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Volume 26 Number 5
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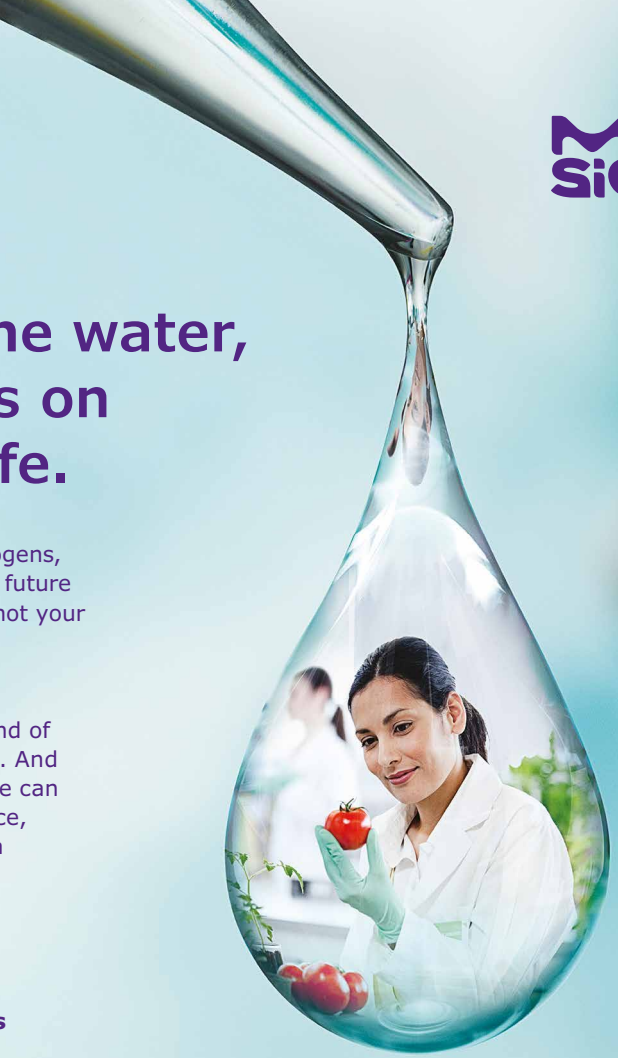

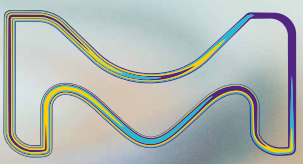

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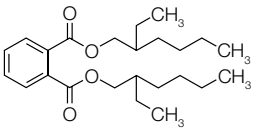

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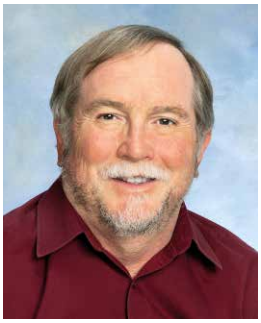
From The Editors

Education Over Training



Many years ago, someone dear to me told me "One trains their dog, but educates a person." That person was my mother, who also happened to be a food science professor at Rutgers University.

Education means that people are not only taught a task, but also understand why they do the task and its importance. People who are trained may do a task by rote, but not know why they are doing it or why they do it the way they have been taught. A classic example in today's world is why processors must educate their workers who do crucial tasks such as critical control point or preventive controls monitoring. These workers are performing a task that is essential to the production of safe foods, so they need to understand not only how to do the work, but why it is important.

An emphasis on education is even more critical given the way third-party audits have evolved and how regulators now conduct audits. Both auditors and regulators will observe when they are in plants and question managers from different departments, and will also interview workers doing the tasks. They will ask how the monitoring is done, why it is important, what the workers will do if there is a process deviation, and how they will keep records.

Education is one of the criteria we use when deciding what to print in Food Quality and Safety. We want to make people think and provide processors with tools to better manage their operations. In a recent issue the piece by Dave Park, "A Food Defense Plan Is Good for Business," is one that food plant management should read. The piece implies that audits are a snapshot whereas assessments can be more in depth.

But many processors talk training instead of education, constantly looking for tools to "better train" their people. In addition, there are now programs that are mandated by law, such as Better Process Control Schools for processors of low-acid foods and the program for Preventive Controls Qualified Individuals. Inexpensive alternatives to these are programs available online rather offered in a classroom. If your company decides to go this route, think hard about whether your workers will be trained or educated. If the people who participate in these programs are simply trying to "pass a module," my guess is that they are not really being educated but trained. Think about it...

Richard Stier
Co-Industry Editor

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NEWS & NOTES

U.S. worker, food-safety advocates sound alarm over new hog slaughter rules

U.S. food safety and the health of plant workers will be at risk from new federal rules that allow meat companies to slaughter hogs as fast as they want and shift the role of government inspectors, food and environmental advocates said on Tuesday.

The warnings about the U.S. Department of Agriculture's first update of inspection procedures at hog slaughterhouses in more than 50 years come after several high-profile recalls in the meat sector.

The USDA earlier on Tuesday published a final version of rules that will eliminate limits on how fast companies can slaughter pigs – a change long sought by meatpackers.

The companies can instead determine their own slaughter speeds based on their ability to prevent fecal contamination and minimize bacteria, according to the rules.

Packers can also have employees, rather than USDA workers, remove meat with certain defects from the slaughtering process. Government inspectors will continue to check all live animals before they are killed as well as meat products after slaughter.

The changes could contribute to food contamination, said Wenonah Hauter, executive director of advocacy group Food & Water Watch.

"The implementation of the rule will result in the fox guarding the henhouse," Hauter said.

Tyson Foods, the biggest U.S. meat producer, slowed chicken processing to protect food safety this year after it recalled millions of pounds of poultry products over concerns they contained extraneous materials like rubber and metal.

Tyson, Hormel and Smithfield did not immediately respond to requests for comment on the USDA's new rules. The North American Meat Institute, which represents the packers, said companies will continue to produce safe pork.

Slower processing leads to higher costs for companies and limits profits, but advocates say extra caution protects workers.

"Increasing pork plant line speeds is a reckless corporate giveaway that would put thousands of workers in harm's way as they are forced to meet impossible demands," said Marc Perrone, president of the United Food and Commercial Workers International Union, which represents slaughterhouse employees.

The USDA ran a pilot program for the new rules that was announced in 1997. Participating slaughterhouses do not operate significantly faster than the current maximum speed of 1,106 pigs per hour, according to the agency.

The pilot program showed the rules are unlikely to cause a higher prevalence of *Salmonella* on pork and may reduce the prevalence of *Salmonella*, the USDA said. Under the new rules, the agency will require hog slaughterhouses to establish procedures to prevent meat from being contaminated by certain pathogens and fecal material.

"This regulatory change allows us to ensure food safety while eliminating outdated rules and allowing for companies to innovate," USDA Secretary Sonny Perdue said.

–By Tom Polansek, Reuters

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U.S. Beef, Mexican Soft Cheese Behind Multidrug-resistant *Salmonella* Outbreak

A recent multistate outbreak of infections with multidrug-resistant *Salmonella enterica* serotype Newport with decreased susceptibility to azithromycin was linked to U.S. beef and Mexican cheese, according to an epidemiologic investigation.

"Finding the outbreak strain in both cheese and beef indicates that the human illnesses likely originated from presence of the bacteria in cattle in the United States and Mexico," Dr. Ian D. Plumb of the Centers for Disease Control and Prevention (CDC), in Atlanta, told Reuters Health by email.

"It also highlights how antibiotics are a precious resource – unnecessary use of antibiotics increases the risk of resistant bacteria spreading," he added. "Avoiding unnecessary use in cattle of antibiotics that are also used to treat human infections could help prevent the risk of resistant bacteria spreading from cattle to cause human illness."

Between June 2018 and March 2019, 255 cases of infection with the outbreak strain were identified in 32 states, including 10 cases with bacteremia and two deaths, Dr. Plumb and colleagues report in the August 23 issue of Morbidity and Mortality Weekly Report (MMWR).

Most patients (65%) were Hispanic, and 43% reported having visited Mexico in the seven days before the onset of their illness.

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Washington Report

BOONCHUAY1970/SHUTTERSTOCK

Tackling Food Waste

The food industry joins governments and nonprofits in a quest to 'waste not, want not' | BY **TED AGRES**

For years, the U.S. and other countries, along with numerous multinational and private organizations, have been seeking ways to reduce food loss and waste. Despite this, world hunger continues to increase with population growth. In the U.S., up to 40 percent of the food supply goes uneaten, equivalent to an average of 400 pounds of food per person per year and costing an average household of four about $1,800 annually.

This wasteful activity consumes more than $218 billion, or 1.3 percent of the gross domestic product, in futile growing, processing, transportation, and disposal costs. Where does the uneaten food go? EPA estimates that food accounts for 22 percent of all landfill waste.

Internationally, the situation isn't much better. About one-third of all global food production is either lost or wasted annually, at an estimated price tag of $940 billion, according to the Food and Agricultural Organization of the United Nations.

Despite decades of international conferences, scientific meetings, and the issuance of countless reports, the problem of food loss and waste remains seemingly intractable. However, the food industry can play a leading, if not major, role in addressing the problem throughout the food distribution chain, from growing and production, to processing, and to retail and food services, according to a recent report from the Government Accountability Office.

Many proposed solutions involve new technologies. Among these are novel packaging materials and plant environmental management to better inhibit spoilage of produce and meat. Others involve creation of digital apps using blockchain or the Internet of Things (IoT) so food manufacturers and consumers can trace products throughout the distribution chain.

"By using open technologies, like IBM Cloud, blockchain, IoT, and visual recognition, [software] developers are creating solutions to generate better insights about where waste happens, how to track it, and how to share this data across supply chains," John Walicki, chief technology officer at IBM Cognitive Applications, tells Food Quality & Safety.

Other approaches are closer at hand and easier to implement. "Perhaps one of the simplest is to standardize food date labels across all supermarkets and retail stores. With millions of pounds of perfectly edible food filling landfills, a solution needs to be found," says Darcy Simonis, vice president of the food and beverage division of ABB (formerly Asea Brown Bovari).

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Confusing Labels

"Expiration," "Use By," "Sell By," "Best Before," "Best If Used By," and "Enjoy By" are among the various phrases commonly printed on food labels, tending to blur the real date of when a food item is no longer safe to eat and should be discarded. Indeed, a 2007 survey published in the *Journal of Food Protection* found that fewer than half of consumers are able to distinguish among these various phrases. This confusion is responsible for about 20 percent of consumer food waste, according to ReFED, a multi-stakeholder network of business, nonprofit, foundation, and government leaders working to reduce U.S. food waste.

Frank Yiannas, deputy FDA commissioner for food policy and response, recently published an open letter to the food industry. In it, he encouraged voluntary industry-wide efforts to clarify expiration labeling, noting that the agency has found that consumers often throw out food because they misunderstand product date labels or are unsure how to store perishable foods.

Hopefully, the food industry is poised to address the issue. In 2017, the Grocery Manufacturers Association and Food Marketing Institute brought together 25 consumer packaged goods and grocery retail companies to discuss how to "simplify and streamline" product date labels to reduce consumer confusion. The groups recommended using only two introductory phrases for product date labels: "Best If Used By" and "Use By." "Best If Used By" would mean that the product may not taste or perform as expected after the specified date, but would be still safe to use or consume. "Use By" would apply to perishable products that should be consumed by the date on the package and discarded afterward.

Also in 2017, the Consumer Goods Forum, a network of more than 400 major international retailers, manufacturers, and service providers, adopted a "call to action" urging food retailers and producers to standardize and simplify product date labels by 2020, with the overall goal of halving food waste by 2025. The Consumer Goods Forum suggested that producers and retailers display only one label at a time and choose between either a safety or expiration date for perishable items (such as "Use By"), or a quality date indicator for nonperishable items (such as "Best If Used By"). A number of large companies have agreed to these guidelines, including Kellogg's, Walmart, Campbell's Soup, Nestle, Tesco, and Unilever.

> "Perhaps one of the simplest [solutions] is to standardize food date labels across all supermarkets and retail stores. With millions of pounds of perfectly edible food filling landfills, a solution needs to be found," says Darcy Simonis, vice president of the food and beverage division of ABB.

The FDA "strongly supports" the food industry's voluntary efforts to use "Best If Used By" for quality-based information, Yiannas said in his letter. But the agency is not addressing the proposed "Use By" product date label "for safety reasons at this time," he wrote, without further explanation.

Regulated Labeling

Except for infant formula, food label dates are not federally regulated. According to the USDA, "it is important that consumers understand that the dates applied to food are for quality and not for safety." Some lawmakers say this unregulated date labeling needs to be changed to clear up consumer confusion and reduce food waste. Rep. Chellie Pingree, D-Maine, for example, has introduced federal legislation that would end the "arbitrary" dating of food and require uniform, standardized labeling using only two terms: "Use By" or "Best If Used By." Her Food Date Labeling Act of 2019 (HR 3981) and a companion bill introduced by Sen. Richard Blumenthal, D-Conn. (S 2337), would effectively eliminate the "Sell By" date, which is intended for stores, not consumers, and doesn't specify when the item goes bad. Instead, the "Use By" date would signify when the product has reached the end of its shelf life and should be discarded. The "Best If Used By" date would signify when quality may begin to deteriorate but the product remains wholesome and can be consumed.

"This bill is an opportunity for the federal government to reduce confusion across the food supply chain and make sure no one is going hungry or inadvertently hurting our environment," Rep. Pingree said in a statement. "With this piece of legislation, we can help ensure food is being used and eaten, rather than thrown out due to confusion." As of this writing, legislators have not acted on either of the House or Senate bills.

Technology to the Rescue

IBM recently concluded its Food Waste Developer Challenge, or "virtual hackathon," in which more than 100 software development teams in the U.S. competed to create solutions using open source technology. Because data lies at the heart of the food waste problem, "coders can come in to help create a more transparent and real-time supply chain tracking how food is sold and fulfilled with waste reduction in mind," IBM's Walicki says.

IBM announced the winners in September, but has no plans to own or control any potential solutions. "As foundational partners in the open technology community, we feel that innovation can come from many areas and we want to encourage others to build upon the technologies IBM has pioneered to create new breakthroughs to our society's biggest challenges, including food waste," Walicki explains.

Other off-the-shelf traceability software can be applied to the food supply chain. ABB's Manufacturing Operations Management suite could allow consumers to digitally trace the life cycle of a food product. A livestock farmer, for example, could upload into a database an animal's identification number, its age, the date it was slaughtered or milked, the date of packaging, and where it has been distributed. A QR or barcode linking to this information could be printed on the packaging. Once on supermarket shelves, consumers could scan the code to view the product data.

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Market Initiatives

Much Ado About Milk

Quality, safety, and consumer interest research abound in the top three dairy states

BY **LINDA L. LEAKE, MS**

Got Milk may not have been a big marketing thing during the Bronze Age, but folks enjoyed moo juice back then, circa 3000 BCE. So says Christina Warinner, PhD, an assistant professor in the Harvard University Department of Anthropology.

In recent studies, Dr. Warinner and several international collaborators report the first direct evidence of milk consumption—not drawings of people sporting white mustaches, but rather whey protein beta-lactoglobulin (BLG), preserved in human dental calculus from the Bronze Age. "Using protein tandem mass spectrometry, we demonstrate that BLG is a species-specific biomarker of dairy consumption, and we identify individuals consuming cattle, sheep, and goat milk products in the archaeological record," Dr. Warinner relates.

Fast forward to now, the big data age, and we're still drinking milk. Per capita consumption of fluid milk in the U.S. in 2018 was 146 pounds, according to the USDA Economic Research Service's Sept. 4, 2019, report. This represents a steady decline since 1975, when per capita consumption was 247 pounds.

In its Estimated Fluid Milk Products Sales Report dated Aug. 12, 2019, the USDA Agricultural Marketing Service (AMS) says 3.4 billion pounds of packaged fluid milk products were shipped by U.S. milk handlers in June 2019. This was 4.1 percent lower than a year earlier, AMS notes. Milk production in the United States during July 2019 totaled 18.3 billion pounds, up slightly from July 2018, according to the USDA National Agricultural Statistics Service (NASS) Aug. 19, 2019, Milk Production Report.

California leads the nation in number of milk cows with 1.728 million head for July 2019, 60,000 head less than July 2018, and 8,000 head less than June 2019, NASS reports. The Golden State also leads in milk production, boasting 3.378 million pounds in July 2019. Wisconsin ranks second in both number of milk cows, with 1.268 million head, and also in production, 2.606 million pounds, in July 2019, NASS says. New York comes in third in July 2019, with 627,000 milk cows (slightly ahead of Idaho), and fourth (just behind Idaho) in production, 1.288 million pounds, NASS relates.

