQF scheme applied from rookie organizations (i.e., organizations with no food safety plan or process in place) to veteran organizations (those with successful SQF audits across many years) and have seen the SQF scheme applied to very dry products (powder blends), to very wet products (juices), and to products in between (deli salads). In all situations, a very common mindset is keeping a laser-sharp focus on developing SOPs and subsequent documentation (monitoring, verifying, validating) to prove that each step in the SQF code is being followed.

And, as we all know, if something is not written down, it "did not happen." Therefore, this regulatory principle drives the documentation mindset—easily accepted and understood by every-one in the organization, across all levels and functions. However, this ease of acceptance can be the very thing that drives a bias that gets in the way of changing behaviors. This mindset,"If the documents are in place, then we must be doing the right things," is, of course, not sufficient.

Another common belief is that it's easy to let the quality assurance (QA) organization (i.e., quality control, quality, food safety) lead the SQF effort independently—get it done, and report back when finished: As long as the company gets good scores, everything must be OK, right? But, if scores start falling and/or issues continue to occur, whose fault is it?

The Need for Documentation

Documents for food safety must be thorough, accurate, and effective. They must reflect truth—what is really going on. Not having proof of a manufacturing step or a verification measurement

can be a death knell that can result in a recall or regulatory action. Hence, documents are essential; this article is not intended to say otherwise. Further, since everyone needs to embrace food safety, and not just QA, this also applies to documentation. SOPs are not just a QA thing; they need buy-in from everyone in the organization who plays a role in the operation or in the information being documented. Not gaining buy-in for something as straightforward as an SOP makes it nearly impossible to drive behavioral changes.

SQF and Regulatory Demands for Behavior Change

Even though the rules seem to state that food safety is all about documentation, all regulations and guidelines point instead to a requirement for behavior change. Some examples follow (emphasis added):

- **A Culture of Food Safety, A Position Paper from the Global Food Safety Initiative (GFSI):** This entire treatise from the GFSI food safety culture working group is based on food safety culture being defined as "the shared values, beliefs, and norms that affect mind-set and behavior."
- **17 CFR 117.135:** The good manufacturing practices (GMPs) as published in the Code of Federal Regulations specify that preventive controls must be written and require an under-lying systemic approach. For example, each of the mandatory preventive controls (e.g., process, food allergen, sanitation) incorporates the phrase "controls include procedures, practices, and processes."
- **Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food:** FDA defines preventive controls very broadly: "procedures, practices, and processes." These three "p" words cover far more than just documents.
- **Ready-To-Eat Seafood Pathogen Control Guidance Manual:** This guidance from the National Fisheries Institute relates to preventing issues with seafood products. The manual states that "the primary cause of contamination is good manufacturing practices/sanitation."

SOPs are not just quality assurance regulations; they need buy-in from everyone in the organization who plays a role in the operation or in the information being documented.

- **SQF Food Safety Code for Manufacturing:** For "Management Commitment," the code has a mandatory element that the company "continually improve the site's food safety management system." Note use of the word "system" and not "documentation." Similarly, the code requires that senior management ensures that "food safety practices are ... adopted and maintained." Again, note use of the word "practices" and not "documentation." Finally, note the requirement for continuous improvement; this is very important.

The Need for Behavior Change and Continuous Improvement

A basic tenet is that behavior must be improved to affect real change in food safety practices, control, and outcomes. This then requires the proper organizational mindset. Leaving potential change only in the hands of the QA organization will not work in the long run. Simply telling employees to follow changed SOPs will not work either. And speaking of mindsets, to borrow a concept from Carol Dweck, PhD, in her book *Mindset* (Ballantine Books, 2008) the organization (starting with senior management) needs to adopt a "growth mindset"—that is, believing that the organization can improve. As Dr. Dweck notes, the process includes more than just effort. She contrasts the growth mindset with a fixed mindset in terms of people and parents, yet she maintains that these principles apply equally well to organizations.

As another analogy, consider the concepts of micro-optimization versus macro-optimization. A given function (e.g., QA) can do everything in its power to be superb at checking quality and ensuring that GMP behaviors are followed by employees. Similarly, another function (e.g., sanitation) can, in parallel, also do everything possible to ensure that its workers are handling chemicals safely and are following manufacturer recommendations for chemical contact time. Both are examples of micro-optimization, i.e., optimizing the inputs and outputs of single functions independent of other functions. But whose job is it to identify

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the highest risk piece of equipment and ensure that it is cleaned and sanitized properly?

By contrast, the key leadership in a company is focusing on optimizing the inputs and outputs of the entire organization to meet stakeholder needs (e.g., profits, consumer complaints, service). Optimizing the "macro" may even come at the expense of the optimization of a "micro." In the context of continual improvement of food safety behaviors, this may mean that decreased food safety risk requires more time from production to execute certain line changeovers, which minimizes the risk of allergen exposure. This runs counter to the typical production mindset (i.e., pounds per hour), but aligns perfectly with ensuring that the final product is safe.

Companies That "Got It"

Here are proven principles developed and used by food manufacturers that all had significant, but different, SQF issues and turned it all around with significant, but different, behavioral solutions.

One is a rookie organization that has never used a GFSI scheme before and has chosen SQF. They hired an SQF coordinator to write all the SOPs and then train everyone. The company failed its first gap audit miserably. The second company is a veteran organization that has been receiving good SQF scores across multiple plants, year over year. Overall scores were not increasing, however, and some plants were even seeing their scores decreasing. The third company is a veteran organization that has received good SQF scores in the past, but in the last five years found itself with scores decreasing every year so that now they were at risk of surveillance audits. This was a classic case of the leadership team wanting the QA organization to be solely responsible for the SQF output, while the rest of the organization kept doing what it was supposed to be doing (e.g., pounds per hour).

Each of these organizations turned its SQF scores around. In all cases, this took close to two years. Here are the principles that led to success:

1. **Have patience**. Changing employee behaviors takes time, and then it takes more time for the results to be manifested. This could take up to two annual audit cycles, even with all due urgency.
2. **Build cross-functional food safety teams**. Food safety (and quality) improvements cannot be driven solely by the QA/QC organization. Assume that "QA can do it all" is a road to perdition. Trying to implement behavioral changes in functional silos might optimize the "micro" but will fail at optimizing the "macro." This is especially true if QA is not directly reporting to top leadership in the company and/or if QA is not forthcoming with a truthful representation of the actual state of affairs on the plant floor. The latter is insidi-

Even though the rules seem to state that food safety is all about documentation, all regulations and guidelines point instead to a requirement for behavior change

ous, as the leadership of the company could easily be fooled into believing that food safety risks are minimal when they are seeing relatively 'high" SQF scores. In this regard, scores that are clearly decreasing year over year are a huge warning.

3. Build cross-functional corporate leadership. Similarly, although QA can lead the overall food safety team (and it probably should), other functional leaders of the organization (e.g., production, maintenance, purchasing) need to be actively involved. The best results were achieved in the examples above when the CEO/president held all leaders accountable for improved food safety results and when the CEO/president was personally involved.

matter what. Another way to put this is to look at the SQF score not as an endpoint, but rather as just a metric in the overall food safety auditing process to provide a snapshot of the organization's progress (or lack thereof) in improving its food safety culture and practices.

5. Maximize plant-to-plant consistencies. For companies with multiple plants, ensuring that all facilities are consistently putting food safety actions into place is extremely important. If plants are allowed to develop their programs independently (a common belief, since each plant can be different in product mix, equipment, infrastructure, and the like) then, by definition, best practices are not being reapplied

demands an organization's commitment to continual improvement, as does the GFSI Position Paper in its examples of increasing levels of maturity within an organization.

This is not easy work. It's actually much easier to simply revert to generating and changing SOPs; however, changing behaviors one step at a time rather than getting overwhelmed by trying to change everything immediately will lead to success.

Appropriate risk-based SOPs are the basis for action in a plant, and these are effective only if employees are properly trained (and retrained), and this training is only effective if the employees are documenting the right things at the right time, per the SOPs. If all of this happens effectively, behaviors are improved, and new habits are created. Processes and procedures will only succeed when behavior—and the resultant company culture—support them.

Documentation of food safety processes and procedures is critical to

Tips for Integrating an SOP into Your Organization

Tip 1: Figure out what behaviors you are trying to achieve, and then write the SOP to do so. Don't do it the other way around.

Tip 2: Get leaders from each function involved in food safety, not just the quality/food safety team.

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4. Don't focus on the numerical scores. The real goal is to identify food safety risks and decrease them. The way to do this is by focusing on the behaviors that need to be in place. SOPs, documentation, execution, and results will follow, as will improved SQF scores. Please note: A couple-point difference in the score year over year, one way or the other, does not mean that the underlying systems and behaviors are any better or worse. Keeping a focus on risks and proper behaviors will let you sleep at night, knowing that scores will consistently be in the 90s, no

across the corporation. Solutions include forming a food safety team comprising appropriate members from every plant (no matter the size or how "different" they claim to be) and/or creating a corporate food safety team to service each plant with common SOPs and accountabilities. Said another way, if each plant is allowed to operate their food safety system independently, then they might optimize the "micro," but this will likely at the expense of optimizing the "macro."