Fluid Milk Innovation Contest

Doing its part to increase consumer interest in milk, on Aug. 1, 2019, the California Milk Advisory Board (CMAB) announced the launch of what it is touting as "one of the biggest dairy competitions of all time," The Real California Milk Accelerator.

The Real California Milk Accelerator aims to promote innovation in the fluid milk category, according to John Talbot, CEO of the CMAB. "We are looking for ideas for new products that can be as varied as new flavor variations, nutrient or health improvements, marketing or packaging innovations, or that are environmentally conscious or sustainable," Talbot says. "New or improved methods for producing, preparing, and packaging food and beverage products or ingredients and ensuring quality and safety are welcome, as are new and innovative beverage products or ingredients."

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Headquartered in Tracy, Calif., the CMAB, an instrumentality of the California Department of Food and Agriculture, is funded by the Golden State's dairy farm families. The CMAB executes advertising, public relations, research, and retail and foodservice promotional programs on behalf of California dairy products that carry the Real California Milk (RCM) seal, throughout the U.S. and internationally, Talbot relates.

"The Real California Milk Accelerator competition combines two of California's great natural resources: sustainable California milk and California entrepreneurship," Talbot says. "The competition intends to inspire innovation and investment in fluid milk products, packaging and capacity within California."

To that end, CMAB is seeking high-growth potential liquid milk ideas, with cow's milk making up at least 50 percent of their formulas.

"Applicants need to commit to producing the product in California for a period of 12 months, should they win the competition, thus making an economic impact on the dairy farmers of California, as well as the state's dairy processing community," Talbot notes. He mentions that it's OK if applicants use milk from another state in development, but the products the judges taste during the competition must contain only California milk. "Moreover, applicants must agree to have the final product carry the Real California Milk seal," he points out.

Talbot says as many as eight applicants will receive $25,000 worth of support each to develop a protocept while receiving elite mentorship from marketing, packaging, and distribution experts. "Select applicants will also receive an expense-paid business development trip to California, to tour dairy farms and processing facilities, and to meet with industry leaders that will help drive the success of their new ventures," he adds. "The winner will receive up to $250,000 worth of support to get their new product to market."

The Real California Milk Accelerator competition is open to any persons who are legal residents of one of the 50 United States or the District of Columbia, are at least 18 years of age (or the age of majority in their state of residence if greater than 18), and who offer a promising liquid cow's milk concept.

Applications for the competition were due Aug. 31, 2019. The judging process culminates with the announcement of the winner on Nov. 8, 2019, in the San Francisco Bay area.

Beverage Innovation Center

A new Beverage Innovation Center is in the works in America's Dairyland at the Madison, Wis.-based University of Wisconsin (UW) Center for Dairy Research (CDR), according to John Lucey, PhD, UW professor of Food Science and CDR director. "The Beverage Innovation Center will allow the CDR to work with companies and entrepreneurs to develop shelf stable milk-based beverages," Dr. Lucey says. "We expect to be fully operational by June 2020."

"Microbial spoilage issues occurring due to postprocessing contamination can largely be addressed with improved cleaning and sanitation of equipment that contacts milk after the pasteurization stage, particularly fillers and filler areas," Dr. Wiedmann advises.

A $750,000 grant awarded in April 2019 by the Wisconsin Economic Development Corporation, along with a $250,000 grant from the Dairy Farmers of Wisconsin, are funding the Beverage Innovation Center.

"We will have a 3,000-square-foot pilot plant outfitted with the specialized equipment needed to run small batches of extended shelf life and aseptic beverages," Dr. Lucey relates. "We will also provide technical assistance to dairy producers and entrepreneurs that want to create new beverages using milk and milk-based ingredients. When the Beverage Innovation Center is up and running, we believe there will be no other public facility quite like it in the United States."

Relative to packaging in the Beverage Innovation Center, Dr. Lucey says the initial goal is to have a small-scale, aseptic bottling system that has undergone some validation as being safe for human consumption. "We plan to set up a system that will be able to generate a couple hundred bottles from a single batch within about two hours," he relates. "In the future, we hope to explore pouch packaging possibilities."

Shelf-stable beverages that contain some dairy ingredients are an area of promising growth and innovation for the dairy industry, Dr. Lucey points out. "These products offer high-quality dairy proteins and can have other unique characteristics like being lactose free," he says. "In addition, since these products are stable and have a long shelf life, they could potentially be exported."

Exciting Quality and Safety Tools

Data analytics and molecular biology are two of the most exciting tools available for determining milk quality and safety today, according to Martin Wiedmann, PhD, Gellert family professor of food safety in the Department of Food Science at Cornell University, Ithaca, NY.

These tools are especially important in light of what Dr. Wiedmann believes are the biggest quality and safety issues presently impacting fluid milk: post-pasteurization microbiological contamination and spore-forming spoilage organisms surviving pasteurization.

"Microbial spoilage issues occurring due to postprocessing contamination can largely be addressed with improved cleaning and sanitation of equipment that contacts milk after the pasteurization stage, particularly fillers and filler areas," Dr. Wiedmann advises.

Gram-positive psychrotolerant endospore-forming bacteria (simply stated as spore formers) represent a more challenging problem in terms of microbial spoilage, Dr. Wiedmann says. "These organisms can survive many types of pasteurization heat treatments, and then they can germinate and grow during subsequent refrigerated storage," he relates.

Dr. Wiedmann supervised research published in 2018 that showed refrigeration at 39.2 degrees Fahrenheit had a

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Legal Update

A Check on the FDA

A pet food company is suing the agency over its zero-tolerance *Salmonella* standard, and the outcome could have long-lasting implications

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

CHARLES MANN/ISTOCKPHOTO

Lystn LLC, which does business as Answers Pet Food, is suing the FDA along with numerous other defendants over zero-tolerance *Salmonella* standards applicable to pet food. Answers is challenging the FDA's authority to promulgate binding rules through the issuance of purportedly non-binding guidance materials. If the FDA prevails, the practical result would be a significant broadening of the agency's rulemaking authority. That, in turn, could have wide-ranging repercussions for food companies.

Answers is seeking declaratory and injunctive relief. Declaratory relief is, in short, a judicial declaration stating what the law is. In this case, Answers wants the court to declare that the FDA has no authority to enforce the zero-tolerance *Salmonella* standard. Injunctive relief seeks to stop (or enjoin) something from happening. Answers is asking the court to enjoin the FDA from enforcing the zero tolerance *Salmonella* standard.

Answer's arguments, as set forth in their legal complaint, are proffered in a colorfully worded and legally complex tapestry of jurisdictional issues, statutory analysis, constitutional principles, and allegations of regulatory overreach. In simple terms, however, the arguments can be summarized as follows: The FDA's enforcement of the *Salmonella* rule is unconstitutional because the rule was created through the promulgation of guidance materials, which, as a matter of federal law, the agency has no legal authority to enforce. Put differently, the FDA overstepped its authority. There are important constitutional principles underpinning the allegations by Answers.

In drafting the U.S. Constitution, the Founding Fathers were principally concerned with limiting the power of the federal government. To prevent tyranny, they sought to divvy up governmental power between multiple branches with competing interests. Accordingly, Article 1 of the Constitution grants the U.S. Congress the ability to pass laws, Article 2 grants the executive branch the ability to enforce the laws, and Article 3 grants the judiciary the ability to interpret the laws. This is often referred to as the "separation of powers" and is intended to prevent the consolidation of power in any single branch of government. Those limits would be meaningless if federal agencies, as part of the executive branch, could both create and enforce their own legally binding rules. Yet, despite the limitations, it is administratively necessary for federal agencies to be able to create some types of regulations. This inherently creates a gray area.

As a matter of law, the FDA's rulemaking authority is generally limited to developing and implementing regulations that are necessary to administer or enforce the laws passed by Congress (e.g., the Food Safety Modernization Act and the Food Drug and Cosmetic Act). What is "necessary," however, is itself a subjective determination (the gray area). The FDA and the entities it oversees naturally have very different viewpoints on what constitutes "necessary." The Administrative Procedure Act (APA), a federal statutory scheme that governs the process and limitations by which federal agencies create regulations, further constrains the FDA's authority and

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serves as an important check on executive authority.

Formal vs. Informal Rules

Ultimately, effective rulemaking is about striking a balance. In the case of the FDA, that balance encompasses granting the agency authority to efficiently and effectively enforce the laws, but not such expansive authority that it can violate the constitutionally mandated separation of powers.

The APA is comprised of numerous individual statutes. The APA's rule-making statute, 5 U.S.C. § 553, grants federal agencies such as the FDA the authority to make two types of rules: formal and informal. Suffice it to say that formal rules are vastly more onerous to enact than informal rules. Formal rules typically take years—or even decades—to enact. Informal rules, on the contrary, are nonbinding and do not create legally enforceable responsibilities. This is perfectly logical inasmuch as enforceable rules should be more difficult to create. Importantly, the rule-making statute exempts "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" from the requirements. Here again is the gray area alluded to earlier: When does a statement of policy become a formal rule?

At the heart of Answer's lawsuit is the FDA's Compliance Policy Guide (CPG) 690.800, "*Salmonella* in Food for Animals." The guidance was published in July 2013, and its stated purpose is "to provide guidance for FDA staff on the presence of *Salmonella* in food for animals." An explanatory paragraph early in the document affirms that, "FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited." Additionally, the words "Contains Nonbinding Recommendations" is printed at the top of each page of the guidance.

These statements are striking, as their effect seems deliberately intended to diminish the document's importance. However, the language of the actual guidance could be interpreted as being inconsistent with the disclaimers that precede it. For instance, the FDA asserts that it "considers an animal feed or pet food that may be injurious to health because it is contaminated with *Salmonella* to be adulterated under [the FDCA]." The FDA justifies this assertion by stating that pet food poses a significant risk to human health when contaminated with *Salmonella,* because humans come into direct contact with these foods. By that logic, almost all raw meat products containing *Salmonella* could be considered adulterated. After all, a consumer's direct contact with the food they eat is almost certainly more frequent than their contact with the food they feed their pets. Consider also that the USDA, which regulates meat and poultry for human consumption, does not deem raw meat adulterated on the singular basis that it contains any serotype of *Salmonella.* The obvious irony is that, at least for *Salmonella,* the FDA applies a more stringent standard to pet food than human food.

The most often utilized counterargument is that raw meat produced for human consumption is intended to be cooked, thereby killing any pathogenic bacteria that may be present. However, that argument is problematic for several reasons. For one, pet food is not meant to be consumed by humans in the first place. Another reason is that our contact with the raw meat we consume is almost certainly more substantial than the contact we have with raw pet food. Many consumers wash raw meat and apply rubs, marinades, etc. At least in this regard, the FDA rule seems somewhat illogical, or at least ungrounded.

Conversely, the adulteration standards are nuanced and complex. The federal adulteration statute must incorporate a complicated nexus of enormously important (and often competing) societal interests. Broadly speaking, food safety brings into play social, political, demographic, and economic factors. Effective adulteration laws, in turn, must anticipate and address all possible risks. *Salmonella* does pose a serious health risk to humans and pets alike. Consequently, many are ambivalent about critiquing the agency for taking a hard line against products contaminated with *Salmonella*.

> The arguments can be summarized as follows: The FDA's enforcement of the *Salmonella* rule is unconstitutional because the rule was created through the promulgation of guidance materials, which, as a matter of federal law, the agency has no legal authority to enforce.

An Important Case

Ultimately, the outcome of this specific case has little to do with *Salmonella* or pet food. This case is really about the rulemaking process and extent of executive authority. If the FDA can create rules simply by issuing guidance that the FDA falsely claims is nonbinding, then where is the ultimate stopping point?

Today, the question is whether the FDA has exceeded its mandate by enacting a binding regulation using an informal rulemaking procedure. How the courts answer that question will likely set a precedent future courts will have to abide by.

On the one hand, the court could significantly expand the FDA's authority, removing an important check on executive power. On the other hand, if the courts rule that the FDA lacks authority to make adulteration declarations regarding foods contaminated with potentially lethal pathogens, then what? It is certainly a very difficult question, and reasonable minds can differ on which is the desired outcome.

Fortunately, we have an independent judiciary composed of thoughtful and remarkably intelligent jurists who look at the law and render judgment on the merits of the respective arguments. It will be interesting to see what happens. ■

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Allergen Control

ROBERT CHURCHILL/ISTOCKPHOTO

Allergen Analysis Is a Partnership

Forming a long-lasting relationship with a lab can help your business thrive

BY **PHILIP JOHNSON, PHD,** AND **MELANIE DOWNS, PHD**

Allergen management for food manufacture is a complex, rapidly changing field. Ensuring an allergen management plan is fit for purpose in a landscape of diverse and malleable regulations can be daunting. Many allergen management plans feature analysis as part of their validation and verification. Testing of ingredients, production surfaces, and final product are frequently parts of ensuring products do not contain unexpected allergens.

The world of allergen analysis is often foreign to manufacturers as it is based on knowledge of analytical chemistry techniques that are distinct to the skill set required for manufacturing. To add to this complexity, detection methods are often situational. Which analysis to use is often dependent on not only the allergen to be tested for, but also the material in which it is present.

It is not, however, all bad news for food manufacturers that want to ensure their products meet regulatory requirements and that want to provide their customers with confidence in the foods they eat. Most allergen analyses take place in a commercial lab, with manufacturers sending samples for analysis on a fee-per-analysis basis. Most of these labs perform enzyme-linked immunosorbent assay detection. Ideally, competent analytical labs will provide more than basic analysis. The best labs are often a rich source of helpful advice, guidance, and interpretation.

Choosing an Analytical Laboratory

The selection of an analytical laboratory is a decision that will impact implementation of your allergen management plan, and one that will (hopefully) positively impact your service for some time. You should, therefore, consider your decision carefully, much as you would any other business partnership.

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The first criterion is the experience of the lab in testing foods for allergen residues. Many commercial labs focus on other types of analyses and have limited experience with allergens. Another obvious criterion for choosing your analytical partner is whether they offer analyses that are suitable for you. You should know which allergens are present in your facility, and have identified which ones you need to analyze. Your ideal laboratory should be able to test for the presence of these allergens, perhaps using more than one type of assay.

They should also be aware of how the detection methods they use perform in a range of different foods and ingredients, preferably the ones your facility uses or manufactures. Your lab should have allergen methods under the scope of a quality assurance framework (such as ISO 17025). Remember that ISO 17025 is not a general laboratory certification, but certification that the laboratory can perform certain specified methods to ISO 17025 requirements. Look for which methods are under the scope of an ISO 17025 accreditation.

Many manufacturers will know the allergens for which they need to test but will not feel that they have sufficient knowledge to select an analytical method themselves. In this case, try asking analytical laboratories which methods they would recommend. Do they present you with clear choices and recommendations with adequate justification? Do they clearly point out strengths and weaknesses of competing methods?

When comparing the analytical criteria of methods, be careful to look at the units presented. A lower number is not always better. For example, kits that report in quantities of β-lactoglobulin (BLG) may appear to be more sensitive than those that give their results in amounts of nonfat dry milk (NFDM). But are they really? A detection limit of 0.1 ppm BLG converts to around 2.85 ppm NFDM. Is your chosen lab aware of these unit differences and will they help you convert one unit to another? Do they answer your questions in a timely fashion? If you can answer positively to these questions, it is more likely that this laboratory will serve your needs well into the future.

Finding a lab that can conduct your full range of required analyses is tempting. It is worth remembering, however, that allergen analysis and data interpretation can be very different compared to other types of testing for food safety. It's best to find an allergen analytical service that has a good understanding of food allergens, testing, and regulations. The advice such laboratories can offer in developing and carrying out an allergen management plan is potentially of more value than the convenience of using one supplier for all analytical needs. This being said, if a laboratory can offer both comprehensive food testing and expert guidance and interpretation, this should be a preferred option.

Sending a limited number of samples to an analytical lab can be a useful "road test" of a future relationship. Turnaround time is, for some food safety applications, a crucial factor. The laboratory may give a maximum turnaround time from receipt of samples, but how fast is shipping to their location? How your analytical data is presented to you is also extremely important. The quality and detail of result reporting can be surprisingly varied. Does the lab report contain all of the data you need for your allergen management plan and to satisfy potential auditors? ISO 17025 reporting requirements are a good reference for what constitutes a complete report. The method used and the units in which this method reports are essential information. It is important that the company help explain or further interpret data contained in the report.