6. Focus on continual improvement. As noted above, the SQF code

minimizing regulatory risk. Equally important, if not more so, is aligning SOP development with the leadership necessary to change behaviors in the plant across all functions. Transforming improved behaviors into beneficial habits is tantamount to decreasing food safety risk. Lower risk means that everyone sleeps better at night, including the eventual consumer of the food.■

Lijana is a subject-matter expert for food safety of RTE foods, prepared meals, and pasteurized juices. He has 35+ years of food manufacturing experience. Reach him at boblijana@gmail.com.

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Pet Food Safety

How FDA regulates pet food, and how it's closely related to human food oversight

BY **LORI VALIGRA**

One in five U.S. households adopted a pet during the COVID-19 pandemic, according to the most recent statistics from the American Society for the Prevention of Cruelty to Animals, highlighting the importance of safe food for dogs and cats as they become part of the family for companionship, protection, and comfort.

People increasingly want a balanced diet derived from safe, high quality ingredients for both their pets and human family members, and both types of foods are regulated by FDA. But, there are some key differences that make food quality and safety for pet food challenging says Austin Therrell, PhD, executive director of the Association of American Feed Control Officials (AAFCO), a Champaign, Ill.-based nonprofit that guides state, federal, and international feed regulators with ingredient definitions, labels, and laboratory standards, adding, "Complete and balanced pet food is comparable to baby formula for humans in many ways [in that] in most cases our pets rely on the same source of food every day to meet all their nutritional needs."

He says that any nutrient imbalances in pet food can potentially cause deficiencies or toxicities that are food safety challenges. Therefore, he says, it's important for regulators to ensure that ingredients used in commercial pet foods have gone through the appropriate reviews to confirm that they are safe for their intended use and diet because animals have different needs at different ages.

The nutritional needs of dogs and cats also differ. "With pets mainly eating one brand of pet food that is complete and balanced, it is essential [that] all the nutrition they require for their species and life state is maintained in the product in every single batch," he says. "There have been several instances of recalls related to nutritional toxicities or deficiencies."

At the federal level, section 210(f) of the Federal Food, Drug, and Cosmetic Act defines food as articles intended for food or drink for man and other animals. There are similar definitions in title 21 of the Code of Federal Regulations parts 117 and 507. Dr. Therrell says that, while regulations for food for humans and for other animals are closely related, there are some big differences in nutritional and labeling requirements due to the number of different types of animals.

Cross Contamination, Other Risks

Another safety risk is potential sickness, because more pets are living in homes and acting as part of the family, even sleeping with their owners. People may feed their pets at the same time they are preparing their own food, increasing the risk of cross contamination between the foods. Their close proximity as family members puts humans and their animals at risk if the pet food is contaminated, Dr. Therrell says.

If pet food were contaminated with a zoonotic pathogen such as *Salmonella*, humans handling the food or those who are exposed to pets that consumed it could get sick even if the pet is not showing symptoms of salmonellosis, he adds, noting that children are particularly at risk. "Regulators have to account for more transmission pathways of any contaminants or adulterants in pet food," Dr. Therrell says. "The pet food industry has to consider many of the same risks that the human food industry does, if not more, because of the diversity of the animals consuming the products and the humans handling the products."

Another difference between animal and human food is regulations for allergens, which do not apply to pet food. Food ingredients rarely cause allergic reactions in pets, says Marissa Herchler Cohen, PhD, area specialized agent for animal food safety at North Carolina State University in Raleigh, N.C. Allergens are also not typically a consideration in

assessing exotic ingredients. They have to go through the same approval process at the FDA level with a food additive petition, be generally regarded as safe, or go through the AAFCO definition process, each of which shows the ingredient is proven to be safe for its intended use, she adds.

Imported ingredients are addressed through FSMA both in pet and human food using the Foreign Supplier Verification Program (FSVP). For countries with less stringent food safety rules than the United States, importers must evaluate their food safety system and ensure that it meets FSMA specifications. Imported ingredients from countries whose food safety systems are considered equal to or better than that in the U.S. require FSVP approval. Ways to comply with FSVP requirements include on-site audits of supplier facilities, documentation reviews, or product ingredient testing, depending on the nature of the facility, Dr. Cohen says.

Day to day, pet food producers must address different challenges depending on the type of food they are producing. Raw pet food manufacturers need to closely monitor temperature changes within their production to ensure that products do not thaw enough to create an environment where pathogens can thrive, she adds. Producers also must be careful about sourcing and storing ingredients to minimize the presence of pathogens.

Since the raw pet food industry has no kill step, there is potential for pathogens growth, Dr. Cohen says. Some raw food pet manufacturers are using methods such as high-pressure processing, a non-cooking method for destroying microorganisms that maintains the raw product. Consumers need to be made aware of the potential risks with feeding these diets and understand how to handle them safely, she adds.

States' Roles in Labeling

Regulations for labeling pet food can be inconsistent from state to state, which is challenging for producers that ship their products to different states; they must meet the labeling requirements in each state in which their product sells. FSMA federal regulations for pet food remain the same regardless of the state where the manufacturing occurs.

Each state can adopt all, some, or none of the AAFCO recommendations for labeling. There are some rules, however, that dictate what can and cannot appear on a label. Misleading information or claims cannot appear on a label—for example, "human grade" or "human quality"—nor can drug claims that a food or ingredient has a medical benefit. "The terms 'human grade' or 'human quality' only refer to products that are ready to eat and produced under the Current Good Manufacturing Practice regulations enforced by the FDA," says Dr. Cohen. They don't apply to raw pet food, she adds, because it generally is not ready to eat. Also, once a pet food is mixed with an ingredient that is not considered edible by humans, the end product cannot be considered "human grade," she says.

Dr. Therrell says there is a need for additional state feed laws. Some states accept the use of ingredients tentatively approved by AAFCO, while others require them to be "officially approved." Other states accept ingredients that are "self-affirmed GRAS" because they have qualified staff to review data.

PURR Act Aims to Streamline Regulations

Congress introduced a new act to streamline the federal regulatory process for pet food on February 15, 2024. H.R. 7380, the Pet Food Uniform Regulatory Reform Act of 2024, or PURR Act, has been widely supported by pet food manufacturers and the industry group, the Pet Food Institute, in Washington, D.C.

The act would prohibit state governments from directly or indirectly establishing or enforcing any authority on the marketing or labeling of pet food. It would place label and ingredient approvals in FDA hands. State agriculture departments still would oversee quality inspections and product registrations.

"We are supporting federal legislation that would replace the current inefficient patchwork approach between states and the federal government with consistent national standards that are predictable, clearly defined, and encourage innovation and speed to market," Dana Brooks, president of the Pet Food Institute (PFI), said in a statement.

Pet food makers produce nearly 10 million tons of food annually, and outdated regulations have made it difficult for pet food manufacturers nationwide to invest in research and development for new and improved products, said Rep. Jake LaTurner (R-Kansas), in a statement in February 2024 when PFI announced its support of the legislation. Rep. LaTurner, along with Henry Cuellar (D-Texas), Sharice Davids (D-Kansas), Josh Harder (D-Calif.), and Steve Womack (R-Ark.), sponsored the bipartisan legislation.

AAFCO, however, has concerns about the current version of the legislation, saying it could have negative impacts on consumer protection and reduce pet food label transparency. "State feed programs are the first line of defense protecting consumers from misleading or mislabeled pet food products," Dr. Therrell says. State regulators proactively inspect pet food labeling before products hit the market, he says, and ensure that marketing claims on the label are accurate and have scientific data to validate them. "Under the new PURR Act, this important layer of consumer protection would completely go away," he adds.

He says there are ways to improve efficiency and bring more innovation to the market, but it needs to be done in a safe and transparent manner and requires states to remain involved.

The PURR Act also could impact more than dog and cat food producers, Dr. Cohen says. Because it is specific to food for those animals, the legislation could increase the regulatory burden for producers who make dog and cat food, as well as livestock feed or pet foods for rabbits, rodents, and other small animals. Those manufacturers would have to comply with different regulations, as would ingredient processors and suppliers to both the dog and cat food industries, as well as to producers of food for other animals.

"Though having uniform expectations for labeling and expedited ingredient approval is helpful to the industry as a whole, I think there are some unintended consequences that should be considered," Dr. Cohen says. "There may be room for compromise." ■

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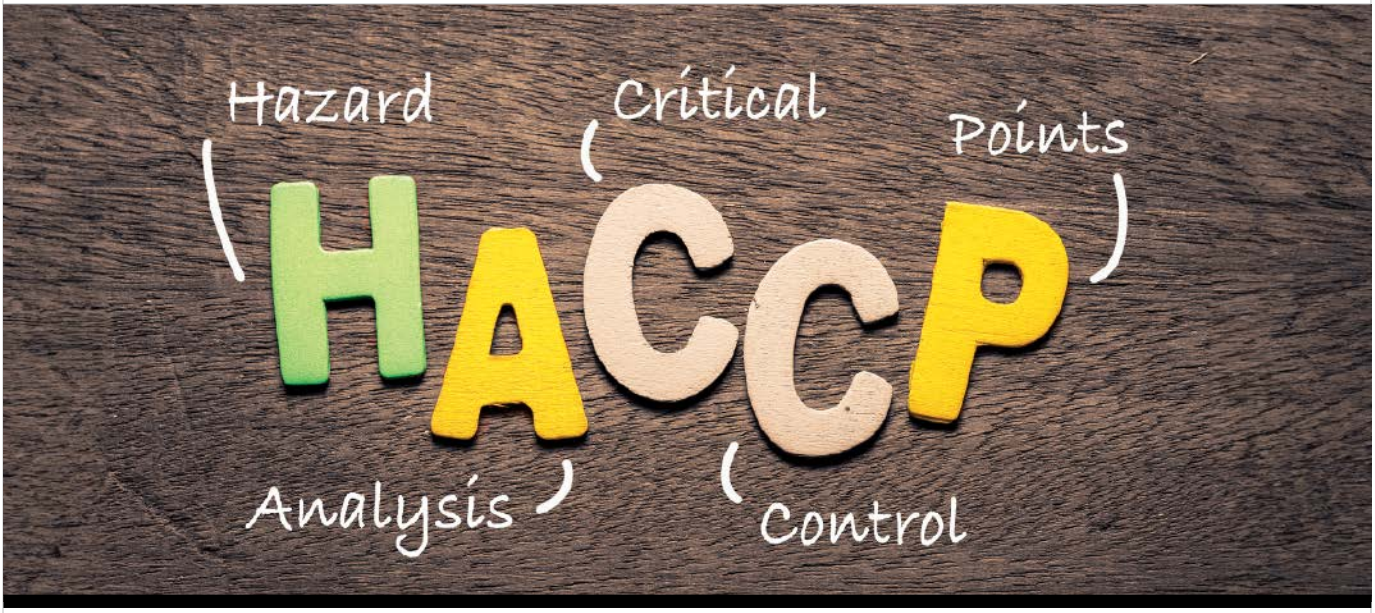

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HACCP for Food Facilities

Ensure quality and safety standards in food production

BY **STEVEN JOHN CUMPER**

The Hazard Analysis and Critical Control Points (HACCP) system serves as a frontline defense in the battle against foodborne illness, helping food facilities nationwide maintain high safety and quality standards. This proactive approach identifies and controls potential hazards at specific points during food production. The points below will help guide you in integrating this essential system into your food facility.

What Is HACCP?

HACCP is a structured and scientific approach to identifying and controlling potential hazards at specific points in the food production process. It matters significantly as it helps to prevent food safety issues before they occur, rather than relying on end-product testing alone.

This proactive method plays a central role in ensuring consumer safety and maintaining high standards of food quality. Companies that implement HACCP effectively demonstrate a strong commitment to producing safe and trustworthy products, thereby fostering trust with consumers and standing firm against the backdrop of rising food safety concerns globally.

The Importance of Implementing HACCP in Food Facilities

Implementing HACCP in food facilities holds paramount importance in today's food production landscape. HACCP stands as a rigorous, science-backed approach that pinpoints and controls potential threats during food processing. Instead of merely reacting to foodborne illnesses, this system emphasizes proactive prevention, reducing the risk of contamination at its source. In doing so, it offers facilities a reliable blueprint to consistently produce safe and high-quality products.

Consumer trust is a valuable asset and a robust HACCP system can bolster a brand's reputation. In an age where consumers are increasingly conscious of what they consume, integrating HACCP not only meets regulatory requirements but also aligns with the rising demand for transparency and commitment to health. And it's quite vital given that 9 in 10 Americans use the cleanliness of a food facility as a deciding factor for repeat purchases, according to USDA statistics.

Key Principles and Concepts

The HACCP system revolves around a set of distinct principles, each designed to ensure the utmost safety and quality in food production. By understanding and applying these HACCP principles, food facilities can rigorously guard against potential threats and uphold stringent standards of excellence.

Principle 1: Conduct a Hazard Analysis. At the heart of the HACCP system lies the initial step of conducting a comprehensive hazard analysis. This process involves identifying potential risks in the food production cycle, ranging from biological to chemical or physical threats. Recognizing these hazards early allows facilities to implement targeted measures, ensuring each product remains safe for consumption.

Principle 2: Determine Critical Control Points. Once potential hazards are identified, the next pivotal step is to pinpoint the critical control points (CCPs) in the process. These are stages where intervention can prevent, eliminate, or reduce a food safety risk to an acceptable level. Correctly identifying CCPs allows for targeted and effective control over

potential risks, ensuring a safer product. Examples of CCPs include:

- Temperature control: Ensuring foods reach safe temperatures during cooking and cooling processes.
- pH levels: Maintaining appropriate acidity levels to prevent bacterial growth.
- Cleaning protocols: Regular and thorough cleaning of surfaces and utensils to prevent cross-contamination.

Principle 3: Establish Critical Limits. After determining the CCPs, it's essential to set measurable and actionable critical limits for each point. These limits define the boundaries within which a food safety hazard can be controlled or eliminated. To set critical limits, facilities must define specific criteria that dictate the transition from safe to unsafe conditions for a product. These criteria can encompass a variety of aspects, including:

- pH values;
- Salt content;
- Sugar content; and
- Temperatures.

Each represents a physical, chemical, or procedural boundary to maintain product safety.

Principle 4: Establish Monitoring Procedures. These procedures actively track and record the CCPs to ensure they remain within the established critical limits at all times. Rigorous monitoring enables timely detection of deviations, facilitating immediate actions to correct any impending hazards and maintain the safety standards in the food production process.

Principle 5: Establish Corrective Actions. Food facilities must have clear corrective actions ready for implementation when deviations from the critical limits occur. This involves identifying the issue, taking steps to correct it, and recording the incident to prevent future occurrences. Corrective actions encompass three tiers:

- Immediate responses to restore process control;
- Short-term strategies to manage affected products effectively; and
- Long-term solutions to eliminate the root cause and prevent recurrence.

Principle 6: Establish Verification Procedures. To ensure that the HACCP system functions effectively, food facilities must set up verification procedures. These processes confirm that the established critical limits and corrective actions consistently work in practice.

Principle 7: Establish Documentation. An integral part of a robust HACCP system is maintaining comprehensive documentation. This involves recording every detail of the HACCP plan, from hazard analyses to monitoring records. Keeping thorough documentation not only offers a transparent trail for audits but also serves as a reference, ensuring continuous improvement and adherence to safety protocols over time.

Step-by-Step Guide

Here's a breakdown of the steps needed to facilitate a smooth initiation into this fundamental food safety system, fostering a culture of excellence and consumer trust in your food facility.

- Gather a Skilled Team: Assemble a team of professionals with diverse expertise to design and oversee the HACCP plan.
- Analyze Hazards: Identify all potential hazards in your production process, focusing on chemical, physical, and biological risks. Ensure all team members are trained in basic first aid and have access to first aid kits.
- Determine CCPs: Pinpoint critical stages in the process where intervention can prevent or reduce hazards.
- Establish Critical Limits: Set definitive boundaries at each CCP to control identified risks effectively.
- Develop Monitoring Procedures: Create regular check routines to ensure CCPs operate within the set critical limits.
- Define Corrective Actions: Outline clear strategies for immediate, short, and long-term actions to address any deviations from the plan.
- Setup Verification Procedures: Establish systems to verify the efficiency and effectiveness of the HACCP plan.
- Maintain Documentation: Keep detailed records of all processes and modifications to facilitate transparency and continuous improvement.

Common Challenges and Solutions in HACCP Implementation

HACCP is crucial for food safety but putting it in place can be tough for some food businesses. Knowing these challenges and getting ready for them, however, can make adopting the system smoother and more successful.

- **Limited resources:** Implementing a HACCP system can be costly and time consuming. To overcome this challenge, businesses can seek support from local government agencies, industry associations, and other organizations that provide funding or technical assistance.
- **Lack of knowledge and training:** HACCP requires specialized knowledge and training. To overcome this challenge, businesses can provide training to employees and hire consultants with expertise in implementation.
- **Resistance to change:** Bringing in a HACCP system can mean altering how things are currently done, and not everyone might be open to this. To get everyone on board, include employees in setting up the system and clearly explain how it will make things better.
- **Inadequate record-keeping:** HACCP requires accurate and complete record-keeping. To overcome this challenge, businesses can develop record-keeping procedures and provide training to employees on how to maintain records.
- **Failure to update the plan:** HACCP plans must be updated regularly to reflect changes in processes, products, and hazards. To overcome this challenge, businesses can establish a system for reviewing and updating the HACCP plan on a regular basis.

The Future of HACCP: Emerging Trends and Technologies

Emerging trends and technologies are expected to further enhance the effectiveness of the HACCP system. For example, artificial intelligence (AI) can enable more efficient and accurate monitoring of critical control points, reducing reliance on manual inspections. The use of sensors and internet of things (IoT) devices can also help monitor food safety parameters in real time. These emerging trends and technologies have the potential to revolutionize the way the HACCP system is implemented and improve food safety. ■

Cumper is the founder of Medshop. He has a background in biomedical science and osteopathic medicine.

Quality

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Sweet Science

Advancing quality control in confectionery production through continuous measurement

BY **KEVIN GREEN**

Imagine that disaster strikes on the production line just weeks before a candy company's famous treats flood grocery store shelves. Poor process controlled to crystallized sugar being added during a stage that destroyed the batch. When alarms sounded hours later, thousands of candy boxes had already been filled with grainy goods.

With their signature smoothness missing, the brand's sub par candies became an embarrassing and costly mistake. Lacking control of operational processes can hinder product excellence and negatively affect brand reputation; however, inline, accurate, repeatable process monitoring can prevent quality and safety catastrophes from the earliest stages of transforming raw materials to putting on the finishing touches.

When every sugar crystal, drop of syrup, and piece of candy demands accurate process monitoring, the art of cane and beet sugar processing, syrup production and confectionery production meets the science of measurement accuracy.