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Working with Your Analytical Laboratory

After selecting a laboratory a good first step is to establish a point of contact. Being able to deal with the same knowledgeable person within a lab can smooth the process of getting the information you are after. This person will also have a good oversight of different analytical methods and validation data.

Get into the habit of contacting your partner laboratory before sending samples that are different from samples you would usually send. This might include differences in the material composition of the samples, which can cause issues for labs in terms of something as simple as grinding, or mean that results may be affected in ways in which the lab can help to predict. As noted previously, the food matrix on which an analytical method is used can greatly affect the results and their interpretation. Many heavily processed materials may give lower than expected analytical results. In some cases, methods may give false positive results when used with certain food matrices. Interpretation of analysis of materials that have been fermented or distilled can be particularly problematic. A good laboratory will be able to advise you ahead of time regarding the applicability of methods to your situation. Your partner lab will also appreciate advanced notice that you will be sending large numbers of samples so that it can plan for a heavy workload and pre-order necessary supplies.

In some cases, food manufacturers may be loath to disclose compositional

The selection of an analytical laboratory is a decision that will impact implementation of your allergen management plan, and one that will (hopefully) positively impact your service for some time.

details for confidentiality concerns. Such reluctance is often unjustified, as the terms of service of most analytical labs include guarantees of confidentiality. It is always worth checking these to assure yourself that you may speak freely to the analytical lab regarding details of your samples. The ability to fully describe the sample you are analyzing can often be crucial to selection and performance of methods as well as interpreting what results may mean.

Regardless of whether or not product compositional information is disclosed, it can also be beneficial to provide positive and negative controls to an analytical lab, particularly when analyzing a new ingredient, product, or formulation. You should also keep replicate samples of those sent for analysis. Not all analytical labs retain portions of analyzed samples, so if the lab needs to a repeat an analysis you may need to provide another sample. If possible, build sample replication into your analytical strategy. Taking replicate samples of ingredients or finished product may be relatively simple, but taking replicate swabs may be more challenging. When faced with unexpected analytical results, however, you will not regret the effort.

What to Expect from Your Lab

The benefits of maintaining a good relationship with a well-run, knowledgeable analytical laboratory will become evident over time. However, many clients do not request help beyond the analysis itself, thereby denying themselves a potentially invaluable source of information.

As expert users of detection methods, people who work in allergen analysis laboratories, particularly those in management positions, are often uniquely qualified to interpret results and advise on the suitability of different methods. Provision of such additional information is most often part of providing an analytical service, so do not be afraid to ask questions. More complex, time-consuming advisory services are sometimes dealt with through consultancy arrangements that (typically larger) analytical laboratories may provide. However, many relatively simple questions should be fully addressed by the lab as part of an analytical service.

You should be satisfied as to what an analytical report means, and what its implications are. Reports can appear complex and full of jargon to the uninitiated. Your lab should be able to tell you, in clear and plain language, what any problematic terms mean and what the implications might be. Much of the language may be standardized, and appear on most reports of the same type, regardless of which laboratory performs them. In some cases, different lab practices may result in terminology that you are not familiar with. For example, labs may subsample materials you send for analysis. A lab code for this subsample may be used in reporting. You should understand if this has occurred, and how such subsample names are derived.

Labs should be able to provide guidance on analytical methods that you perform yourself. Frequently, an allergen management plan may feature both in-house and lab-provided analyses. Lateral-flow devices, for example, are most often designed so that analysis may be performed entirely within a manufacturing facility. A good analytical lab should be able to inform you which in-house analyses to use within your allergen management plan, and how to perform them properly.

You should be confident that your analytical method is detecting the allergen it is meant to detect, and have some idea as to how sensitive it is. In theory, this should be simple. An egg detection method should detect egg, and measures of sensitivity (e.g., limit of detection and quantitation) should be available from the manufacturer of the method. However, methods differ widely in how they detect allergens in different types of food, or after processing (usually heating). Your lab may be able to provide information as to how your selected allergen detection method is likely to work in your individual circumstances.

A good first choice in finding this information is in validation reports from the kit manufacturer. It may be that the method was tested under conditions that are similar to those that you are testing under. If not, the analytical lab may have tested under similar conditions and be able to inform you of how well the method is likely to function.

If you are testing a "difficult" food matrix, or an extensively processed material, and no information on test performance already exists, it may wise to validate the method for your particular conditions. This will typically involve a "spike and recovery" type experiment where the method's ability to detect a known amount of allergen in your food matrix is determined. Validation is more useful if you will be analyzing the same material many times using the same method, and you have reason to believe that the method is not functioning well. Your laboratory should be able to help you decide whether such a validation is necessary, and, if so, to design and conduct this type of validation with your input.

Allergen analysis may be more prone to interference and subject to interpretation than comparable chemical analyses. For the most part, this is due to the regulatory necessity of having to analyze for the presence of whole food, such as peanut or egg, rather than well-defined chemicals. It is also problematic that regulators do not stipulate levels at which allergens are deemed to be safe. The nuances of allergen detection make the relationship between food manufacturer and analyst more important than is the case for other food analyses. As with any relationship, communication is the key to success. ■

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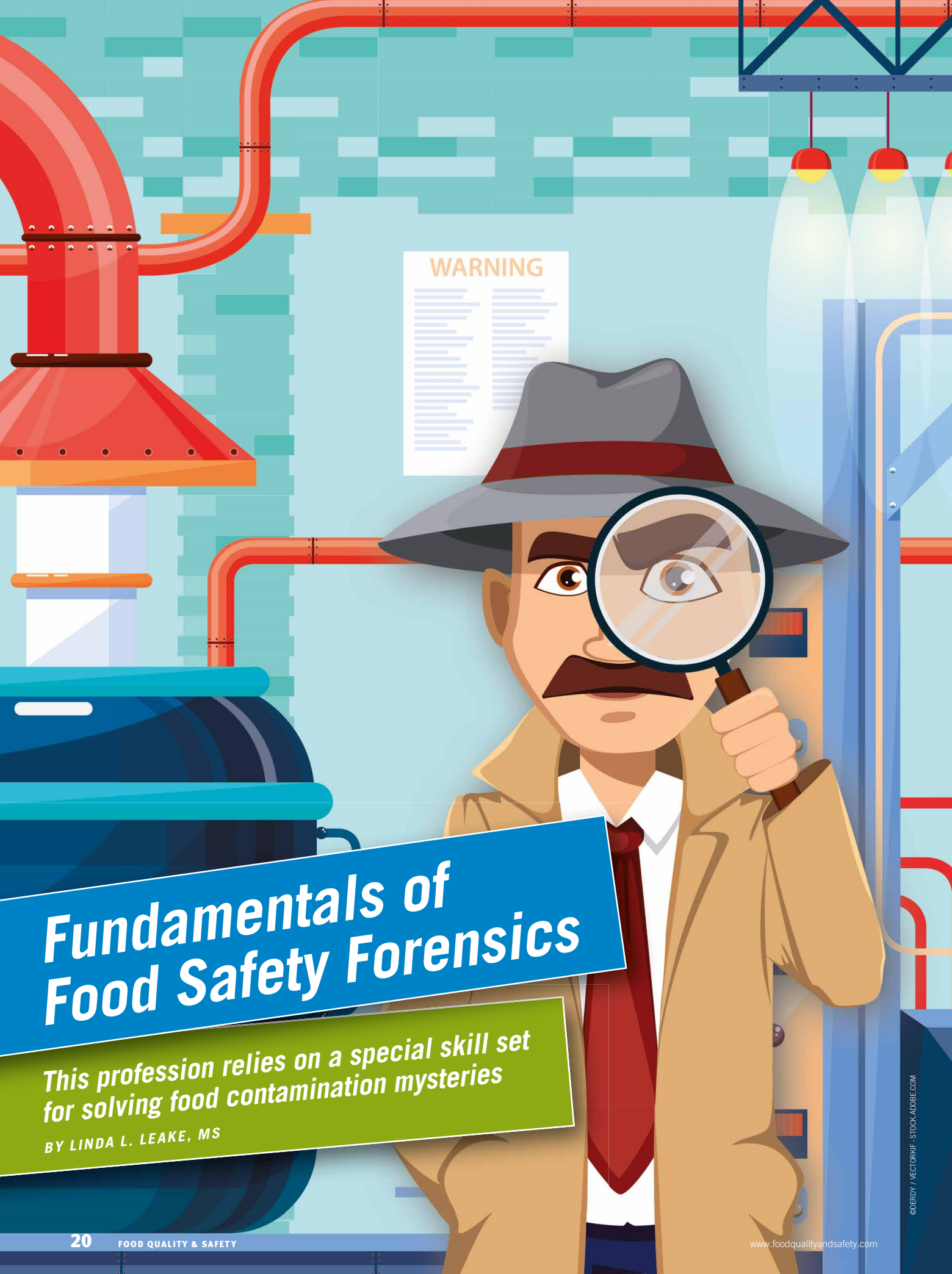

Fundamentals of Food Safety Forensics

This profession relies on a special skill set for solving food contamination mysteries

BY LINDA L. LEAKE, MS

Some people call Jeffrey Kornacki, PhD, the Lieutenant Columbo of food safety microbiology. Without the trench coat. Or the cigar. Or the 1959 Peugeot convertible, Model 403. Or the basset hound.

Signature wardrobe, iconic props, and lovable pet notwithstanding, what Dr. Kornacki has in common with the irrepressible TV sleuth is his ability to solve tough mysteries, albeit in food manufacturing plants. Dr. Kornacki doesn't tackle murder cases, but, as president and senior technical director of Kornacki Microbiology Solutions, Inc., Madison, Wis., he does unravel potentially life-threatening food contamination puzzles with the same relentless attention to detail as Columbo.

Dr. Kornacki says he pursues any of three types of investigations: microbiological product contamination, environmental contamination, and risk assessment. "With product investigations, a client asks me to determine how a contaminant got into a product," Dr. Kornacki elaborates. "With environmental investigations, they ask 'How did a contaminant get to this place in my facility?' Relative to risk assessment, the client says they don't have a contamination problem, but they want to know what the risks are."

The Investigation Process

Regardless of the task, ahead of any visit Dr. Kornacki asks to see the plant's standard operating procedures for cleaning and sanitation, their process flow chart, and a diagram of the facility.

"Ideally, this is a plant diagram that shows areas where they may have found contamination in the past, providing potential clues for further investigation" he explains. "Also requested is a general understanding of product formulation, including water activity, acidity, and post-lethality (after the kill step) ingredients, as well as ingredient test results and certificates of analysis."

Upon arrival at the plant, Dr. Kornacki spends time with management, asking them what specifically they want to accomplish and how can he help meet their needs. Often, a backward plant tour comes next, starting with finished product and ending with intake of raw ingredients, during which time Dr. Kornacki takes notes of his observations. "Most food contamination problems occur post-lethality," he points out.

With frequency, he climbs ladders and crawls on his hands and knees to search for clues in out-of-the-way, typically overlooked places. After a tour, Dr. Kornacki routinely turns to sampling the product and environment.

"If the problem is associated with product, I request that skilled maintenance employees pull the equipment completely apart for swabbing," Dr. Kornacki relates. "Management often says, 'Oh, we take this apart all the time.' 'All the way?' I ask. 'Well, we've never had this particular equipment this far apart before,' they often respond when we are done."

There are so many ways to get food processing wrong, so many twists and turns, Keener adds. *"Solving a food safety forensics case is like being in a Sherlock Holmes mystery," he says.*

After sampling, Dr. Kornacki departs and waits for the data to come back from the lab he uses, noting that an initial plant visit usually takes from a one to three days. In some challenging circumstances, however, such as large facilities with multiple lines, visits can continue for weeks, he says.

Through his private consulting work, as well as previous career endeavors in the food industry, Dr. Kornacki has investigated contamination events and helped clients deal with manufacturing issues during at least 850 food processing facility visits throughout the United States and Canada. He's assisted many additional clients by phone. In the process, Dr. Kornacki has guided numerous food manufacturers through high-profile national product recalls.

The Road to This Work

Dr. Kornacki completed all of his studies at the University of Wisconsin, where he earned a BS in bacteriology, an MS in food science with a microbiology option, and a PhD in food science with a microbiology option. He says he was inspired to pursue a career in food microbiology while enrolled in an undergraduate food bacteriology course taught by the iconic Robert Deibel, PhD, founder of Deibel Laboratories.

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"Dr. Deibel was a truly inspiring instructor, as well as an investigator in the food industry," Dr. Kornacki relates. "After completing his course, I decided that, someday, I would like to investigate contamination events in food processing facilities similar to the many such events Dr. Deibel told us captivating stories about in class."

"Food safety forensics" was not a term Dr. Deibel ever used, Dr. Kornacki, mentions, adding that the moniker only entered industry jargon in recent years.

Food safety forensics is the methodology of using food safety principles, detection methods, and processes to solve crimes, or to verify and document food poisoning or adulteration for both humans and pets, according to Darrel Suderman, PhD, president of Food Technical Consulting, Denver, Col. Dr. Suderman is a proponent of food safety forensics being included as an official category of forensic science specialties with the American Society of Forensic Sciences.

Events

OCTOBER

30-31

China International Food Safety & Quality Conference
Beijing City, China

Visit www.chinafoodsafety.com.

NOVEMBER

6-8

Dairy Practices Council Annual Conference
Portland, Maine

Visit www.dairypc.org,
email dairypc@dairypc.org,
or call 607-347-4276

13-14

Sensory Evaluation
New Brunswick, N.J.

Visit www.cpe.rutgers.edu,
email OCPE@njaes.rutgers.edu,
or call 848-932-9271

15

Statistics for Food Scientists
New Brunswick, N.J.

Visit www.cpe.rutgers.edu,
email OCPE@njaes.rutgers.edu,
or call 848-932-9271

JANUARY

28-30

International Production & Processing Expo
Atlanta, Ga.

Visit http://ippexpo.com,
email info@ippexpo.org,
or call 770-493-9401

FEBRUARY

25-28

GFSI Conference
Seattle, Wash.

Visit www.theconsumergoodsforum.com/events/gfsi-conference

MARCH

1-5

Pittcon
Chicago

Visit https://pittcon.org/pittcon-2020,
email expo@pittcon.org.

MAY

4-7

Food Safety Summit
Rosemont, Ill.

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

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"This field is specific to the contamination of food by microorganisms and toxins, and it represents a disciplined methodology for identifying the cause and contributing factors," Dr. Suderman relates. "It identifies sequential 'tracking and tracing' investigative steps, technologies, and detection tools."

When cases in the world of food manufacturing issues get tough, Dr. Kornacki thinks of his late dad, Tom, who had a distinguished career as a police detective, and solved countless cases.

"I often ask myself, 'What would my dad do?'" Dr. Kornacki elaborates.

He says he learned from his dad the essential characteristics for being a successful detective: critical thinking and problem-solving competence, attention to detail, objectivity, persistence, patience, outstanding communication skills, and dedication.

"I try to be really thorough, while also being diplomatic," Dr. Kornacki relates. "During a plant visit, I typically ask my host the same question more than once, in different ways, since the answer can have two or three interpretations. Or I ask two or three knowledgeable employees the same question to get different perspectives."

Dr. Kornacki says mentors helped him develop his interest and skills in food safety forensics. Earlier in his career, Dr. Kornacki worked for 12 years as a laboratory director and investigator at the former Silliker Laboratories Group, Inc. He says Dr. Damien Gabis and Dr. Russell Flowers, both former CEOs and presidents of Silliker, were instrumental in inspiring his investigative approach to food contamination issues.

"Early guidance was also provided by my major professor at UW, the late Dr. Elmer Marth, a pioneer in the area of foodborne *Listeria*," Dr. Kornacki adds.

National and Global Demand

"How soon can you be here?" That's a question Larry Keener often hears on the phone.

As president and CEO of International Product Safety Consultants, LLC, Seattle, Wash., Keener is in constant demand to solve food manufacturing failure mysteries throughout the United States and abroad. Many of his contacts were developed when he worked worldwide as director of product safety and regulatory affairs for Unilever for 11 years.

Calls might start with, "All products on line two are blowing up. We have no idea why. Can you help us?"

Keener completed a BS in medical microbiology at the University of California, Berkeley. His first job after graduation was with the then-National Food Processors Association (NFPA), whose members included the largest food companies that specialize in canning and thermal processing. He started with the NFPA as a senior microbiologist, with responsibility for providing technical service to members, including investigations and analysis of processing failures.

Keener is quick to point out that when he was a college student in the 1970s there were no courses titled "Food Safety Forensics," and there was no mention in any of his microbiology classes of the term "food safety forensics." There were no career opportunities posted anywhere as food safety forensics positions. But, as Keener explains it, with or without the title, food safety forensics has pulled many food manufacturing firms from the brink of failure.