Precise Control from End to End

Every process involved in sweet treat production requires careful process control and measurement accuracy. Accurate, repeatable measurement of raw and in-process liquids at multiple processing steps empowers producers and processors to optimize disparate processes for maximum quality and efficiency within facilities.

Creating sugar from raw materials. Processing harvested sugarcane and sugar beets creates edible sugar. After it is extracted, the juice or syrup is purified to remove any contaminants or solid particles. Heating the clarified liquid helps evaporate excess water, leaving behind a concentrated blend of flavors and sugars. From there, sugar crystals form and separate from the remaining liquid after the liquid sugar solution cools through manipulation of temperature, humidity, and movement.

Strict processing parameter adherence prevents process and product quality deviations. Monitoring Brix levels during raw materials processing ensures an accurate seeding point and optimal crystallization. Inline refractometers continuously monitor the liquid concentration to carefully control the cooked solution and crystallization process. Going beyond the target Brix level risks crystal conglomeration, which can result in wasted batches and costly reprocessing.

Syrups preparation. Syrup producers then blend the concentrated sugar solutions with various flavors and other ingredients to create syrups varying in taste, texture, and appearance. Melters utilize elevated temperatures to achieve the desired solubility, viscosity, and chemistry. Accurate, reliable liquid concentration measurements minimize cooking time and ensure even blending. Even better, the ability to precisely control Brix levels supports the uniformity of the syrup mixture, guaranteeing consistency in taste, texture, and appearance. Confectionery manufacturers then buy the ready-made sugar or syrups to develop their products.

Confectionery manufacturing. Sugar confectionery and chocolate filling makers purchase processed sugars or syrups to create their products. These sugary treats include candies, chocolate fillings, chewing gum, marshmallows, and other desserts rich in sugar and carbohydrates. To maintain a specific shape, texture, flavor, consistency, and overall quality, the sugar content in the products must be concentrated at a desired level through cooking and evaporation of water.

Inline process refractometers provide continuous, real-time information throughout the pipeline to help determine the end point and ensure consistent product quality. Ideal for confectionery manufacturing and candy filling manufacturing machinery, these retractable instruments eliminate the need for sampling, prevent process disruptions, and save valuable processing time; however, measuring liquid concentration and Brix

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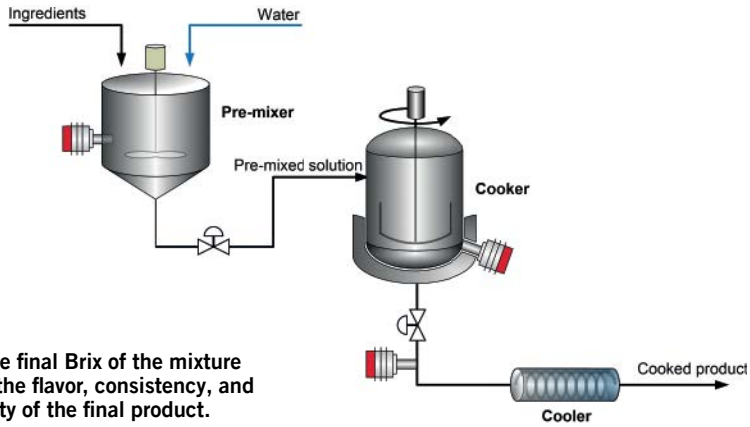

Figure 1. The final Brix of the mixture determines the flavor, consistency, and overall quality of the final product.

during different applications to craft the perfect sweet treat comes with its share of difficulties.

Inline, Continuous Measurement

Temperature, natural variations in the raw material-filled juice concentration and the sugar content of syrups and other confectioneries, and additional factors can impact the final product quality, thereby affecting customer satisfaction.

First, sugar processing involves multiple stages with varying temperature requirements exceeding 150°C. From melting to evaporation to refining, each process involves incredibly high heat, so refractometers must endure temperatures up to 150°C, or 300°F, for accurate functionality.

Sugar syrups, confections, and candy fillings often involve intricate mixtures of various ingredients, each contributing to the end product's overall flavor profile, appearance, consistency, and more. Measuring the liquid concentration of syrups, sugar confections and chocolate fillings throughout blending and mixing processes can be difficult—and unreliable—with a handheld refractometer and manual sampling dependent on human error.

With inline process refractometers reliably measuring the liquid phase and Brix across each process in real time, from processing to syrup prep to confectionery and filling production, decision makers can realize numerous advantages and produce top-grade products.

Liquid Concentration

While sugar processing, syrup preparation and candy-making processes all pose technical hurdles, the benefits of proper liquid concentration and Brix measurement benefits are substantial.

Improved product quality and consistency. Accurate measurements drive the creation of confections with unparalleled quality and consistency. Confection makers can create products that reliably meet or exceed consumer expectations by ensuring consistency across batches. Preventing under- or overconcentration eliminates flavor disruptions, strange textures, or variable melt points.

Substantial cost savings. Without accurate Brix data, manufacturers might struggle to stay within recommended material levels, quickly running through resources to adjust the sweetness or flavor. Fine-tuning various processes based on accurate liquid concentration and Brix measurements enables manufacturers to reduce waste and extract the maximum value from their materials. Optimized process control translates into sizable cost and ingredient savings.

Fewer labor-intensive tasks. Between manually monitoring the crystallization, evaporation, extraction, blending, mixing and other confectionery production processes, as well as taking samples and making adjustments in the event of deviations, each step from raw material processing to confirming the final product quality can be arduous and time-consuming. Automated inline measurements reduce the need to collect samples, run tests, and control processes manually to account for divergence.

Peace of mind. Overall, Brix gives confectioners a window into multiple process parameters beyond enhancing quality and efficiency. Reliable inline Brix measurement also provides invaluable peace of mind. Avoiding intermittent manual sampling eliminates risks associated with human error and contamination. Tight instrumentation regulation, within limits, ensures that any variations or deviations are caught instantly before they impact the end product. Additionally, by avoiding taking manual samples from product during heating or melting, technicians are no longer exposed to burns. Germs and particles introduced through manual sampling are also avoided.

As sugar mills and refineries, syrup producers, and various confectionery and filling makers depend on the reliability of refractometry for liquid concentration measurements in myriad applications, advanced continuous, inline measurement and monitoring systems maximize production efficiency, product quality, and profits by decreasing discarded ingredients, failed batches and repetitive manual steps.

Harness Innovation

Countless confectioners face catastrophic quality failures and losses stemming from poor process and quality control. Accuracy, repeatability, and safety unlocked by inline measurements are the keys to perfection in the world of candies and sweets.

Off-target concentration levels critically impact product quality, flavors, melt properties, and more. Inline process refractometers equip sugar processors, syrup preparers, and confection makers with a powerful tool to elevate their products, providing real-time, continuous monitoring of liquid concentration and allowing for instantaneous adjustments.

With inline refractometry, decision makers finally eradicate the crippling product quality issues and profit shortcomings rooted in poor concentration control. Precisely measuring edible sugar, sugar syrups, and confectionery creations at every stage translates directly into improved product quality and safety, reduced costs, and enhanced process control, all of which contributes to consumer delight, bite after bite. ■

Green is a regional sales manager at Vaisala, a provider of industrial measurement and instrumentation solutions for the food, beverage, and agriculture industries. He has a background in mechanical engineering and brings experience in instrumentation, sales, and product management. At Vaisala, he is primarily focused on measurement applications applied to food and beverage production.

In the Lab

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Prep Rally

Five crucial steps for keeping your food laboratory squeaky clean

BY **KELSEY KOTECKI**

Safety is the foundation of food quality. It's critical that any laboratory, manufacturing plant, and production facility that handles food maintains the highest standard of safety and follows careful procedures to the letter. There's no room for error; a single isolated shortcut can lead to disastrous results.

The USDA estimates that one in six Americans become sick from foodborne illness each year. Since New Year's Eve 2023 alone, the agency's Food Safety and Inspection Service (FSIS) site's Recalls and Public Health Alerts page (fsis.usda.gov) has featured multiple cross-contamination incidents. The alerts warn consumers away from specific food products, with concerns such as "possible *Salmonella* contamination," "possible *E. coli* contamination," and "possible extraneous material contamination."

Here are five safety steps that are absolute musts when it comes to preventing cross contamination and running a squeaky clean and safe laboratory.

1. Institute, Document, and Mandate Cleaning Procedures and Techniques

Everyone who steps foot in a lab space should be educated about agreed-upon safety procedures so they can be consistently followed. Methods must to be adhered to without fail; something that was "barely used" or "looks clean" is not acceptable.

- Prevent cross contamination by moving from high to low in a cleaning cycle, such as cleaning shelves above a workspace before the workspace itself.
- Avoid cleaning while testing is taking place.
- Keep equipment clean at all times, without exception. This means wiping down equipment after every use and scheduling regular deep cleaning as applicable.
- Establish and follow a cleaning checklist to prevent the risk of a missed or over-looked step. Checklists can also help keep others in the lab informed so there is no miscommunication.
- Know the risks of cross contamination and institute fail-safe cleaning methods. For example, pipettes are a leading cause of cross contamination within a lab setting. Best practice in equipment sanitation is to completely sterilize, not just clean, if possible. Sterilization can include disassembly and autoclaving for at least 20 minutes at 121°C (252°F). Each lab should have the procedures for the type of use and equipment outlined in detail.

2. Maintain Proper Air Circulation and Ventilation

Surfaces are not the only source of contaminants; the air within a closed room can harm employees and contaminate food or samples. Air handling in a food lab is not the same as air handling in a non–food-related commercial operation.

- Air handling in a food lab begins with a risk assessment to identify the unique risks within the building. For example, establishing positive air pressure zones is an important aspect of air flow design in a lab, but older buildings tend to have multiple exhaust fans, and exhaust fans create negative pressure zones.
- Hygienic design of air handling units (AHUs) and ducts is imperative to food safety. Employ an HVAC engineer to design a system with the appropriate number of air turns

per hour to fit the facility and its operations.
- Standard ventilation filters could be blowing contaminants in the lab. The level of food micro-sensitivity will dictate the level of filter standards and the type of filter needed.
- Air sampling can help to determine if the air within a lab space has high levels of microbiological activity.

3. Maintain a Tidy Workspace

While this may sound as if it goes without saying, workspaces that aren't carefully cleaned can harbor microorganisms, bacteria, and allergens. This can endanger employees within the lab and increase the risk of cross contamination.

- Labs should be organized so that expectations are crystal clear. A good rule to follow is the "5-S" process: sort, set in order, shine, standardize, and sustain.
- Dispose of expired products promptly and ensure that they don't come into contact with lab equipment or samples.
- Use only designated cleaning tools, solutions, and products, and create timetables to regularly switch them out.
- Clean the lab area in the moment and/or at regular intervals throughout the day (whichever comes first).
- Mandate and provide gloves and other personal protective equipment for all personnel to protect against cross contamination and contain lab testing within smaller areas.
- Utilize designated disposal bins for different testing waste, keeping biohazard waste and chemicals separate from non-biohazard waste.
- Design storage with safety in mind. Designated safety cabinets help workspaces stay organized, but they can also increase safety levels in a lab.

4. Keep Equipment in Pristine Condition

Faulty equipment escalates multiple risk factors—namely, biohazard risk, food safety risk, and personal safety risk. Even if equipment is perfectly clean, it can leak or create other messes that contribute to an unsafe lab if it's not in top condition.

- Document and communicate regular maintenance and inspection schedules. Equipment needs to be regularly tested and proactively inspected to verify its condition.
- Implement a robust system of checks and balances to ensure that maintenance activities are not isolated.
- Clean equipment according to the operator's manual. For example, distilled water and specialized cleaning agents may be required to keep equipment operational and prevent corrosion.
- Keep equipment free of dust, dirt, grease, and of course bacteria to improve performance and increase safety.
- Focus on preventative maintenance to extend the life of equipment productivity.

5. Test, Test, and Re-Test Within Your Lab Setting

Even the cleanest facilities need to ensure that their cleaning procedures are effective.

- Perform regular environmental testing to check the lab environment.
- An environmental monitoring program (EMP) can determine whether or not an environment is sanitary and verify if pathogen controls are working.
- Utilize negative control plates when using microbiological samples to check for cross contamination.
- Enlist food safety partners to assess tests within the lab (additional checks/balances).

The Cleaning Supply Chain

As in the distribution supply chain, one weak link in a laboratory can affect the entire chain. A lab may have extensive protocols in place to keep equipment clean and fully operable, but if a new employee is unfamiliar with the equipment, the process can start to break down.

Training at All Levels

Food labs and production facilities can amp up the level of safety by seeking supply chain partners that offer training on the equipment they provide, including usage, maintenance, and cleaning. At the other end of the chain, a food distributor, wholesaler, or retailer needs training to continue the chain of safety.

A Culture of Safety

Another important aspect to be aware of in a supply chain partner is company culture. While this can be harder to discern at first glance, there are red flags that can indicate that an organization's values may inadvertently affect the level of safety. For example, a focus on speed over all else may lead to shortcuts or hasty cleaning protocols that increase safety risk all the way across the chain.

> Everyone who steps foot in a lab space should be educated about agreed upon safety procedures so they can be consistently followed.

Consumer Safety

Both contract and in-house labs help prevent contamination and foodborne illnesses. As time goes on, their role in analyzing and mediating safety issues at a larger scale is increasing. In other words, food labs are equipped with the tools and expertise to perform analytical and preventive work that can support the entire food system, not just its direct partners.

A Look to the Future

Labs that are efficient, productive, and clean enable vendors and suppliers to provide safe food to the growing populations of consumers across the globe. Impeccable cleaning protocols can protect public safety and also allow food companies to channel resources toward growth initiatives, rather than using those same resources to cover the damaging expenses of recalls. With safety as a foundation, food labs play a central role in the future of our food systems. ■

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Manufacturing & Distribution

Gear Shift

Drive a responsive, sustainable, and efficient food supply chain amid rising food prices and a rapidly changing market

BY **ADRIAN WOOD**

The food and beverage (F&B) industry has always been highly responsive to changes in consumer behavior, but rising food prices have brought about new challenges, pushing manufacturers to search for new ways to adapt and remain competitive in a rapidly changing market.

Due to inflation and rising food prices, consumers are becoming more frugal in grocery spending, which can be seen in a variety of ways. A 2023 Deloitte study identified consumer food spending trends, such as buying based on what food was already at home and buying only what was essential in an effort to waste less food ("Consumers Confront Inflation with Frugality," published February 23, 2023, available at deloitte.com). Some consumers also switched to lower cost meats or meat cuts or cheaper store brands. This could have important strategic implications for retailers and F&B manufacturers, including pricing strategies, marketing, promotion, product mixes, and volume expectations.

Let's take a closer look at the food manufacturing supply chain and some of the key challenges it faces.

What Is Sustainable Food?

Consumer behavior is also changing due to an increasing demand for healthy and sustainable foods. Health-conscious consumers seek products that are high in nutrients and low in calories, and F&B manufacturers are responding by introducing new products to cater to this trend. This can range from plant-based foods to organic and non-GMO products and functional foods with health benefits beyond basic nutrition.

The growing demand for convenience is pushing manufacturers toward foods and beverages that are easy to prepare and consume on the go. Some examples of ready-to-eat and ready-to-drink products include pre-packaged salads, protein bars, and energy drinks; however, rising commodity prices are putting pressure on manufacturers to find ways to reduce costs while maintaining quality, because raising product prices could lead to a loss of customers. In response, some manufacturers are turning to cheaper alternatives, such as:

- Using alternative protein sources such as peas or insects;
- Reducing portion sizes; and
- Changing product packaging to save costs.

The other way manufacturers can adapt to rising food prices is by focusing on production efficiency and sustainability, which can be done by investing in new technologies and processes to help to reduce waste and conserve resources. For example, some companies have implemented sustainable packaging solutions that use biodegradable materials to reduce their environmental impact.

> Unlocking improved supply chain visibility and agility is only possible when F&B manufacturers commence the digitalization of manufacturing and operations.

The effective implementation of sustainability goals on emissions, circularity, waste reduction, and the recyclability of materials requires a transformation of company operations spanning the entire supply chain, a key part of which is digital transformation. F&B manufacturers that can quickly accept this reality and transform their operations are well positioned to achieve greater efficiency and drive a competitive advantage in their industry.

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Cool Down

Cold brew coffee safety involves stringent storage practices to mitigate the risk of bacterial growth

BY **KEITH LORIA**

Cold brew coffee's popularity has surged in recent years, but it occasionally poses some food safety hurdles. Although generally safe for consumption, cold brew coffee is not immune to contamination risks.

"Cold brew has been massively growing in popularity over the years. It was virtually unknown 10 to 15 years ago, whereas now nearly 80% of adults have heard of it, and around one out of five drank a cold brew in the past week," says Mark Corey, PhD, director of science and policy for the National Coffee Association (NCA).

Brandon Clendenen, a safety quality food (SQF) practitioner for Cold Coffee Laboratories and former director of cold brew for Press Coffee Roasters, specializes in cold coffee production and food safety, and says that it's a challenging industry from a food safety standpoint. "The biggest issue is that cold brewing as a whole is a low-acid product, which requires certain handling," he says. "If you don't have strict procedures and an understanding of critical control points, you are putting the product at risk for a contamination."

It's common practice to brew at room temperature, Clendenen says, which gives him a lot of concern, especially with the rapid increase in cold brew production.

Dr. Corey adds that, because cold brew is a low-acid food that can sometimes be held and distributed in packaging with an air-tight seal (such as a keg), manufacturers and brewers face specific challenges and must take great care with cold brew safety. "While contamination issues with cold brew are very rare, bacterial or other contamination could arise if conditions are not carefully man-aged according to the FDA regulations and industry best practices," he adds.

At the Plant

Ready-to-drink (RTD) cold brew is brewed at a manufacturing plant and bottled in aseptic conditions, having undergone a time/temperature heating step to make it commercially sterile. This destroys pathogens and is tightly regulated by FDA's low-acid food regulations.

NCA's Cold Brew Toolkit for industry provides detailed guidance for manufacturers on these issues. "Cold brew manufacturers are subject to the Food Safety Modernization Act (FSMA), which requires cold brew manufacturers to comply with a wide range of regulations and practices, including conducting hazard analyses and implementing current Good Manufacturing Practices (cGMP)," Dr. Corey says.

Legally, Clendenen notes that many of the procedures sit on the manufacturing side of the cold brew journey, not the retail side.

Retail Challenges

Typically, retail cold brew is brewed on-site overnight, using roasted ground coffee and filtered water in pre-sanitized containers at temperatures that range from room temperature (~70°F) to refrigeration (~40°F). It can then be stored for up to seven days from the date of production, depending on product characteristics and local regulatory requirements.