"Perhaps 99 percent of dairy plants don't have proper filters on compressed air," Blomquist relates. *"And 100 percent of compressed air without proper filters is contaminated."*

He credits on-the-job challenges for his own special training in food safety forensics. Like Dr. Kornacki, he also emphasizes the importance of having role models in the field.

In particular, Keener acknowledges the late Allen Matsuyama, NFPA's former director of food processing sanitation and editor of the definitive text *Principles of Food Processing Sanitation*. "He opened my eyes to the intricacies of complex and oftentimes dangerous food processing operations," Keener says of his former supervisor. "I still reap the benefits of his tutelage."

Keith Ito, PhD, former director of the Berkeley NFPA lab and Keener's first boss, who helped develop and implement the FDA's low acid and acidified canned food regulations, also inspires Keener. "Keith was the industry's longtime go-to authority on *Clostridium botulinum* and food safety," he says.

A third icon for Keener was the late George York, PhD, a microbiologist at the University of California, Davis. "He would talk about food processing failure analysis at various meetings and he always stressed that 'the bugs will tell the story,'" Keener recalls.

As one example of his many captivating case stories, Keener followed the bugs to determine why cans of green beans were blowing up, and even disintegrating in his hand. "Exploding cans are never a good sign," he quips.

He reviewed every step of processing and was able to rule out botulism, even though the contaminating organisms were spore formers. "I scrutinized the packaging and, using fluorescein dye leak detection and luck, finally discovered that beads around the body of the can were imbedded too deep and thus fractured with heating and cooling," Keener relates. "The paper label masked the resulting small fractures in the can body that led to contamination of the beans." Mystery solved: It was a can manufacturing flaw.

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Often, when a spoilage event occurs, plant personnel panic and make immediate changes on the production line, Keener says. "So, they contaminate the crime scene, so to speak," he points out. "That means when I get there, perhaps as soon as a day or two later, the circumstances have changed and it's now a different crime scene. That adds to the challenge of solving the case."

There are so many ways to get food processing wrong, so many twists and turns, Keener adds. "Solving a food safety forensics case is like being in a Sherlock Holmes mystery," he says.

Dairy Specialist

David Blomquist, president of DFB Consulting, Hastings, Minn., says he has visited close to 1,000 food manufacturing plants, mostly dairy, over the course of his career.

Blomquist, now a private consultant, has worked for Schwan's Sales Enterprises, Marshall, Minn., (Schwan's Home Service, Inc.) and, more recently, as executive technical affairs specialist for Ecolab for 27 years through 2016. His work has helped him put his BS in food science with a chemistry emphasis from the University of Minnesota to good use. He's often called to troubleshoot food safety issues, especially related to cleaning and sanitation, at facilities throughout the United States and Canada.

Sometimes clues are easy to spot, Blomquist says. Compressed air is what he refers to as low-hanging fruit—that is, an obvious clue for solving dairy contamination mysteries.

"Perhaps 99 percent of dairy plants don't have proper filters on compressed air," Blomquist relates. "And 100 percent of compressed air without proper filters is contaminated."

According to Blomquist, if compressed air is used to blow out a 2 percent milk filler line before skim milk is run through the same line, for example, and improper filters are used, sporadic contamination of the skim milk is likely to occur. "Plants will not always recognize this due to the sporadic nature of the contamination," he says.

Blomquist is quick to point out that not all food safety mysteries are easy to solve. "Many times, I spend the better part of a week at a plant with little to show for it," he laments.

Tips for Success in Food Safety Forensics

"For success in this field, one must learn the basics about the way microbes grow, die, survive, and are found in the environment and in foods," Dr. Kornacki emphasizes. "A good mentor is also critical. Working in a commercial food testing lab may provide experiences an aspiring food safety detective will not get otherwise."

Describing food safety forensics as yet an emerging area of study, Keener recommends that those seeking a career in this field study microbiology, water and wastewater microbiology, entomology, and food engineering. "I highly recommend working on the production floor in as many food manufacturing operations as possible," he says.

"A good background in food science and the basics of food manufacturing will give you a foundation to begin your work," Blomquist adds. ■

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Quenching India's Thirst

Hindustan Coca-Cola receives Food Quality & Safety Large Business Award

BY **LORI VALIGRA**

Instilling food safety and healthy practices from the ground level up to management are the twin pillars of all operations at Hindustan Coca-Cola Beverages. The beverage company has established processes, incentive-based key performance indicators, training for all personnel, and individual role goals revolving around the safety of its products.

For its high level of quality and safety, Hindustan Coca-Cola was recently named the winner of the Food Quality & Safety Award for 2019 in the large business category. The award honors the dedication and achievement of organizations making significant contributions to uphold the highest food standards supported by quantifiable results. This year, a panel of industry judges concluded that Hindustan Coca-Cola Beverages in the large business category and Endangered Species Chocolate in the small business category demonstrated impressive efforts in their technology, certifications, training, regulatory compliance, and risk reduction.

"The inculcation of a food safety culture into the veins of each and every one of our employees has been our first and foremost motto," the company stated in its award application.

Hindustan Coca-Cola was founded in 1997, and the Dasna, India-based plant that won the Food Quality & Safety Award started in 1999. The factory manufactures non-carbonated, water-based flavored drinks, including punches, ales, ginger cocktails, aseptically processed fruit beverages, thermally processed fruit beverages; carbonated water-based flavored drinks; carbonated beverages and sweetened carbonated beverages; and water. Today, it is one of India's top fast-moving consumer goods companies. Fellow Indians, the company says, choose its beverages 477 times per second.

New Technologies

Hindustan Coca-Cola has worked to mistake-proof its processes at every step. This so-called process "interlock" halts operations if any step isn't in compliance with preset food quality and safety measures. The company is also using an upgraded multi-barrier water purification system to ensure the finished product is safe. Ultraviolet treatment is installed at manufacturing lines to mitigate cross-contamination in intermediate lines.

Hindustan Coca-Cola installed clean-in-place and clean-out-of-place automatic systems to ensure food safety, as well as a fully automatic hand-wash station at the entrance to the manufacturing area. Employees' fingertips and hand palms are swabbed before and after hand washing to double-check cleanliness.

Hindustan Coca-Cola has proposed quality corrections in 2019 and 2020 that are aimed at getting to a 90+ good manufacturing practice score. They include its water purification system upgrade, upgrading the factory roof, installing water and ice protection, and getting 100 percent compliance at all process interlocks. The company also installed a new Tetra manufacturing line, placed new epoxy in the SASIB automatic pack line area, installed biometric access control in the filling rooms, and added shuttle racks for first-expired, first-out product handling. They are also working to reduce clean-in-place and changeover times. The canteen and toilet areas also will be refurbished.

Training for Safety

An external agency organizes Food Safety Training and Certification (FoSTaC) for employees as required by the Food Safety and Standards Authority of India. An external agency also organizes internal auditor training for the Food Safety System Certification 22000 and ISO 9001:2015 standards. Food handlers receive personal hygiene awareness training and are told not to wear jewelry during shifts.

While the company follows the Food Safety and Standards Authority of India regulations and the Food Safety System Certification 22000 and ISO 9001:2015 standards as well as its internal food safety plan, it also has audit programs in place both in-house and for its suppliers. The supplier audit is conducted by one of its Coca-Cola corporate business units and on the basis of the score the supplier is authorized to supply material to all bottling plants. Additionally, Coca-Cola provides online software for its plants to check their compliance monthly.

In-house good manufacturing practice audits are done monthly. Additionally, a separate global GMP audit is done to match the practices in the Coca-Cola bottling plants around the world.

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Small Company, **Big Impact**

Endangered Species Chocolate receives Food Quality & Safety Small Business Award

BY **LORI VALIGRA**

Certifications are a constant challenge in assuring food quality and safety, especially for smaller producers with limited resources, says Brent Robinson, director of operations at Endangered Species Chocolate.

But that hasn't kept the Indianapolis, Ind., company from achieving both high food standards and exceptional corporate citizenship that involves donating 10 percent of net profits to support conservation programs for species, habitat, and humanity.

"One of our biggest challenges is the supply chain complexities. This involves everything from potential risks and their mitigation, resulting in brand protection while meeting the ever-changing consumer needs. That's probably our biggest hurdle," Robinson says.

Shelby Troyer, the quality programs manager at the chocolate manufacturer, says sustaining quality standards also can be a struggle.

"In the food industry, the biggest struggle that a lot of companies are seeing is sustainment," she says. "You can obtain certifications but the issue is sustainment long term, keeping those programs alive every day." And she says Endangered Species Chocolate is able to do that.

For its high level of quality and safety, Endangered Species Chocolate was recently named the winner of the 2019 Food Quality & Safety Award in the small business category.

The award honors the dedication and achievement of organizations making significant contributions to uphold the highest food standards supported by quantifiable results. This year, a panel of industry judges concluded that Endangered Species Chocolate and Hindustan Coca-Cola Beverages, which won in the large business category, demonstrated impressive efforts in their technology, certifications, training, regulatory compliance, and risk reduction.

Endangered Species Chocolate, founded in 1993, has close to 50 employees and two locations in Indianapolis. In 2018, it added 26,000 square feet of satellite warehouse space at a second Indianapolis location. The company is committed to supporting conservation efforts worldwide through its annual Give Back program, which has donated more than $1.7 million over the last three years to conservation partners around the globe.

Sustainability Inside and Out

Endangered Species Chocolate produces and sells 28 different flavors of all-natural chocolate bars that vary in size. They are made from beans purchased from fair trade sources where the income benefits local communities. Part of the company's goal is to work with fair trade businesses that pay a fair wage and offer humane working conditions.

All of the company's chocolate bars and treats are named after an endangered animal. Consumers can read about the plight of the animal inside each label.

The company publishes an impact report on its activities every year. This year's partners for its GiveBack program of 10 percent of net profits are the Dian Fossey Gorilla Fund International and the National Forest Foundation.

New Technologies

To keep quality and safety measures high, Endangered Species Chocolate has added technology in several areas throughout the past year.

One is its metal detection program for quality checks on all finished products on its three production lines. The program includes screening products for potential ferrous, non-ferrous, and stainless steel metals. Metal detection is now included in its food safety

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plan as a critical control point, and as the technology evolved, it has greatly reduced false rejections.

"Metal could be introduced anywhere, in stainless pipes and tanks, in-line screens, pumps with gears, and in the foil in which some of the candy is wrapped," says Troyer. "The metal detectors are calibrated to detect small amounts of metal."

The company has also improved its work-in-progress procedures. In the past year it automated steps in its carton packaging system that reduced the number of necessary employees. Those employees now work in other parts of the company, Robinson says.

That procedure automation, which is part of the continuous improvement program, increased efficiency by 10 percent and reduced waste from 3 percent to 1 percent in its first year of production. The system automatically folds cartons rather than having them folded less accurately by hand, Robinson says. The carton system also decreased potential food contact and contamination from humans through its automated conveyor belt.

The company has also invested in several conveying systems that led to a new wrapper for its new 1.6-ounce ESC DUOZ and 1.5-ounce ESC ONE chocolate bars. The depositing system allows two different fillings to be inserted into the chocolate at the same speed and time. The chocolate bar also uses a new wrapper technology that heat-seals end-to-end film around the bars, leading to less contamination after wrapping. (The company's 3-ounce bars still are wrapped in foil and then a paper wrapper sealed by food-grade glue.)

The company's smallest chocolate bites, 3-ounce bars, ESC DUOZ and ESC ONE bars all use a newly improved ink jet system that date codes all products, ensuring a digital double check for the lot code dates in the inventory system.

A new electronic warehouse management system contains lot codes for a new warehouse tracking system for inbound and outbound finished products and all raw materials. The raw materials also have electronic certificates of analysis.

In the company's first warehouse, which has a 10-foot-high clearance, pallets were picked from floor level. The satellite warehouse, which has 20-foot ceilings, allows the company to stack pallets on racks. "Our top-moving products are on gravity flow racks, which results in a first-expired, first-out process," Robinson says.

Finally, the company's production line switched to a one-step sanitation tablet that has increased the effectiveness of cleaning throughout the factory. The sanitation team previously used bleach-dosing procedures to clean. Pre-op and post-op procedures now include adenosine triphosphate and allergen swabbing to validate the change in the sanitation program.

Training for Safety

Internal auditing has increased audit scores for all third-party certifications. For example, the company achieved Safe Quality Food (SQF) Level 3 certification in May 2019 with a 96, Excellent score. That score is up 25 points and one level up from the score the company received in 2018.

The company said internal training sessions have helped employees strive for the highest quality when handling products during production and when talking about them with customers. Production employees wear a uniform and a hair or beard net, if applicable, Troyer. says They also wear gloves that are changed frequently.

Endangered Species Chocolate implemented its food safety plan in 2012. It didn't make any major changes until an additional line was added in 2014. Other updates included a snack bite line addition in 2016, a satellite warehouse in 2018, and the ESC DUOZ product in 2019. The Food Safety Plans have continued to evolve as the company has grown.

"You can obtain certifications but the issue is sustainment long term, keeping those programs alive every day," says Shelby Troyer, quality programs manager for Endangered Species Chocolate.

It has two safety plans, one for production and one for warehouse processes. Depending on the process, the food safety plan ranges from two to three critical control points. The two plans are reviewed annually. Additionally, each plan is validated every time new equipment or a process is added, or when a raw material is altered. The company's food safety plan team comprises five members: the warehouse manager, production manager, director of operations, quality control technician, and quality programs manager. All five members have Hazard Analysis and Critical Control Points certification.

Suppliers and Audits

Each of the company's suppliers is required to be part of its supplier approval program, and each must supply the following documents:

- Third-party certificates (SQF, BRC, FSC22000, organic, Kosher, Fairtrade, non-GMO, Gluten Free)
- An entire audit with corrective actions
- Letter of guarantee
- Traceability procedure
- Address of its manufacturing facility
- Allergen statement
- Specification sheet
- Origin statement

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Each supplier also must undergo a risk assessment of the material it supplies. The risk score is based on biological, chemical, and physical sources of error as well as common issues with the supplier. Depending on the risk, the supplier is given a low, medium, or high score that is updated annually.

Additionally, Endangered Species Chocolate conducts its own monthly internal audits and develops a corrective action plan to be performed within 30 days or at the next monthly audit. If the auditors discover any issues they inform the production and warehouse managers to ensure corrective action is taken. The company said conducting the monthly internal audits throughout the plant helps with continuous improvements and the sustainability of food safety and quality of its products.

The quality manager (SQF practitioner) and the director of operations (back-up SQF practitioner) conduct an annual internal audit. The company also performs weekly GMP audits to assure all employees have good manufacturing practices in mind.

Endangered Species Chocolate's third-party auditors include the FDA, Indiana State Health Department, SQF Food Safety and Quality, Fairtrade, Gluten Free, non-GMO, and Kosher certifications. Each certification body requires an annual audit encompassing all food safety and quality measures.

Minimizing Contaminants

Even though the factory doesn't have high pest activity, Troyer says, McCloud Pest Control services both the production and warehouse facilities biweekly. Pests at both facilities have been kept to a minimum and are actively monitored for pest activity, the company says.

The company's environmental program includes swabbing for zones one through four for the entire facility each week. It tests for *Enterobacteriaceae* in zones one and two. *Salmonella* and *Listeria* are tested for alternating in zones three and four from week to week.

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Getting Candid About Environmental Monitoring

A food safety consultant tells us everything companies need to run their own program

BY **RICHARD STIER**

Recently, I had the opportunity to sit down with Cliff Coles, president for over 20 years of Clifford M. Coles Food Safety Consulting, Inc., to discuss what makes an effective environmental program. Here's how the conversation went:

Richard Stier: Should every company put together a hygiene monitoring program? Why or why not?

Cliff Coles: A hygiene monitoring program should reflect the risk assessment on the product being made. Certainly, a ready-to-eat product such as a salad or a cold-cut sandwich should and would have a more in-depth significance, whereas a beverage facility producing shelf-stable juices would be concerned with economic spoilage organisms, such as yeast, molds, and perhaps *Lactobacillus* or *Alicyclobacillus*. Whatever the case, it becomes the report card that justifies the efforts and dollars being spent by a company to remain in the marketplace. With respect to food safety, keep in mind that regulatory officials do not need to prove that a product is contaminated. They simply need to show that the product is being manufactured in an environment whereby it may become contaminated. This is a big difference, and if a company fails to monitor and control the environment, it could fail the test.

RS: Do you have a preference for the type of tests used?