"There has been a lot of confusion in how retail cold brew should be regulated," Dr. Corey says. "Health inspectors from across the country will often refer to FDA's Food Code or their own state or local equivalent to regulate retailers on cold brew safety and compliance. Since the Food Code is a model that health inspectors can interpret and use at their discretion, this can create inconsistencies in how regulations are enforced across jurisdictions."

For instance, health inspectors may at times consider retail cold brew to be a TCS food, referring to FDA's category of time/temperature control for safety foods, where a cooking step is required

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(Continued from p. 33)
to destroy pathogens; this is unless safety data, such as those found in a product assessment, can be shown that demonstrates that neither pathogens nor toxins will form in cold brew evaluated over storage.

"In order to further minimize risk, a health inspector may also require cold brew stored in an air-tight container such as a keg to be considered a reduced oxygen packaging (ROP) process," Dr. Corey says. "With a few exceptions, they may also require a HACCP and variance depending on the circumstances. In a retail environment, the inspector could either require the cold brew to be stored for less than 48 hours, or for it to be discarded, removed from the package, or unsealed."

Krzysztof Barabosz, co-founder and head of coffee for Poland-based Hard Beans roastery, notes that at the retail level, ensuring food safety with cold brew coffee involves maintaining stringent storage practices to mitigate the risk of bacterial growth. "Proper refrigeration at optimal temperatures is necessary to prevent the spread of pathogens in the beverage," he says. "Additionally, potential contamination from handling by staff and customers appears to be a significant risk factor. Instances of poor hygiene practices, such as touching a cold drink dispenser tap with unwashed hands, can introduce harmful bacteria into the drink, compromising its safety."

Furthermore, the possibility of cross-contamination heightens if cold brew coffee is stored or served in close proximity to other food items that might harbor pathogens, necessitating careful separation and storage protocols to maintain the integrity of the product.

While not universally mandatory, health inspectors can require a HACCP plan for a retailer's cold brew program. "Health inspectors may interpret regulations to require a HACCP framework if retail cold brew is brewed, held, and served above 41°F, or if the dispensed cold brew is held in a keg or other closed container with an airtight lid for more than 48 hours," Dr. Corey says. "If the cold brew is refrigerated, held in a container that allows air exchange, and dated less than seven days after production, it's unlikely that a health inspector would require a HACCP plan. But it's always a good idea to have one, just in case."

When it comes to regulations, the retail environment is more challenging, as currently no federal food code specific to cold brew coffee exists. "Instead, health inspectors are left to interpret and enforce food code requirements based on their own assessments, creating a proverbial patchwork of code enforcement across jurisdictions," Dr. Corey says. "This means that business owners and local and regional health inspectors can sometimes face challenges interpreting and applying food code standards."

While contamination issues with cold brew are very rare, bacterial or other contamination could arise if conditions are not carefully managed according to the FDA regulations and industry best practices.

—MARK COREY, PHD

Possible Pathogens

Contamination issues with cold brew are very rare as unsweetened, plain cold brew lacks nutrients for most organisms to grow; however, given the right conditions, cold brew's low-acid pH and placement in airtight packaging could give an opportunity for unwanted bacteria to grow. "The pathogen *Clostridium botulinum* is the one we tend to think about most, particularly if cold brew is stored in an airtight container for more than 48 hours and above 41°F," Clendenen says. "You have to control this with cold chain or other preventative measures."

There is limited research on this, but microbes such as *E. coli*, *Listeria monocytogenes*, *Salmonella*, *Staphylococcus aureus*, and *Bacillus cereus* could also potentially impact low-acid foods stored in low-oxygen environments if not produced following food safety regulations and industry best practices, Dr. Corey says.

"There definitely needs to be more research done on cold brew and coffee as a whole," Clendenen adds.

What's Ahead

Alongside its growing popularity comes a need to strengthen the regulatory framework to address cold brew's specific conditions. "The development of a robust policy framework for cold brew coffee is urgent, necessitating a science-driven approach to both food safety and quality assurance," Barabosz says. "Such a policy should define precise standards governing the entire production continuum, covering aspects from initial production to storage, handling, and distribution. This holistic approach aims to reduce the potential for microbial contamination and maintain the safety of the final product.

Key elements of this policy should include the implementation of rigorous monitoring protocols, regular testing schemes, and comprehensive audit mechanisms at manufacturing plants and retail outlets. "These measures are critical not only to ensure compliance with applicable food safety regulations, but also to strengthen and maintain consumer confidence in the integrity of cold brew coffee products," Barabosz adds.

NCA is working with the Conference for Food Protection, a nonprofit organization comprising health inspectors, researchers, and industry volunteers who collaborate to develop guidance for health inspectors and retailers on the safety and compliance of retail cold brew. "Specific food code guidance would be helpful to retailers, as it would limit room for error in interpreting compliance requirements for safe cold brew preparation and storage," Dr. Corey says. "Thankfully, contamination issues with cold brew are very rare, but when it comes to ensuring food safety, we can't be too careful. Further developing cold brew regulations would be helpful for the continued success of the cold brew category overall."■

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The investigators concluded that, when troubleshooting elevated LPC, it is beneficial to know what the predominant type of thermoduric bacteria are that are contributing to the LPC. "Overall, our research shows that organic raw milk quality is very good, but some producers occasionally deal with high bacteria levels, and often it can take a lot of time and resources to resolve those issues," Dr. Martin says. "So, when a farmer is dealing with this issue, it is a big problem for them."

FDA Says Applesauce Contamination May Have Been Deliberate

FDA has confirmed that lead and chromium detected in the cinnamon in applesauce pouches imported from Ecuador are from lead chromate. Three brands of applesauce pouches, manufactured in Ecuador and sold under WanaBana, Weis, and Schnucks brands, were recalled last November due to lead contamination.

Historically, lead chromate has been illegally added to certain spices increase to their weight and enhance their color, which increases the monetary value of the adulterated spices, the agency said in a February 29, 2024 statement. FDA's leading hypothesis remains that this was likely an act of economically motivated adulteration.

FDA has limited authority over foreign ingredient suppliers who do not directly ship product to the U.S. This is because their food undergoes further manufacturing/processing prior to export. Therefore, FDA has limited ability to take direct action with Negasmart, the supplier of cinnamon to Austrofoods, or Carlos Aguilera, the processor of the cinnamon sticks.

Ecuadorian officials in Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) have reported that Carlos Aguilera of Ecuador, is the likely source of contamination and is not in operation at this time.

The investigation is ongoing. ■

Rare Case of Bird Flu Detected in Dairy Worker in Texas

BY **KEITH LORIA**

A Texas dairy worker has tested positive for the highly pathogenic avian influenza (HPAI) H5N1, according to the CDC. The person inflicted has a mild case and is believed to be just the second human ever to have contracted the virus.

The news comes on the heels of USDA confirming detection of HPAI in seven dairy herds in Texas, two in Kansas, and one a piece in Idaho, Michigan, and New Mexico. The National Veterinary Services Laboratories is performing additional tests on presumptive positive results from Kansas, New Mexico, Ohio, and Texas.

"This infection does not change the H5N1 bird flu human health risk assessment for the U.S. general public, which CDC considers to be low," USDA said in a statement.

Richard Webby, PhD, director of the World Health Organization Collaborating Centre for Studies on the Ecology of Influenza in Animals and Birds, and a virologist at St. Jude Children's Research Hospital, tells Food Quality & Safety that dairy herd infections are extremely rare. "There were some hints of data that suggested cows could be sporadically infected with influenza A viruses, but many, including me, never thought of cows as likely hosts of the virus," he says. "No one knows how the cows got infected and how it is moving between them now. There were reports of sick birds on the initial farms, but how the virus got from there to cows is unclear. If we can understand how the virus is moving, we can likely do many things to reduce the risk."

He notes that this virus remains very much a bird virus, even after replicating in cows. As such, the risk to humans is low. "It is of course higher in those with close contact with the sick animals," Dr. Webby adds. "Risk to the general population is very low, rock to workers is low, but certainly not zero, as highlighted by the one conjunctivitis case."

A joint statement released by the National Milk Producers Federation, the International Dairy Foods Association, the U.S. Dairy Export Council, and Dairy Management Inc., noted that routine testing and well-established protocols for U.S. dairy will continue to ensure that only safe milk enters the food supply. "In keeping with the federal Grade A Pasteurized Milk Ordinance (PMO), milk from sick cows must be collected separately and is not allowed to enter the food supply chain," the statement reads. "This means affected dairy cows are segregated, as is normal practice with any animal health concern, and their milk does not enter the food supply."

Since 2022, HPAI has been detected in wild, commercial, and hobbyist bird flocks in more than 82 million birds across 48 states and 512 counties, according to the CDC. ■

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Challenges and Solutions

What are the must-haves for making innovations and sustainability happen in the consumer products sector?

Manufacturing and operations technology: Modern digital solutions can help F&B manufacturers make data-driven decisions better and faster, while implementing more sustainable practices. This transformation is long overdue, as the continued use of legacy planning tools, systems, and processes has led some companies to lag behind the current pace of innovation. Embracing digital and automated processes will enable increased traceability of ingredients and improved inventory monitoring for faster and more efficient processing. Unlocking improved supply chain visibility and agility is only possible when F&B manufacturers commence the digitalization of manufacturing and operations.