CC: A company needs to decide how it will set up an environmental swab program. Will the program include Zone 1 swabs (direct food contact surfaces) or Zone 2, Zone 3, and Zone 4 only? Those who choose to include Zone 1 areas may opt for testing for "indicator" organisms, such as coliforms, as their choice over the other options. Several companies have chosen non-specific ge-

netic testing (performance testing) to gauge the effectiveness of the sanitation on Zone 1 and Zone 2 environmental areas.

The options for monitoring an environment are plentiful, each has its own pros and cons, and each can be used to support the other. While plate counts and other counting methods require incubation time and can be cumbersome, counts can be used to determine levels of a specific organism and identify indicator organisms. Adenosine triphosphate (ATP) is a longstanding technique that is sometimes misunderstood. ATP results do not equate to the microbial load on a surface being sampled but do reflect the presence of organic material that can be the source of bacterial contamination, or at least be a food source for bacteria. A word of caution however: If the sanitation chemicals contain phosphates (the "p" being "phosphate" in ATP) and the chemicals are not sufficiently rinsed off of equipment surfaces, then the ATP swab results will naturally be consistently over the action limits that a company has deemed as acceptable.

Allergen swabbing is not a measure of microbial sanitation, but again, if the cleaning for microbial contamination is insufficient it's pretty much a guarantee that the allergen proteins, if present, will remain. Environmental monitoring has to include the presence of allergens within the facility if allergenic ingredients are used. If gluten is the allergen of concern for example, the monitoring program needs to include ancillary areas of the production zones like walls, overhead structures, air ducts and air filters, and other product contact surfaces on adjacent equipment and in Zone 1 and Zone 2.

RS: If a company gets positives in its hygiene monitoring, what do you suggest as a corrective action?

CC: How a company reacts to a positive should be dictated by where the positive is found. Unless the company is doing ATP swabs, non-specific genetic performance testing, indicator organism swabs, or protein swabs on Zone 1 sites, finding a positive swab implicates finished products, while a Zone 2 or Zone 3 positive may not have a direct impact on the finished product. A Zone 1 positive for a pathogen should at a minimum indicate that the finished products manufactured since the last break-and-clean should be placed on hold.

This also assumes that the company has a hold-and-release program in place. The dilemma some industries face (produce for example), is the shelf life of the product dictates that almost immediately after packaging the product is into distribution—often before results are available. The response to that situation is the company should have a well-founded, extensive sanitation program, environmental monitoring program (EMP), and one heck of a Work in Process testing program with rapid methods that are: 1) reliable, 2) recognized reliable and applicable to your matrix, and 3) being used effectively to provide the warnings *before* the product gets out of the control of the company.

The FDA has always taken the following approach: You cannot test enough samples to prove the product is not contaminated or test your way out of a problem. This is basically why most companies do not test for the pathogen but rather test for an indicator that does not incriminate the product. Keep in mind that by not testing Zone 1 sites, it doesn't mean the product does not represent a potential health hazard in the marketplace. Should that product be associated with an illness outbreak, there are severe consequences to:

- Failing to keep the product safe;
- Having a paper trail that indicates you knew, or should have known, there were potential issues associated with the finished product based on the Zone 1 swab result, or lack thereof; and
- Testing the product, finding nothing in the few samples you tested, and assuming that the rest of the "untested" production was acceptable.

Finding a positive environmental swab result, regardless of the Zone, still requires the offending area be cleaned and that subsequent swabs are negative. I will also add that if the remedial actions and result aren't documented, then you didn't do them.

The Food Safety Modernization Act (FSMA) has expanded the swab zone to be a 12-inch-by-12-inch area. The increase in size represents an increased potential of finding a positive, and that is exactly the point of any well-designed environmental program. John Butts, PhD, one of the foremost authorities on *Listeria* and environmental sampling, preaches the Seek and Destroy mission, which is the fundamental foundation of every environmental swab program. Seek out the niche places that harbor the offending microorganisms and adjust the sanitation programs and environmental surveillance to destroy that harborage. The FDA expects:

- A positive environmental swab to be attacked and eliminated;
- Negative results for a minimum of three consecutive swabs be conducted on separate dates;
- That the once-positive site be monitored and continually swabbed for at least six months; and
- Documentation, documentation, documentation!

Positive environmental swab results are telling you something, and you need to listen. A positive result in a drain that is cross-connected to other drains tells you all the drains are potentially positive, and cleaning that one single positive in no way ensures you've eliminated the source of the problem. Establish the fact that you have a drain cleaning program and use things like quaternary-containing socks or appropriate biocides throughout the production day to minimize the chances that aerosolization of the drain water is not allowing pathogens to become airborne. Having an intermittently positive drain may also indicate that your cast iron drain pipe is harboring a biofilm and continuing to put chlorine and other harsh chemicals down the drain in an attempt to eliminate the problem is actually making it worse.

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"A proactive environmental program requires every level of management from the very top down to be engaged in the goals and execution of a sound EMP." —CLIFF COLES

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The corrective action to consider is to isolate the entire drain area with floor-to-ceiling polyethylene and sandblast the corrosion off the inside of the drain. Once the drain is again smooth, a metal epoxy coat should be applied to the inside of the drain to prevent further rust development or pitting. Consider inserting a cleanable, stainless steel insert that extends significantly down into the drains.

Many companies will expand the swab site following a positive environmental sample. This vectoring-out concept will keep reaching further away from the initial positive until the positive detections are no longer found. In many cases, this can be several feet to several yards from that original finding, but this is the definition of Seek and Destroy.

One effective tool in eliminating pathogens is the use of silver ion-containing compounds. I find PURE Bioscience is helpful in eliminating *Listeria* and *Salmonella* from environmental niches.

RS: Should companies routinely do air testing of any sort? Do you have suggestions for the best means to do so?

CC: Air testing should be an integral part of an effective environmental program. All air sampling programs should include a sample of the environmental air outside the facility as a baseline. Granted, it will vary day to day and season to season, but when it is done in conjunction with the samples being taken in the production area, it will give a perspective as to how effective the air filtration system is.

Similar to the swab results, air sampling is telling you something. If you investigate, you might find the excessive counts in the facility in comparison to outside air indicate that the PM for changing filters is not occurring at the frequency the plan requires. Maybe there is a tear in the filters or there are no filters; I encountered both situations during plant visits to determine the high rate of mold contamination of finished products. The air sample program also indicated that access doors directly across from the filling lines were left open far too long or too often, and the dust and debris from a neighboring non-food manufacturer were infiltrating into the food plant's production areas.

The very best method for air sampling is to purchase equipment that actually pulls definable volumes of air into the unit and impinges the targeted microorganisms onto differential growth media. The results can be expressed as count per "X" liters of air or converted to counts per cubic foot.

Many companies continue to rely on air exposure plates. While it can be a reasonable indicator of air quality, realize the downside to the method is that results are obtained only when a random spore or microbe happens to settle on the open plate of growth media. Not very scientific, but if the plates are exposed in areas of high pedestrian or vehicular traffic, or directly under an air exhaust vent, the data can still be valuable and indicative of a need to initiate corrective actions.

RS: What steps should companies take to develop an EMP? Should they do it in-house or go outside?

CC: Start with a comprehensive risk assessment of the process, the raw materials being used, the product being manufactured, and an assessment as to whether the "category" of the product has been recalled or implicated in a foodborne outbreak. The entire management team needs to be on board with the program, the implications, the responsibilities of each department, and the fact that the FSMA requires the environment be monitored. This is not just another *"Oh there goes QC again!"* program. A proactive environmental program requires every level of management from the very top down to be engaged in the goals and execution of a sound EMP. It is also not a bad time to engage the corporate or outside legal counsel with the intent of the program and how Zone 1 swabs are handled or not conducted at all.

Does the process have a kill step? Should it and could it have a kill step? Does it have something that could be or should be a kill step? Blanching might be considered a reduction step or in some corners a kill step. If you are applying a heat step to the product and the product still contains pathogens, there's a problem. You have re-contaminated the product through the environment, unclean equipment, handling practices, or whatever. If the product is manufactured under conditions whereby it may become contaminated, the FDA and other regulatory agencies will hold you accountable.

Getting a qualified consultant in to provide onsite assistance in evaluating the program and suggesting improvements or even deletions to a program can be valuable. It has always been my opinion that the program belongs to the company and the company must be responsible for executing the EMP. It is not something to pass off to a third party. It is imperative the company understands and completely owns the program. ■

Stier, industry editor for *Food Quality & Safety*, is a consulting food scientist with international experience in HACCP, plant sanitation, quality systems, process optimization, GMP compliance, and food microbiology. Reach him at rickstier4@aol.com.

Figure 1. Pictograms warning of (from left to right) corrosion, health hazard and acute toxicity (fatal or toxic).

Safety Data Sheets and Food

SDSs are a requirement in manufacturing facilities where a chemical used in food processing warrants precautions

BY **ROBERT KAPP, PHD, FELLOW ATS, FRSB, EUR REG TOX (ERT-UK)**

Safety Data Sheets (SDSs), formerly known as Material Safety Data Sheets (MSDSs), are a critical component, required by law, of safe manufacturing operations as they contain basic information about a chemical or product which helps to ensure the safety and health of the user at all stages of its manufacture, storage, use, and disposal. But are they really needed in food production?

As explained in the Guidance for Hazard Determination For Compliance with OSHA Hazard Communication Standard (29CFR1910.1200), manufacturers and importers are responsible for performing a hazard determination on the chemicals they produce to determine if, under normal conditions of use, their product could result in a hazardous exposure situation for downstream employees who will be working with or otherwise handling that product. "Chemical" is broadly defined in the Harmonized Communication Standard as "any element, chemical compound, or mixture of elements or compounds." Chemicals, therefore, include food and food additives.

SDSs in the Food Facility

Food products, like any other chemical product, must be evaluated for their downstream hazardous exposure potential. As an example, employees who work with flour may be exposed to the potential hazards of explosion or combustion that may occur if flour becomes airborne in sufficient concentrations. Chemicals added to the food, such as sodium nitrate and sodium nitrite in processed foods, that could be hazardous must also be identified on an SDS.

Both of these cases represent potential physical hazards that would have to be noted on an accompanying SDS for that food product. In these cases, in addition to preparing an SDS, employers must also train employees about operating safely with those chemical hazards in the workplace. SDSs for all chemicals must located at or near the point where the chemical in question will be introduced so that the information is readily accessible. They must be updated at a minimum every five years. SDSs are an important component of food safety plans. Facilities without them, or without all that are required, will be found in violation during an FDA inspection or third-party certification audit.

SDS History

Interestingly, SDSs have a long and involved history, extending back into time as far back as 4,000 years ago when MSDS-like records described pharmaceutical use in Egypt. A thousand year later, the Greeks recorded not only their own observations, but also some of their early experimental work on similar documents. Skipping ahead another millennium, chemical data sheets were continuously being developed by chemists at avante garde chemical companies as a way of transmitting various data to fellow chemists, including melting/freezing/flash points, viscosity, density, with additional items such as reactions and fire hazards. While health, safety and toxicological data had been in development over thousands of years, it

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is only recently that this information has been included on data sheets for an all-inclusive document.

The U.S. federal government got involved in the mid-1960s, developing its original Form LSB-00S-4 to meet the needs of maritime workers and adding safety and hazard information for the first time to a chemical safety sheet. With the passage of Public Law 91-596, on Dec. 29, 1970, OSHA was established within the Department of Labor and Form LSB-OOS-4 became Form OSHA-20, issued as "revised May 1972."

On Nov. 25, 1983, OSHA issued its final regulation requiring MSDSs for all shipments of hazardous chemicals leaving a manufacturer's workplace and from all importers of such on all shipments, to be implemented by November 1985. Distributors and employers were to comply as of that same date. All employers were to follow all provisions of this section, including initial training requirements for all current employees, by May 25, 1986. At that time, the formatting for MSDSs was fluid and varied considerably from company to company and from country to country. The European Union standardized the format into what is now the 16-section document, and the U.S. government created the Hazard Communication Standard (HCS) (29 CFR 1910.1200(g)), revised in 2012, requiring that the chemical manufacturer, distributor, or importer provide an SDS for each hazardous chemical to downstream users, with a standardized and more effective format to communicate chemical hazards than the MSDS. Additionally, the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) was set up with core elements that included standardized hazard testing criteria, universal warning pictograms, and harmonized safety data sheets that provide users of dangerous goods with a host of information on toxicity and safety protocols. The system also acts as a complement to the United Nations' system of regulated hazardous material transport.

As of 2017, the system has been enacted to a significant extent in most major countries around the world. This includes the European Union, which has implemented the United Nations' GHS into EU law as the CLP Regulation, and OSHA standards. When creating an SDS it is important to be aware that the proper labeling and warnings are included for the country where the product will be sold—the place that regulates the product.

SDS Sections

The 16 sections of an SDS are in a strict order. Sections 1 through 8 contain general information about the chemical, identification, hazards, composition, safe handling practices, and emergency control measures (e.g., firefighting). This information should be easily available to those who need to get the information quickly.

Sections 9 through 11 and 16 contain other technical and scientific information, such as physical and chemical properties, stability and reactivity information, toxicological information, exposure control information, and other information including the date of preparation or last revision.

Basic toxicological information is placed methodically in Section 11. While the specific format is not set, the acute data is a generally good place to start. Toxicological data such as the oral and dermal LD50s (the dose at which 50 percent of the specified animal exposed would be expected to die–this is a calculated formulaic number from a limited number of animals) as well as the inhalation LC50s (the concentration of a chemical in the air at which 50 percent of animals exposed would be expected to die). Basic information on skin, mucous membrane, respiratory and eye irritation as well as any repeated dose information also would be inserted in this section, as well as cancer listings from the International Agency for Research on Cancer, the Environmental Protection Agency, the National Toxicology Program, the American Conference of Governmental Industrial

SAFETY DATA SHEET

Section 1: Identification

Product Name: Hydrogen sulfide
Chemical Name/Synonyms: Dihydrogen monosulfide, Sulfur hydride, H_2S
Company: XXX Chemicals
123 Main Street
Any Town, USA
1-234-5678-8901
In emergency call: 1-234-5678-8990

Section 2: Hazard(s) Identification

Hazard Classification:
Flammable gases (Category 1), H220
Gases under pressure (Liquefied gas), H280
Acute toxicity, Inhalation (Category 2), H330
Acute aquatic toxicity (Category 1), H400
Chronic aquatic toxicity (Category 1), H410
Signal Word(s): DANGER
Hazard Statements:
H220 – Extremely flammable gas.
H280 – Contains gas under pressure; may explode if heated.
H330 – Fatal if inhaled.
H335 – May cause respiratory irritation
H410 – Very toxic to aquatic life with long lasting effects.
P210 – Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P284 – Wear respiratory protection in case of inadequate ventilation
P304 + P340 + P310 – If inhaled: Remove victim to fresh air and keep calm in a position comfortable for breathing. Immediately call a Poison Center or doctor/physician.
P377 – Leaking gas fire: Do not extinguish, unless leak can be stopped safely.
P381 – Eliminate all ignition sources if safe to do so.
P391 – Collect spillage.
P403 + P233 – Store in a well-ventilated place. Keep container tightly closed.

Pictograms:

Further Readings

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Silk JC (1992). Introduction in Material Safety Data Sheets: The writer's desk reference. Molinelli RP, Reale MJ and Freundenthal RI (eds.) pp 1-16.

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Hygienists, and the National Institute for Occupational Safety and Health, or OSHA. Any repeated dose studies that generate the no observed adverse effect level (NOAEL) should be briefly included here. Some companies insist on a full toxicological profile of the chemical in this section, while others put only minimal information.

There are other sections that depend on the information found in the toxicology section. For instance, Section 3, the Hazard Identification, applies the toxicological data to direct how the user must handle the product. This includes things other than toxicity (e.g., flammability, volatility, etc.). Any serious issues in handling the product must be pointed out here. Sometimes potential health effects also are detailed in this section. If the sheet is for global/EU use, then warning pictograms must go in this section (See Figure 1).

Section 4 is about first aid. There are stock phrases that appear in this section based upon the toxicological profile of the material. Section 5 covers firefighting measures and also can relate back to the toxicology section if the product has the potential for serious chemical reactions.

Section 12 is ecological information. This information is very important in the EU, which puts more emphasis on this than the U.S. historically has. EU regulators want to know the potential ecotoxicity to fish, daphnia, and algae, and if the product biodegrades or bio-accumulates, which can produce long-term harm to the environment.

The relevant regulatory information including exemptions, what agency takes precedence, rules to follow in the country that product is in, Toxic Substances Control Act (TSCA)–1976 Public Law 94-469) listing, etc., should be in Section 15.