Supply chain planning and execution: Supply chain innovation is now a necessity for the F&B industry to gain improved visibility and collaborative planning across the value network. This requires all stakeholders, from farmers to suppliers, manufacturers, and downstream users, to align strategies to drive more efficient and sustainable production. Given the current volatile state of the industry, companies need accurate demand and supply planning so they can create lean plans and make data-driven decisions based on simulated scenarios to achieve outcomes aligned with organizational objectives.

Daily disruptions to operations and business: Some of the daily disruptions food manufacturers face include production timeline pressures, equipment downtime, ingredient shelf life, stringent regulations, and risk of contamination. Adding to this complexity are external factors such as fluctuating commodity prices from climate or geopolitical events as well as shifting market demand, all of which make it difficult to control operating costs and maximize profits. To overcome these challenges, F&B companies need an integrated platform approach that enables them to optimize production, scheduling, and execution, giving them the leverage they need to drive increased efficiency—and better profits—to gain a competitive advantage.

Modern digital solutions can help F&B manufacturers make data-driven decisions better and faster, while implementing more sustainable practices.

Tackle Complexity in F&B Manufacturing with Confidence

The F&B industry is facing an increasingly challenging business climate due to changes in consumer behavior and rising food prices, which forward-thinking companies could successfully overcome by:

- Introducing products that meet changing consumer needs;
- Reducing costs by using alternative ingredients; and
- Focusing on production efficiency and sustainability.

To adapt and thrive in this ever-evolving market, F&B producers require the capability to integrate the different planning levels, departments, and teams within a supply chain. With the right solution, producers should have the ability to see the impact of every planning decision on fulfillment levels, inventory levels, customer satisfaction, and profit margins, empowering companies to make the best decisions and seize opportunities for efficiency gains.

Transform for a Future-Ready Value Network

To transform how you plan your supply chain, you need a comprehensive virtual twin that covers the entire product development process, from conceptualization to production and distribution. This holistic virtual twin experience—augmented with optimization technology—is part of a smart, integrated system that helps you adapt to any market condition and overcome critical challenges. With planning algorithms that consider all planning horizons (strategic, tactical, and operational), you can empower your supply chain with the agility and flexibility to better meet changing business needs and mitigate disruptions. ■

Wood has been the director of strategic business development for DELMIA at Dassault Systèmes since 2019.

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NEW PRODUCTS

Portable Mixers

Indoco Quic Mixers provide a portable, lightweight solution for mixing materials in 5-gallon pails. A ring mount provides a low center of gravity for steady mixing in open-topped or closed 5-gallon pails. Air or electric motors are available, and all models are supplied with quick-change coupler and shaft design featuring a shaft pin that locks in place during rotation. The single-phase electric motor option operates at a fixed speed of 1750 rpm. The newest model in the product line, the MVS-Q, features variable speed control from 35-1750 rpm. Indoco Quic mixers can be used for mixing colorants into paint, remixing settled materials, blending powders into liquids, and other general purpose mixing applications in 5-gallon pails. **Indoco, indoco.com.**

Pneumatic Component

Norgren air preparation products currently offered by Automation24 include regulators, filters, combination units (filter/regulator/lubricator), valves, and accessories. These products are built to overcome the challenges of using compressed air. The Norgren Excelon Plus quarter inch PTF combination unit combines several system-critical components: a 40 µm filter for particle and moisture removal, a high-performance pressure regulator, and a highly effective lubricator. The combination of these elements ensures compressed air control while protecting sensitive equipment and extending the life of system components. **Automation24, automation24.com.**

Industrial Camera

Opticom Tech is offering a CC04-IP5MV3 camera, an upgrade to the CC04-IP3MV camera. The new CC04 camera offers a higher resolution than its predecessor—5 megapixel compared to 3 MP. It also supports artificial intelligence functions such as object detection, intrusion detection, line crossing, and object counting. The camera is NDAA compliant, uses the ONVIF protocol and can withstand high-vibration, hazardous, and controlled environments. It can also withstand direct hits by logs, boards, rocks, and other objects, making it compatible for industrial facilities. **Opticom Tech, opticomtech.com.**

Ductless Workstation

The MicroFlow III is a Class 1 ductless carbon filtered workstation equipped with particle pre-filter and Activated Carbon filtration ideal for fumes, odors, and non-hazardous chemical vapors. Dimensions are 24” wide X 20.75” high X 24” deep. It is self contained with an integral recessed work surface to contain spills. A clear viewing sash surrounds the work area for user protection. The sash can be conformed for use with a microscope and is removable. Variable speed fan control allows for high speed 100f/m air flow through the sash opening, or medium and low flow for sensitive operations. The hood is available with a mobile table. **Hemco, hemcocorp.com.**

COURTESY OF INDOCO / AUTOMATION24 / OPTICOM TECH / HEMCO

CO_2 Compressor

The HGX56 CO_2 T, provides a solution for industrial and commercial refrigeration, including cold storage, as well as for large industrial heat pumps. With a 6-cylinder capacity, customers can reduce the number of compressors in their system, resulting in lower system complexity and investment costs. With the approaching HFC phasedown and transition to natural refrigerants, the HGX56 CO_2 T transcritical compressor range is designed for demanding conditions with natural refrigerant R744 in commercial and industrial applications. The expansion to 6-cylinder capacity allows for a wider spread and faster uptake of large CO_2 heat pumps and industrial refrigeration systems. Additional benefits are low noise and vibration, a compact and lightweight design, and a minimal oil carry-over rate**. Danfoss, danfoss.com.**

Protein Analyzer System

Agilent Technologies has released an automated parallel capillary electrophoresis system for protein analysis. The Agilent ProteoAnalyzer system is designed to simplify the efficiency of analyzing complex protein mixtures. Capillary electrophoresis (CE) has established itself as an indispensable tool for protein separation, as it offers rapid, high-resolution analysis with minimal sample consumption. Automating the separation and data processing, and simplifying sample preparation steps streamlines the analysis workflow. The system also can analyze a wide range of sample types. **Agilent Technologies, agilent.com.**

Metal Detector

The Profile Advantage pipeline metal detector inspects liquids, slurries, and purees for metal contamination. Accompanied by a diverter valve reject device, this pipeline system automatically transfers rejected product to a diversion bin for analysis to help ensure food safety while maximizing yields. The new conveyor, designed for the meat/protein industries, features stainless steel construction, toolless removable rollers and skid rails, cable trays and pigtails for cable management, captive hardware and an optional magnetic drive for energy efficiency. It can withstand harsh washdowns for sanitation and longevity. **Mettler Toledo, mt.com/pi.**

COURTESY OF DANFOSS / AGILENT TECHNOLOGIES / METTLER TOLEDO / EAGLE PRODUCT INSPECTION

X-Ray Inspection System

Eagle Product Inspection has launched a hygienically constructed inspection system designed to maximize product throughput while ensuring that safety standards are met. The machine is equipped with image analysis software, SimulTask PRO, and enhanced dual energy detector, PXT, to deliver bone and metal detection, reduce false rejects, and minimize operational challenges related to manual labor. Its dual lanes can run up to 120 pieces per lane per minute. **Eagle Product Inspection, eaglepi.com.**

SCIENTIFIC FINDINGS

For access to the complete journal articles mentioned below, go to "Food Science Research" in the April/May 2024 issue at foodqualityandsafety.com, or type the headline of the article into the website's search box.

Novel Animal Product Substitutes

Many consumers are adopting plant-centric diets to address the adverse effects of livestock production on the environment, health, and animal welfare. Processed plant-based foods, including animal product analogs (such as meat, seafood, egg, or dairy analogs) and traditional animal product substitutes (such as tofu, seitan, or tempeh), may not be desirable to a broad spectrum of consumers. This article introduces a new category of plant-based foods specifically designed to overcome the limitations of current animal product analogs and substitutes: novel animal product substitutes (NAPS). NAPS are designed to contain high levels of nutrients to be encouraged (such as proteins, omega-3 fatty acids, dietary fibers, vitamins, and minerals) and low levels of nutrients to be discouraged (such as salt, sugar, and saturated fat). Moreover, they may be designed to have a wide range of appearances, textures, mouthfeels, and flavors. Consequently, there is great flexibility in creating NAPS that could be eaten in situations where animal products are normally consumed, for example, with pasta, rice, potatoes, bread, soups, or salads. This article reviews the science behind the formulation of NAPS, highlights factors impacting their appearance, texture, flavor, and nutritional profile, and discusses methods that can be used to formulate, produce, and characterize them. Finally, it stresses the need for further studies on this new category of foods, especially on their sensory and consumer aspects. ***Comprehensive Reviews in Food Science and Food Safety*. Published March 29, 2024. doi: 10.1111/1541-4337.13330**.

Multiple-Frequency Ultrasound for the Inactivation of Microorganisms on Food

A multiple-frequency ultrasound (MFU) technique is proficient in enhancing the effect of acoustic cavitation when compared with a single-frequency ultrasound. This comprehensive review delves into the complex field of MFU and its profound impact on microbial inactivation in food processing. The exploration begins with an intricate examination of the mechanism of power ultrasound, elucidating the intricate interplay of acoustic cavitation and its diverse effects. Subsequently, the mechanism of MFU was provided, which is basically the enhanced cavitation obtained during its application. Delving into the core mechanisms of MFU, the review navigates through microbial inactivation, unraveling the ways in which MFU disrupts and eliminates microorganisms. The exploration extends to the synergistic potential of combined applications, where MFU is applied with other treatment techniques to enhance microbial inactivation. Beyond its microbial inactivation prowess, the review meticulously explores the far-reaching effects of MFU on the nutritional and quality attributes of food products. Furthermore, the diverse applications of MFU were also reviewed. In addition, limitations and adverse effects, emphasizing the importance of optimizing parameters to balance microbial safety and food quality, are also discussed. ***Journal of Food Process Engineering*. 2024;47:e14587**.