Even for all its storied history and seemingly strict rules, the health and safety information found on current SDSs is still sometimes less than optimal. If no data is available for a particular product, then that can be stated and the SDS is in compliance with OSHA regulations. Interestingly, the regulations do not require that a preparer actually test a product/chemical—the preparer often makes their best-educated guesses or uses component toxicology data from the literature. To clarify some readings, such as skin or eye irritation, sometimes in vitro or other studies are run on the products, but this is the manufacturer's prerogative.

An SDS preparer cannot underestimate or misrepresent the toxicity of the product. Therefore, if there are components that can cause irritation or other issues, they must be called out on the SDS. If the in vitro or other test data on the actual product show that not to be the case, then the preparer can put the results of the actual product test data on the sheet. This can help manufacturers if they think their product is less toxic than the chemistry appears (fewer warnings/less hazardous = good marketing). But the data must be available to support such claims.

Who Really Needs SDSs?

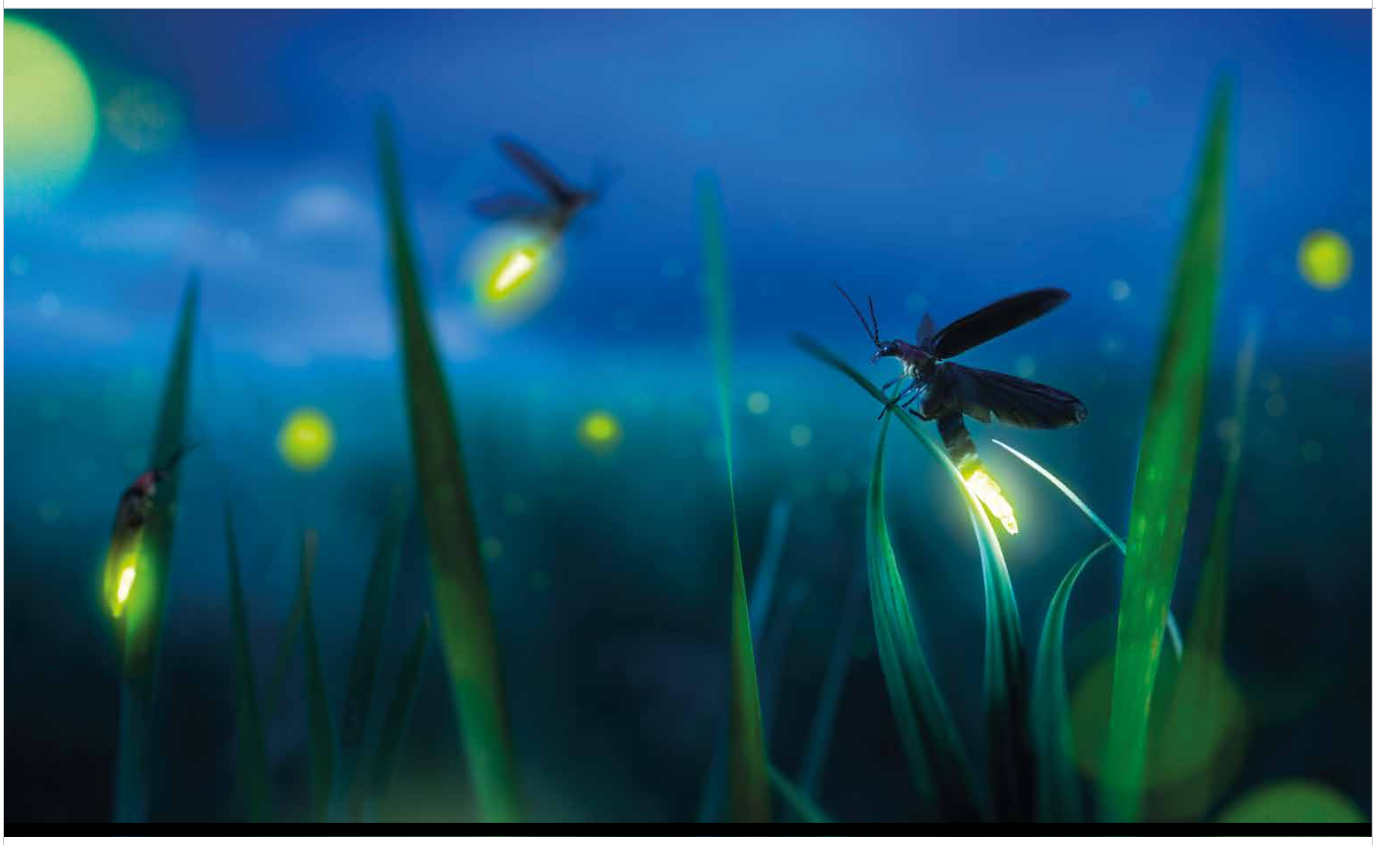
The powers that be determined that the individual consumer should have access to this information only on a "need to know" basis. Therefore, SDSs would not normally be found at the store on the shelves where food products are sold. SDSs are meant for:

1. Employees who may be occupationally exposed to a hazard.
2. Employers who need to know the proper methods for storage, safe use, etc.
3. Emergency responders such as firefighters, hazardous material crews, emergency medical technicians, and emergency room personnel.

At first blush, the fact that consumers do not have access to this information seems counterintuitive; however, the real purpose of the SDS is to protect occupationally exposed individuals and not the occasional home consumer. For instance, most paints contain some rather harsh and toxic materials—if they didn't, they wouldn't work well. If painting were your profession and you were exposed to paint fumes for 40 hours a week, week after week, that SDS data might be considerably more important than it would be for someone who painted a room once a year. It all goes back to the age-old toxicology statement: "The dose makes the poison."

Some companies put a considerable amount of information on their SDSs while others, not so much. As a rule of thumb, the data should be as complete as possible with the information at hand, with toxicological statements evaluated by a certified toxicologist. One should never speculate or overstate the effect of the product—as in all things scientific, be truthful and accurate. ■

Dr. Kapp, an independent consultant for EAS Consulting Group, has over 30 years of experience as a toxicologist involved with the management, development, and safety of new and existing products. Reach him at rkapp@eas-consultinggroup.com.



Checking on Contamination

An ATP bioluminescence system can tell you quickly and accurately how clean your plant truly is

BY **PURNENDU C. VASAVADA, PHD**

The significance of environmental monitoring to verify effectiveness of sanitation programs and minimize or prevent pathogen food contamination is well recognized. Foods, especially ready-to-eat (RTE) foods, can be contaminated with environmental pathogens such as *Salmonella* and *Listeria monocytogenes* through cross-contamination with the plant environment, including contact surfaces, unclean equipment, floor, drains, air, and water. The FDA and USDA expect the industry to have a hygienic zoning and effective environmental monitoring program designed to reduce the potential for contamination.

Many novel rapid and automated methods for microbiological testing of the food plant environment are available commercially and new methods are being introduced regularly. Their acceptance by the industry, however, depends on several factors, including speed (time to result), specificity, selectivity, accuracy and reproducibility. Other things to consider are ease of use, cost, reagents, consumables, need for training, the availability of technical support, and regulatory acceptance.

Microbiological tests designed for detection or enumeration of indicator organisms or environmental pathogens using swabs or sponges and plating are used to obtain quantitative verification of the effectiveness of sanitation procedures. These tests, however, can take days to yield results. Indirect methods like adenosine triphosphate (ATP) testing are a popular option for hygiene monitoring and verification of cleaning and sanitation.

Unlike other methods, ATP testing provides results in seconds and is sensitive, quantitative, effective, and simple. Microbes and product residue contain ATP, an indicator of biological residues that can be easily detected to measure cleanliness because effective cleaning and sanitation remove all ATP from the food plant environment and food contact surfaces. A positive ATP test is indicative of unclean or not adequately clean surfaces.

Many food processors who found hygiene and environment monitoring by swabbing and microbial counts tedious, time consuming, and expensive are considering the ATP bioluminescence system for hygiene monitoring. The proliferation of new kits and luminometers has provided several options for the food processing industry but can cause confusion about the capability and proper application of the technology. The following are some of the main criteria and considerations to keep in mind when selecting an ATP bioluminescence system:

1. Intended Purpose: ATP systems are designed to provide a quick idea about

the cleanliness of food contact surfaces such as equipment, conveyors, pipelines, pumps and valves, or drains. They are NOT intended for determining a level of residual microorganisms (e.g. <100/in2) on a food contact surface.

2. Speed (time to result): All ATP systems currently available on the market provide "rapid" results—the reading time may vary, but a reading is obtained in a few seconds. It is also important to consider the time required for an activated swab to be read in the luminometer. Other factors, such as the number of sampling sites per shift, or per day, the location of sampling sites, and operator-related factors will influence the overall speed in obtaining results.

3. Reagents and Swabs: The ATP bioluminescence systems employee swab devices already containing rinsing buffer and luciferin-luciferase reagent. The convenience of the swabs is obvious. However, reagent stability, shelf-life expectancy, and storage temperature requirements are important considerations. Also, consider if you have to "read" the test immediately after swabbing or can allow some time lapse before reading. You should also look at the quality control of swabs in terms of background reading (if any) and the batch-to-batch variation.

4. Instrument: ATP hygiene monitoring systems are based on one of the two photodetection technologies: photomultipliers and photodiodes. The sensitivity, robustness, accuracy, and precision of the rapid hygiene monitoring device are influenced by these technologies. All ATP bioluminescence systems offer portability, computerized data logging, and visual readout of ATP levels in terms of the RLUs (relative light units) or "zones" of cleanliness. The ruggedness of the instrument, battery life, computer interface with other computers in the plant, and availability of a "hard copy" of the data are other important considerations when selecting a system. For a multiproduct plant, the system's versatility would also be something to look into. Its ease of operations and user friendliness are also important.

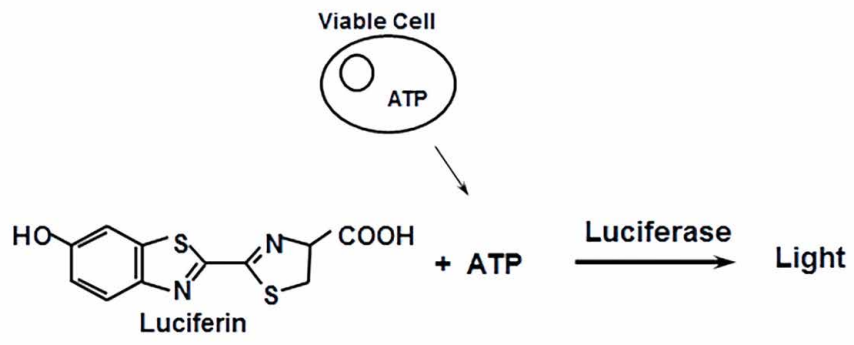
5. Training and Technical Service: When you consider adding an ATP bioluminescence system to your plant, keep in mind the training and technical service required for transition from conventional methods. All major vendors of the instruments and kits provide some training for proper operation and maintenance, but you should try to obtain training specific to your plant and situation. Contact colleagues in other companies who may have experience with a particular ATP system to discuss their experiences. Also, technical service and responsiveness should be available following the purchase. In this regard, you may also want to access training opportunities available through professional organizations and universities as well as keep current with professional reading in pertinent scientific journals and trade magazines.

6. Cost: I would list cost as the last consideration, although it may be the first thing you ask about. The cost of instruments, reagents, swabs, etc. is definitely a factor to be considered, but many variables influence the true cost. Most luminometers and swab devices are priced competitively and may be compared easily on a cost/test or cost/swab basis, and there may be incentives provided by vendors based on the testing volume or leasing versus purchasing the hardware. You may also consider return on investment or the time it will take to pay for the instrument. Savings resulting from improvements in cleaning and sanitation of plant equipment and environment may reflect in improved quality and shelf life and less time spent managing and monitoring the cleaning process and crew.

Microbes and product residue contain ATP, an indicator of biological residues that can be easily detected to measure cleanliness. Effective cleaning and sanitation remove all ATP from the food plant environment and food contact surfaces.

The above criteria and considerations are, by no means, a complete list of dos and don'ts when selecting an ATP bioluminescence system. Current ATP bioluminescence methods can be very useful in verifying effectiveness of plant cleaning and sanitation, becoming a valuable part of your food safety management program and sanitation preventive controls implementation.

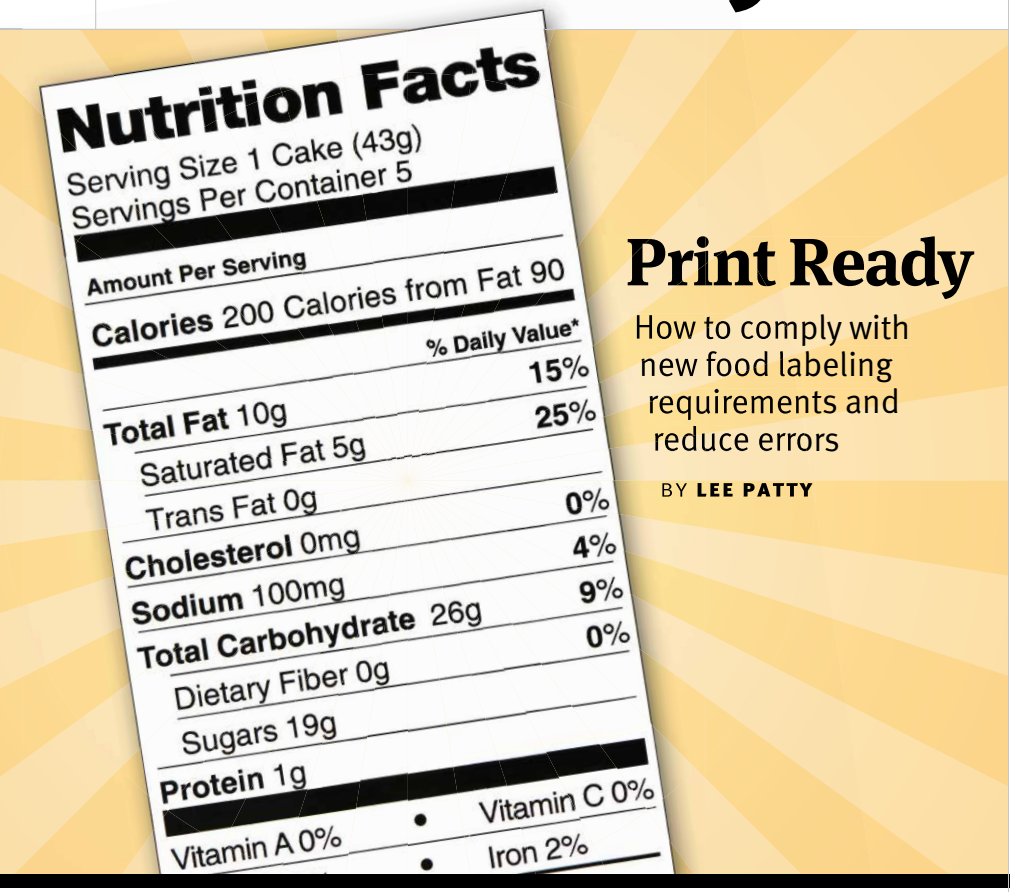
Remember, though: The results from ATP surface hygiene monitoring are different from those of microbial enumeration methods and are not directly correlated to microbial counts or detection of *Listeria* or *Salmonella*. ATP tests are not intended to replace environmental microbial testing, but they can be an excellent way to obtain indication of hygiene efficacy in seconds versus days. ■



Simplified reaction scheme showing ATP and luciferin as substrates for luciferase to generate light.

Dr. Vasavada is professor emeritus of food science at the University of Wisconsin-River Falls and a co-editor of *Food Quality & Safety*. Reach him at Purnendu.C.Vasavada@uwrf.edu.

Quality



Print Ready

How to comply with new food labeling requirements and reduce errors

BY **LEE PATTY**

The FDA recalls almost 100 million units of food every quarter. Prepared foods are the most recalled category at 21.7 percent, and although most of these recalls are due to contamination, mislabeling is also a significant contributing factor.

Mislabeling recalls can happen for a number of reasons. One recent example involves an undeclared allergen in ready-to-eat chicken soup products, while elsewhere, salted toffee chocolate bars were mislabeled as sea salt chocolate bars, resulting in an inaccurate ingredients listing.

Clearly, the consequences of a mislabeled allergen could be very severe, but it's also important to reflect accurate nutritional information on a label. And while compliance may be the main driver behind this, consumers are also becoming more switched on when it comes to watching what they eat. According to Forbes, 81 percent of consumers who are watching their weight read nutritional information, as do 42 percent who are not watching their weight. Mislabeled nutritional information could damage consumer trust and lead consumers to vote with their wallet and switch to brands that have more accurate labeling.