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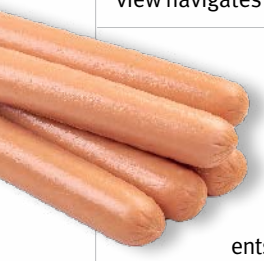
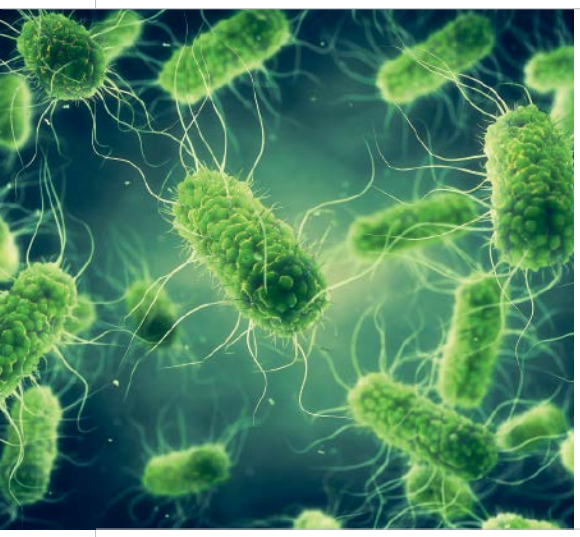


Designing Healthier and More Sustainable Ultraprocessed Foods

The food industry has been extremely successful in creating a broad range of delicious, affordable, convenient, and safe food and beverage products. However, many of these products are considered to be ultraprocessed foods (UPFs) that contain ingredients and are processed in a manner that may cause adverse health effects. This review article introduces the concept of UPFs and briefly discusses food products that fall into this category, including beverages, baked goods, snacks, confectionery, prepared meals, dressings, sauces, spreads, and processed meat and meat analogs. It then discusses correlations between consumption levels of UPFs and diet-related chronic diseases, such as obesity and diabetes. The different reasons for the proposed ability of UPFs to increase the risk of these chronic diseases are then critically assessed, including displacement of whole foods, high energy densities, missing phytochemicals, contamination with packaging chemicals, hyperpalatability, harmful additives, rapid ingestion and digestion, and toxic reaction products. Then, potential strategies to overcome the current problems with UPFs are presented. The central argument is that it may be possible to reformulate and reengineer many UPFs to improve their healthiness and sustainability. ***Comprehensive Reviews in Food Science and Food Safety*. Published March 24, 2024. doi: 10.1111/1541-4337.13331.**



Susceptibility of *Salmonella* Typhimurium Dry Surface Biofilms to Disinfection

In food preparation and manufacturing environments, surfaces contaminated with *Salmonella* can lead to outbreaks of salmonellosis. These authors hypothesize that *Salmonella* resides on dry surfaces in a biofilm form leading to potential environmental persistence and transfer following contact. This is the first study reporting that *S. Typhimurium* can form dry surface biofilm (DSB). Six disinfectants commonly used in the food industry were evaluated for their efficacy against the DSB. The two most efficacious formulations reduced bacterial viability in DSB by ›99.99% when combined with mechanical removal. Five out of six formulations significantly reduced bacterial transfer when combined with wiping. Complete eradication of *S. Typhimurium* DSB was challenging, and mechanical removal was essential to produce a ›99.99% reduction in bacterial viability within DSB. This study highlights a potential mode of survival of *S. Typhimurium* on food-contact surfaces and DSB challenges for disinfection. ***Journal of Food Safety.*** **2024;44:e13117.**

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Whey Protein Hydrolysates and Infant Formulas

Whey protein hydrolysates are recognized for their substantial functional and biological properties. Their high digestibility and amino acid composition make them a valuable ingredient to hydrolyzed whey infant formulas, enhancing both product functionality and nutritional values for infant growth. It is important to understand the functional and biological properties of whey protein hydrolysates for their applications in infant formula systems. This review explored preparation methods of whey protein hydrolysates for infant formula-based applications. The effects of whey protein hydrolysate on the physicochemical and biological properties of hydrolyzed whey infant formulas were summarized. The influences of whey protein hydrolysates on the functional and nutritional properties of formulas from manufacturing to infant consumption were discussed. Whey protein hydrolysates are crucial components in the preparation of infant formula, tailored to meet the functional and nutritional demands of the product. The selection of enzyme types and hydrolysis parameters is decisive for obtaining "optimal" whey protein hydrolysates that match the intended characteristics. "Optimal" whey protein hydrolysates offer diverse functionalities, including solubility, emulsification, and production stability to hydrolyzed whey infant formulas during manufacturing processes and formulations. They simultaneously promote protein digestibility, infant growth, and other potential health benefits. Overall, the precise selection of enzymes and hydrolysis parameters in the production of whey protein hydrolysates is crucial in achieving the desired characteristics and functional benefits for hydrolyzed whey infant formulas, making them

critical in the development of infant nutrition products. ***Comprehensive Reviews in Food Science and Food Safety.*** **Published April 5, 2024. doi: 10.1111/1541-4337.13337.**

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Freeze Concentration Can Impact on Beer Characteristics

Freeze concentration (FC), a low-cost alternative technology to separate and concentrate high-value compounds, was applied to three distinct craft ale beer styles—witbier, bitter, and porter—to investigate its impact on vital beer statistics. A central composite design with freezing temperature and ice fraction as factors was employed, with response surface analysis revealing significant effects on the average ice growth rate, concentration index, and average distribution coefficient of ethanol, total solids, color, and bitterness in the liquid fraction. Results showed that ice fraction primarily influenced solute concentrations and increased with ice fraction due to water removal. The type of beer had a significant impact on color and bitterness, reflecting the specific style parameters. Furthermore, response optimization yielded conditions that significantly altered beer statistics, leading to changes in ethanol content, total solids, color, and bitterness, possibly classifying them as new beer styles. The study demonstrates the potential of FC to influence the beer characteristics and broaden the range of beer styles. ***Journal of Food Process Engineering.*** **2024;47:e14574.**

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thewesternfoodsafetyconference.com

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Profiles

IN FOOD SAFETY

Effie Alberta Read Challenges Food Fraud

BY **MARY BETH NIERENGARTEN**

Effie Alberta Read prepares a microphotographic camera.

COURTESY OF FDA.

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As an instructor of histology and embryology at New York's Medical College of Cornell in 1906, Effie Alberta Read, PhD, MD, helped teach a course on microscopy, histology, and embryology. The class included lectures but relied heavily on laboratory work to allow students to acquire knowledge directly from nature and fulfill what the course catalog described as the aim of the class: "to bring the student into direct contact with the truths of nature."

While this description sounds archaic to contemporary ears, the meaning is apt for the scientific work that Dr. Read performed at a time when "truths of nature" for most women may have better described their own biology as mothers and wives and domestic caretakers. For Dr. Read, it meant applying her years of scientific training at Cornell where she earned three degrees—a bachelors in 1903, a Master's in 1906, and a PhD in 1907, followed by a medical degree at George Washington University (1912)—to a two-decades long career as a microanalyst (and eventual assistant chief) in USDA's Bureau of Chemistry's Microanalytical Laboratory.

It was here at USDA that she applied her hands-on training to develop a simple, reliable method to detect the true nature of food products; more specifically, her method identified adulterated food products to ensure food quality and safety.

Her area of expertise? Tea.

Adulteration Test

Dr. Read's work in developing a rapid reliable way to detect artificially colored imported tea is cited as one of her most prominent accomplishments, which a later FDA report said "represented an unsung scientific cornerstone in the enforcement of the 1906 Pure Food and Drug Act." Implemented under President Theodore Roosevelt, the law made it illegal to move adulterated or misbranded foods, drinks, or drugs across state lines or into the U.S. from foreign countries. It was the first comprehensive consumer protection law ever enacted in the United States and, in effect, inaugurated what would become the modern Food and Drug Administration.

Dr. Read presented the detection method at the 1912 International Congress of Applied Chemistry, described later in an FDA profile of her as a method "in which dust from crushed and sifted tea leaves is streaked along analytical paper and then examined under the microscope." The method was referred to as the "Read Test."

For example, in one court case, a Tea Board working on behalf of the U.S. government used the Read Test to determine that shipments of tea from China imported to the U.S. via San Francisco were of inferior quality due to the presence of artificial coloring. Evidence from the test was used by the government to argue the merits of its decision in a case brought against it by the tea importers, a case that a U.S. district court ultimately dismissed.

Dr. Read's novel method had the added advantage of using equipment that was commonly found in most laboratories.

In Washington, Dr. Read was also an associate member of the Medical Society of the District of Columbia and active in the Woman's Clinic, an organization formed to help indigent women. Colleagues remembered her as "a trained and competent analyst, an able and courageous executive, and a woman of such qualities of mind and character as commanded the respect and admiration of her associates."

Dr. Read died in Washington, D.C., of ovarian cancer at the age of 57 on September 1, 1930, three weeks after retiring from her work at what was then officially called the FDA. ■

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