Complying with the new FDA nutrition facts labeling requirements will certainly be a driver for most food manufacturers in ensuring that they meet those requirements by the Jan. 1, 2020, deadline.

Label Changes

In 2016 the FDA announced the new Nutrition Facts label for packaged foods. The purpose of the changes was to update label information and add more declarations to help consumers make better food and nutrition choices. These changes varied from increasing font sizes for calories, to adding information for new minerals, to amending nutritional information based on changed serving sizes.

The presence of any allergens also must be clear. The Food Allergen Labeling and Consumer Protection Act (FALCPA) requires that all packaged food regulated under the Federal Food Drug and Cosmetic Act (FFD&C) must comply by listing any major food allergens, and in the case of nuts and shellfish, the species must be declared.

But complying with regulations doesn't have to be difficult. Selecting a labeling system that can streamline the process and reduce the risk of errors enables food and beverage companies to maintain quality and safety standards and reduce the number of product recalls. In fact, companies can use this as the driver to digitally transform their whole labeling process. And understanding the market challenges and compliance requirements will ensure that food and drink manufacturers have a robust, adaptable, and resilient labeling system to see them well into the future.

Barriers to Standardization

Todays' consumer has a heightened knowledge about health as well as the environment. In terms of health, customers want to look at labels and easily see how the product contributes to their overall energy, vitamin, and fat intake. They also are especially interested in how "natural" a product is and whether it contains artificial additives.

Closely linked to this is a requirement to know where the food comes from. The greater the food miles, the greater the contribution to global warming. Consumers are keen to support more sustainable food manufacturers as well as local farmers and producers. Providing this information on food labels can be a great differentiator.

In addition, maintaining competitiveness in the marketplace is not easy, and many food manufacturers have relied on mergers and acquisitions to keep pace. However, this can result in inheriting a wide range of legacy labeling systems as well as label and direct marking printers from a variety of manufacturers.

These challenges can make it difficult to standardize the labeling process. For instance, some labeling systems support only label printers while some direct marking printer manufacturers support only

/SHUTTERSTOCK

their own brand of printers. Indeed, having so many isolated printers in the label and direct marking process doesn't smooth the way for standardization, making it difficult for manufacturers to meet compliance demands let alone meet other consumer requirements.

And having such a wide range of hardware also impacts integration with Manufacturing Execution Systems (MES) and Enterprise Resource Planning (ERP) systems. Multi-location manufacturers often handle printer integration with MES on the local level. This means many local system integrators are subcontracted to build integrations, and they have to provide local IT support.

To further complicate things, many companies don't integrate direct marking devices with business systems because the lot and expiration date information that is commonly printed is seen as minimal and not worth the complex integration. Each location might use a different integration method, making standardization and support a challenge. Local production sites might choose varying levels of integration and introduce manual data entry on standalone systems.

For those organizations that want to integrate all of their labeling requirements with master data to respond to changing regulatory compliance and consumer demands, a modern labeling system is the answer.

Digitally Transforming the Labeling Process

A modern label management system enables manufacturers to implement a standardized and controlled method for producing labels or marking packaging throughout the entire organization. It involves having a centralized web-based document management system where labels and history are kept. Local facilities can use templates to produce the labels they need, and all changes and updates are done centrally and pushed out to the individual factories.

The most effective label management systems are able to interface with a variety of labeling and direct marking printers, regardless of manufacturer. They can also integrate direct marking and labeling with the master data in business systems to eliminate manual data entry errors. This saves companies the cost associated with reworking labels or discarding product, decreases the upfront investment companies have to make to standardize, and increases their ability to roll out a unified label process throughout their organization. Implementing a label management system is the key to creating a more productive, agile, and efficient organization.

A disconnected label-printing environment results in a time-consuming and costly process that requires users to create multiple label variations for each product, which are often manually entered. This has an obvious effect on efficiencies, and errors are also more likely to occur. However, a modern label management solution allows labels to be updated from one central location and makes it easier to identify any label errors by integrating labeling with an MES or ERP system. This makes it easier for users to have "single-source-of-truth" master data and allows them to preview any changes prior to printing. Modern systems also allow specific user roles and issue unique logins for each user, providing greater transparency across all factories that produce the product. This means that, when responding to new regulatory requirements, adjustments only need to be made in one place, saving time when new products need to be incorporated as a result of a merger or acquisition.

> Selecting a labeling system that can streamline the process and reduce the risk of errors enables food and beverage companies to maintain quality and safety standards and reduce the number of product recalls.

Improving Cost Efficiencies

The costs associated with the labeling process aren't always easy to quantify. While the obvious ones such as the cost of the printers and software are easy to identify, other costs associated with label change requests and quality assurance aren't so obvious. But these costs can have a dramatic impact on the bottom line.

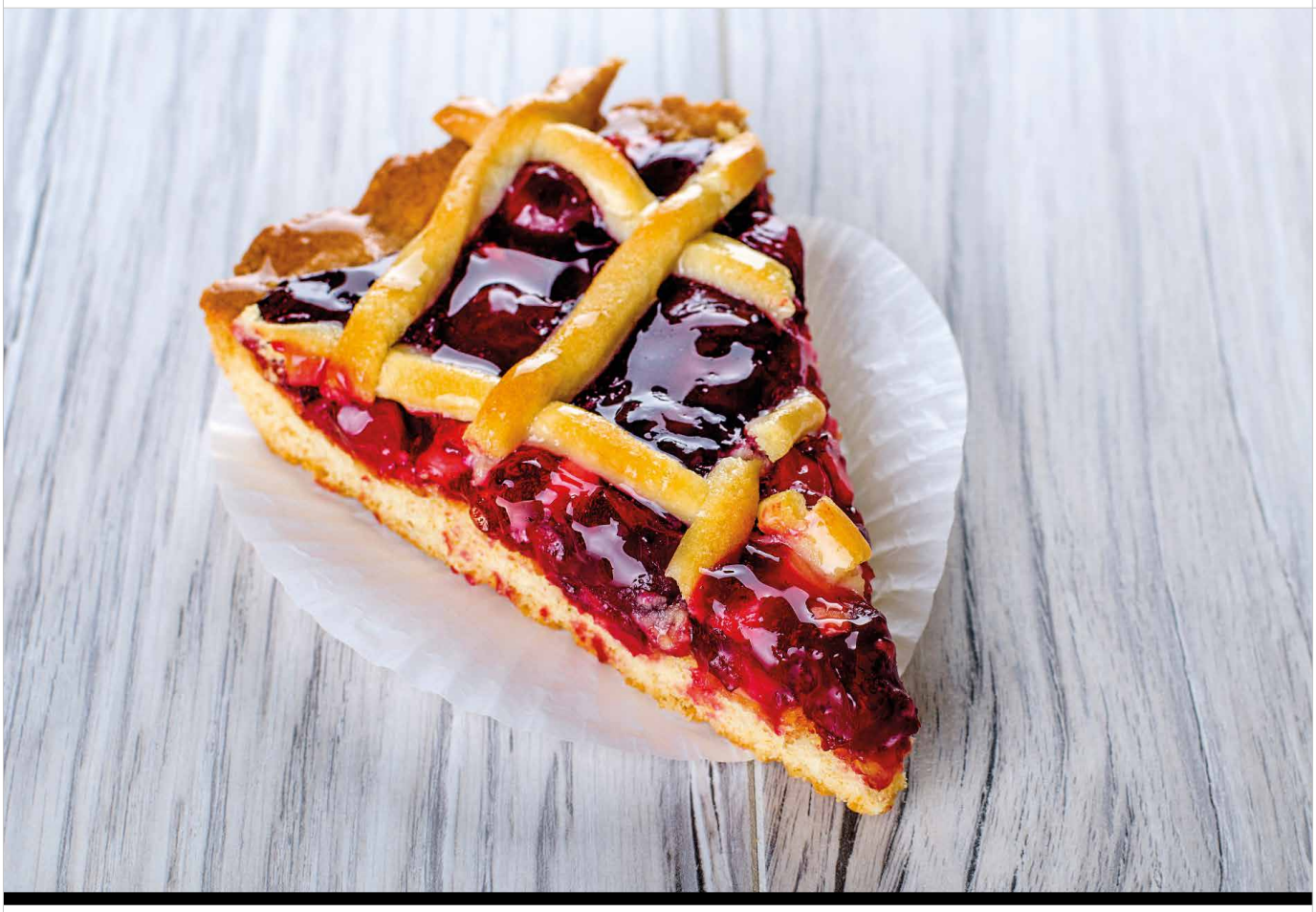
Implementing a label management system can save countless man-hours and increase employee productivity by using pre-made templates and streamlining the whole quality assurance process. Digitally transforming the labeling process eliminates manual data entry, which drastically reduces the likelihood of errors and therefore mitigates product quarantine, recalls, and scrappage, leading to cost savings. In addition, standardizing on a system that can work across a wide range of label and marking printers enables businesses to continue to use their existing hardware. And selecting a system with a familiar user interface, particularly one that has a Microsoft Word look and feel, means that anyone can quickly design professional labels without barcoding, design, or advanced computer skills.

Cost savings can also be realized through more effective use of IT resources. Many food and beverage manufacturers use a combination of local and corporate IT support, which can be difficult to coordinate on a global level. A label management system removes the IT requirement needed for coding and development through uncomplicated web-based interfaces to enter the document management system and to make changes. The need for programmers is also eliminated, freeing up IT budget, which can be reinvested into other parts of the manufacturing process.

Labeling for the Future

Food and beverage manufacturers are under pressure to transform their businesses while improving cost efficiencies and competitiveness. Regulations are also changing and the demand for more transparency and information on every label isn't going to slow down. However, those companies that have already implemented a modern label management solution are in an excellent position to meet the new FDA rules now and adapt to any future changes both quickly and efficiently. In addition, modern labeling systems can help to reduce product recalls, reduce labeling errors, improve productivity, and satisfy consumer demands. ■

Patty is VP and general manager at NiceLabel Americas, where he oversees the company's sales, project delivery, and operations in the Americas. Reach him at lee@nicelabel.com



How Sweet It Is

Allulose is an emerging sweetener that has it all

BY **MICHELLE SMOLARSKI**

Recommendations to reduce sugar intake, like the World Health Organization's suggestion to limit the intake of free sugars, have left many companies weighing the pros and cons of reformulating existing products or innovating with new ones.

On one the hand, replacing sugar with a low- or no-calorie sweetener seems like an obvious solution to maintain the sweet taste consumers expect. On the other hand, food manufacturers can't consider altered taste in isolation when substituting sugar with another sweetener: They must also ask if the end product will have the same technical characteristics such as mouthfeel, texture, and melting or freezing points. Companies may also consider whether replacing sugar with a sugar substitute will positively impact the Nutrition Facts label and help justify the costs of reformulation. Finally, it has become important to consider how the growing group of consumers seeking out foods and beverages with fewer and more familiar-sounding ingredients will perceive products reformulated with sugar substitutes.

Results from the 2019 International Food Information Council's annual Food and Health Survey indicate that the food industry may have no choice but to reformulate based on consumer opinion. According to the survey results, limiting sugar intake is the most common way consumers have changed their diets. And of the 80 percent of consumers looking to limit or avoid sugars, many have looked at Nutrition Facts labels to choose products with less sugar, have used low-calorie sweeteners, or have switched from full-calorie beverages to low- and no-calorie options.

In the face of consumer preference for natural, sweet products that are low in sugar and calories, allulose is gaining popularity.

A Rare Sugar with Benefits

Allulose is one of many sugars that exist in nature in very small quantities. Initially identified from wheat, it has since been found in fruits such as jackfruit, figs, and raisins. It can also be made from fructose as well as corn, which has helped make it cost-effective and scalable. Although allulose has long existed in nature, the FDA officially acknowledged its status in 2012, when the agency termed it to be Generally Recognized as Safe. In April 2019 the FDA published draft guidance on labeling products containing allulose. Given this recent publication and the current global

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dialogue around sugar reduction, it is no surprise the sweetener is receiving increased attention.

Allulose, sometimes written as D-psicose, is chemically classified as a monosaccharide. More specifically, allulose is considered a ketohexose, a six-carbon monosaccharide. The key to the unique sensory and physiological characteristics of allulose is the rotation of a hydroxyl group on the rare sugar's third carbon. Due to this rotation, allulose is absorbed, but not metabolized, and is excreted intact in the urine.

While some researchers estimate that allulose provides 0.2 calories per gram or fewer, others believe it contributes 0.4 calories per gram. To ensure the caloric contribution of allulose is not underestimated, the FDA has stated in its recent draft guidance that it intends to exercise enforcement discretion for companies using a caloric value of 0.4 calories per gram, "pending rulemaking to consider amending 21 CFR 101.9(c)(1)(i) to require the use of a general factor for caloric value of allulose of 0.4 kcal/g." In addition to determining its negligible caloric contribution, nutrition researchers have also found that allulose does not impact blood glucose levels, and may even suppress the glycemic response of other carbohydrates consumed at the same time.

While there is no regulatory definition for "natural," and as we await the FDA's new definition for the term "healthy," allulose is poised to be used in more natural-type products. Although allulose is generally seen as a new ingredient on the market, its established safety, backed by robust scientific research and general consumer acceptance, make its use as a natural low-calorie sweetener a viable option. As a more important determinant of likeability, allulose has what is considered a "clean sweetness" similar to that of sucrose, and without any off-flavors or bitterness.

It is important, however, that consumers are not misled to believe the sweetener will have the same physiological effects of what has traditionally been defined as sugar. The examples that fall under the FDA's current definition for "sugar" include monosaccharides like fructose, galactose, and glucose, as well as disaccharides. Further, the FDA's definition of "added sugar" describes those that are added during the processing of foods or packaged alone as such. Under the Nutrition Facts and Supplement Facts Label final rule issued in 2016, a monosaccharide like allulose would, by default, be required to be listed as an Added Sugar under the Total Sugar listed on packages. In that final rule, however, the FDA stated that it needed more time to consider information provided in citizen petitions and in public comments regarding allulose.

In addition to determining its negligible caloric contribution, nutrition researchers have also found that allulose does not impact blood glucose levels, and may even suppress the glycemic response of other carbohydrates consumed at the same time.

One of the citizen petitions submitted by Calorie Control Council member company Tate & Lyle recommended exempting allulose from the 2016 proposed labeling requirements based on the following premises:

- Allulose is not metabolized like sugar;
- Allulose does not raise blood glucose levels;
- Allulose has negligible calories; and
- Labelling allulose as sugar will lead to confusion, especially for those with diabetes and consumers who may be otherwise monitoring their blood glucose levels.

In addition, the petition reminded that, "the FDA has previously provided labeling exemptions for two other foods where the Agency determined that the product did not provide metabolizable energy for humans (wax esters in orange roughy; 21 CFR part 101) and for not being considered a source of fat or calories and because it is not absorbed and thus not unavailable to the body (olestra; 61 FR 3118 at 3126)."

FDA Exemption from Total and Added Sugars

The FDA announced in the draft guidance its decision to exercise enforcement discretion for excluding allulose from the Total Sugars and Added Sugars declared on labels. The agency explained that Total Sugars have traditionally been determined based on chemical structure. However, "due to advances in food technology, novel sugars are now available that are not metabolized and that do not contribute 4 kcal/g to the diet like other traditional sugars. Consequently, we need to consider how information about sugars like allulose should be captured on the label."

The FDA goes on to explain its current thinking, stating "... we should consider not only the chemical structure of sugars, but also other evidence including their association with dental caries, their effect on blood glucose and insulin levels, as well as their caloric contribution when determining whether a sugar should be included in the declaration of 'total sugars' on the label."

Since allulose does not significantly impact glycemic and insulinemic responses, contributes far less than 4 kcal/g, and does not promote dental caries, the FDA intends to exercise enforcement discretion with respect to the exclusion of Total Sugars, and its subset of Added Sugars, including the % Daily Value declaration. However, the FDA determined that a physiological effect-based definition would not be appropriate for allulose under Total Carbohydrates because of the wide variety of physiological effects elicited by different types of carbohydrates (e.g., starch, dietary fiber, sugar alcohols, etc.), as opposed to the common effects shared by traditional sugars.

Larger Manufacturing Scope of Use

Now that the FDA has clarified how the unique sugar substitute may be labeled in order to comply with the new Nutrition Facts label requirements, manufacturers are free to take advantage of the diverse technical functionalities of allulose. Whereas alternative sweeteners have been used for decades in beverages like diet soda, their application in foods that face freezing or baking temperatures has proven to be a more difficult challenge.

(Continued on p. 42)

(Continued from p. 41)

Allulose's chemical structure as a monosaccharide helps it closely mimic sucrose, which, as a disaccharide, has a similar structure. While allulose is considered to be approximately 70 percent as sweet as traditional sugar, allulose dissolves quickly in water or other liquids, and also behaves like traditional sugar in items like baked goods and ice cream.

When formulating foods with allulose, food technologists must consider several technical characteristics aside from sweetness and solubility in liquids. Such characteristics include browning, crumb structure, freezing point, stability, and compatibility with other sweetening ingredients. In baked goods, allulose browns even more than sucrose, making it an ideal sweetener to lower the calories and sugar in products like cookies expected to have a deep golden hue. Adding allulose to desserts like cake also results in a crumb structure similar to sucrose or high fructose corn syrup. At the same time, allulose maintains good moisture-holding properties that can protect the moist, tender texture of finished baked goods.

Just as allulose acts like traditional sugar in baked goods, it also functions well in frozen desserts. As a monosaccharide, allulose behaves like a sugar: It decreases the freezing point of frozen products, and remains stable during freezing conditions. Frozen products made with allulose versus sucrose demonstrate similar "meltdowns," although allulose-sweetened products may melt more quickly considering sucrose's chemical structure as a disaccharide. Furthermore, in foods and beverages with low pH systems such as products with acidic fruit, allulose has good processing stability, even under high temperature processing conditions.

Finally, while the benefits of allulose are versatile enough for the sweetener to stand on its own, allulose may also be combined with more high-intensity sweeteners like sucralose and stevia, in cases where the desired level of sweetness is greater than the 70 percent allulose provides. In addition, when combined with these high-potency sweeteners, allulose has a temporal profile closer to sucrose, meaning that the onset and dissipation of sweetness is comparable.

A Sweet Hit?

Allulose is proving to be a sweetener that, in fact, has it all. The rare sugar contributes negligible calories and does not raise blood sugar levels, yet at the same time is able to impart the same sweet taste, texture, and other technical attributes consumers have come to love about foods and beverages sweetened with traditional sugar.

With the recent FDA draft guidance clarifying that allulose does not need to be labeled as a Total or Added Sugar, and can be calculated as 0.4 kcal/g, many are predicting allulose may be the next ingredient to hit consumers' taste buds. ■

Smolarski is a regulatory & scientific affairs manager at the Calorie Control Council. Reach her at msmolarski@caloriecontrol.org.

Acesulfame Potassium

First Published: Prior to FCC 6
Last Revision: FCC 7

Acesulfame K
6-Methyl-1,2,3-oxathiazine-4(3*H*)-one-2,2 Dioxide Potassium Salt

$C_4H_4KNO_4S$ Formula wt 201.24
INS: 950 CAS: [55589-62-3]
UNII: 23OV73Q5G9 [acesulfame potassium]

DESCRIPTION

Acesulfame Potassium occurs as a white, free-flowing crystalline powder. It is freely soluble in water and very slightly soluble in ethanol.
Function: Non-nutritive sweetener; flavor enhancer
Packaging and Storage: Store in well-closed containers in a cool, dry place.

IDENTIFICATION

- **A. Procedure**
  Sample solution: 0.3 g in 1 mL of glacial acetic acid and 5 mL of water
  Analysis: Add a few drops of sodium cobaltinitrite TS to the *Sample solution*.
  Acceptance criteria: A yellow precipitate forms.
- **B. Ultraviolet Absorption**
  Sample solution: 0.01 mg/mL
  Acceptance criteria: The *Sample solution* shows an absorption maximum at 227 ± 2 nm.
- **C. Infrared Absorption**, *Spectrophotometric Identification Tests,* Appendix IIIC
  Reference standard: USP Acesulfame Potassium RS
  Sample and standard preparation: *K*
  Acceptance criteria: The spectrum of the sample exhibits maxima at the same wavelengths as those in the spectrum of the *Reference standard*.

ASSAY

- **Procedure**
  Sample: 200–300 mg, previously dried at 105° for 2 h
  Analysis: Dissolve the *Sample* in 50 mL of glacial acetic acid in a 250-mL flask. [Note—Dissolution may be slow.] Add 2 or 3 drops of crystal violet TS, and titrate with 0.1 N perchloric acid to a blue-green endpoint that persists for at least 30 s. [**Caution**—Handle perchloric acid in an appropriate fume hood.] Perform a blank determination (see *General Provisions*), and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 20.12 mg of $C_4H_4KNO_4S$.
  Acceptance criteria: 99.0%–101.0% of $C_4H_4KNO_4S$, on the dried basis

IMPURITIES

Inorganic Impurities

- **Fluoride**, *Fluoride Limit Test, Method III,* Appendix IIIB
  Sample: 4 g
  Acceptance criteria: NMT 3 mg/kg
- **Lead**, *Lead Limit Test,* Appendix IIIB
  Sample solution: 2 g in 20 mL of water
  Control: 2 µg Pb (2 mL of *Diluted Standard Lead Solution*)
  Acceptance criteria: NMT 1 mg/kg

Organic Impurities

- **Organic Impurities**
  Mobile phase: Acetonitrile and 0.01 M tetrabutyl ammonium hydrogen sulfate (40:60, v/v)
  Standard: 4-hydroxybenzoic acid ethyl ester
  Sample solution: 10 mg/mL
  Dilute sample solution: 0.2 mg/L
  Chromatographic system, Appendix IIA
  Mode: High-performance liquid chromatography
  Detector: UV or diode array (227 nm)
  Column: 25-cm × 4.6-mm (id) stainless steel, or equivalent, packed with 3- to 5-µm reversed phase C18 silica gel, or equivalent
  Flow rate: About 1 mL/min
  Injection volume: 20 µL
  Elution: Isocratic
  System suitability
  Suitability requirements: The resolution, R, between acesulfame potassium and 4-hydroxybenzoic acid ethyl ester is NLT 2.
  Analysis: Inject the *Sample solution* into the chromatograph and obtain the chromatogram. If peaks other than that caused by acesulfame potassium appear within three times the elution time of acesulfame potassium, carry out a second analysis using the *Dilute sample solution*.
  Acceptance criteria: The sum of the areas of all peaks eluted in the analysis of the *Sample solution* within three times the elution time of acesulfame potassium, except for the acesulfame potassium peak, does not exceed the peak area of acesulfame potassium in the analysis of the *Dilute sample solution* (NMT 20 µg/g of UV-active compounds).

SPECIFIC TESTS

- **Loss on Drying**, Appendix IIC: 105° for 2 h
  Acceptance criteria: NMT 1.0%
- **pH**, *pH Determination,* Appendix IIB
  Sample solution: 10 mg/mL
  Acceptance criteria: Between 5.5 and 7.5

Figure 1. Example of an FCC monograph

A Common Language

Ingredient standards are vital to supply chain integrity

BY **STEVEN M. GENDEL, PHD**

Maintaining food security and safety depends on protecting the integrity of the entire food supply chain. While our food has become multinational, diverse, and nonseasonal, these improvements have come with a reduction in supply chain transparency. At the same time, industry and governments have become increasingly aware that transparency is fundamental for ensuring safety, quality, and food defense. Consumer interest in the origin of foods as well as in production practices for food products continues to grow. All of these factors have combined to create unprecedented information needs.

Complex supply chains pose a risk to food quality and integrity because they include many touchpoints and material manipulations, each of which creates an opportunity for misunderstanding, misrepresentation, and adulteration. And the longer the supply chain, the more difficult it is to ensure that the information needed to maintain traceability and transparency is accurate and complete. When products move between nations, for example. different regulatory requirements and enforcement policies can result in critical documentation gaps.

Finding Fraud

Economic pressure on supply chain integrity occurs when prices fluctuate or when there are rapid changes in demand. Because production is often slow to respond to these changes, suppliers may be tempted to adulterate or misrepresent products to take advantage of market opportunities. Even when supply and demand are relatively stable, there are economic incentives for adulteration, such as when an ingredient can be replaced or diluted with a less expensive non-food-grade substitute or when a generic form of an ingredient can be substituted for a more valuable form (e.g., conventional produce labeled as organic).

Given these economic incentives and the many opportunities for things to go wrong in food supply chains, it is not surprising that fraud occurs. A report from the Grocery Manufacturers Association (GMA) estimated that various forms of fraud have a $10 billion to $15 billion negative impact on the industry each year. Recent data suggests that up to 25 percent of some high-value products, such as spices, are adulterated.

The results of the joint Interpol/Europol OPSON program indicate the widespread nature of the problem. Each year, this program carries out coordinated multinational operations for about four months. As shown in Table 1, products worth €150 million to over €200 million have been seized during these brief, yearly

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periods. Clearly, fraud and adulteration are significant ongoing and issues.

Even when fraud and adulteration are not problems, suppliers and manufacturers need to have a common understanding of the expected identity and purity of the ingredients they use. As with all commercial transactions involving physical goods, it is important that the parties involved agree on acceptable characteristics for the material involved. Just as there are standards that define measures for size and weight, composition standards can be used to describe the appropriate characteristics of food-grade ingredients.

Creating Common Understanding

The best way to define acceptable ingredient characteristics, minimize fraud, and facilitate information continuity is by establishing and using public ingredient standards. According to the GMA, "ingredient standards provide a solid basis for identifying and classifying raw materials." Ingredient standards act as a dictionary to create a common vocabulary that facilitates clear and consistent communication. Because standards describe what a substance should be, including what it means for a substance to be food-grade, they can be used to determine when a sample of an ingredient is not what is expected. When this happens, it could be an indication of quality problems, adulteration, or other kinds of fraud.

Referring to a publicly available standard when manufacturing, testing, selling, or purchasing an ingredient creates a level playing field for everyone along the supply chain. Standards also play an important role in protecting transparency and traceability by fostering the use of consistent (or at least interchangeable) terminology through multiple transactions.

Ingredient standards describe substances as they are used in the real world, not as abstract chemical entities, and are intended to be for material that is legally used in food or food production. Because regulatory requirements differ around the world, however, the existence of a standard does not necessarily mean that the substance described is allowed in specific jurisdictions or for all potential uses. Safety and toxicologic evaluations can be used to inform some components of a standard, such as limits on byproducts or contaminants.

Table 1. Results of OPSON Operations#

OPSON	Year Initiated	No. of Countries Involved	Value of Goods Seized (in Millions of Euros)
III	2013	33	150
IV	2014	47	NR*
V	2015	57	230
VI	2016	65	235

* NR – Not Reported
\# Information from reports available from the OPSON website

Table 2. Examples of Food-Related Standards Development Organizations#

SDO	No. of Ingredient Standards	Scope
Food Chemicals Codex (FCC)	~ 1,251	Food-grade chemicals, processing aids, food ingredients, flavoring agents, vitamins, and functional food ingredients.
Joint FAO/WHO Expert Committee for Food Additives (JECFA)	~ 520 (Ingredient Standards excluding flavors and toxicological/safety evaluations)	Food additives and processing aids (considered food additives).
ISO (TC 34)	~ 860 (Includes foods, food ingredients, and related standards)	Human and animal foodstuffs, covering the food chain from primary production to consumption.
American Oil Chemists Society (AOCS)	NA*	Methods for testing fats and oils.
Cereals & Grains Association (AACC)	NA*	Methods for analysis of grains and grain products.
AOAC International (AOAC)	NA*	A broad spectrum of analytical methods, including foods and dietary supplements.

* NA – Not applicable
\# Information from organization websites

Writing Standards

Standards are developed by entities called standards development organizations (SDOs). There are several organizations that develop standards for foods and food ingredients (see Table 2). These organizations collaborate and exchange information with each other to maximize consistency. The range of foods and substances covered by each organization, however, the depth of information provided, the process used to develop standards, and the organizational mandates differ.

One example of how these standards are developed and structured is the approach used by the Food Chemicals Codex (FCC). The FDA and the Institute of Medicine created the FCC in 1966 to "define the quality of food-grade chemicals in terms of identity, strength, and purity." FCC standards are developed by a committee of expert volunteers working with FCC scientific staff and are based on the best scientific information available. Each draft standard undergoes an open and transparent public review and comment process through publication in the FCC Forum before being finalized and published.

The FCC is an independent SDO and the only one where standards are developed by independent experts, not organizational representatives. The FCC currently contains over 1,250 standards in

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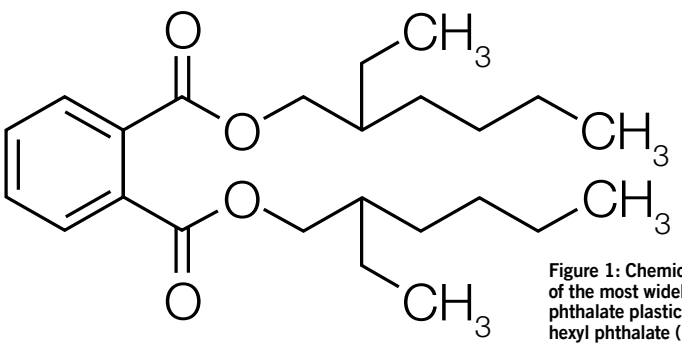

Figure 1: Chemical structure of the most widely used phthalate plasticizer, diethylhexyl phthalate (DEHP).

Finding Phthalates

Improve detection of these contaminants in fatty foods using advanced GC-MS workflows

BY **DANIELA CAVAGNINO, PHD**

Phthalates are an emerging class of contaminants due to their widespread applications across industry. For many years, phthalates have been used in the manufacturing of food packaging, and today also can be found in many plastic kitchen tools. Recent cases of phthalate contamination in certain food products and ongoing health concerns over the consumption of phthalates have led some regulators to set new phthalate limits in food contact materials (FCMs) and foodstuffs.

To support adherence to these regulatory limits, robust and sensitive analytical methods are required. While gas chromatography-mass spectrometry (GC-MS) is widely used for this purpose, the reliable identification and quantitation of phthalates can be challenging, particularly when it comes to analyzing fatty food matrices such as cooking oils. Here, we look at a novel GC-MS workflow for phthalate testing that overcomes these challenges to enable accurate determination in foods.

Phthalates in the Food Industry

Phthalates are a family of man-made chemicals that are commonly used across a number of industries such as plasticizers to soften plastics such as polyvinylchloride (PVC). Diethylhexyl phthalate (DEHP) (Figure 1) is one of the most widely used, accounting for almost 40 percent of global phthalate consumption.

In the food and beverage industry, phthalates are often used to increase the flexibility and durability of film packaging and plastic materials. Because they are weakly bound to the polymeric matrix, however, phthalates can potentially leach out into food, especially in the presence of heat or solvents. Due to the lipophilic nature of phthalates, leaching into fatty foods is of particular concern.

Phthalates can also enter food items during processing due to the use of PVC in food production and processing systems, as well as from other environmental sources, such as indoor air dust. In some countries, phthalates are intentionally added as a clouding agent to a variety of foods and beverages, including sports drinks, fruit juice, and tea-based drinks.

In the United States and Europe, contaminated food has been identified as the main source of human exposure to phthalates. Cream-based dairy products and vegetable oils in U.S. and EU consumer markets have been found to contain high concentrations of DEHP, and consumption of these products has been linked to increases in DEHP urinary metabolite levels.

Phthalate Consumption Health Risks

Phthalates have been used as plasticizers in the food industry for more than 50 years, but only relatively recently have they been understood to pose a risk to our health. Epidemiological studies link high phthalate metabolite levels to endometriosis in women and decreased male reproductive hormones, while prenatal exposure to phthalates is associated with reduced masculinization in newborn boys. Phthalate exposure also has been linked with autism development, although this has recently been disputed. DEHP is also listed as "reasonably anticipated to be a human carcinogen" according to the U.S. National Toxicology Program.

Given these health risks, phthalate residues in foods and beverages are regulated internationally, and several expert panels, mostly in the EU and U.S., have carried out risk assessments on these compounds. For example, a special EU Food Safety Authority panel (the Food Contact Materials, Enzymes, and Processing Aids Panel) recently released an updated draft opinion stipulating a group tolerable daily intake of 50 µg/kg body weight per day for four phthalates, including DEHP. This corresponds to a limit of 0.1 percent of phthalates in FCMs.

Challenges with Detecting Phthalates in Food

Given the potential risk to human health, phthalate testing is necessary to ensure foods adhere to regulatory guidelines. Since phthalate compounds need to be detected in food at low concentrations, GC-MS is widely used to determine the phthalate content of foodstuffs due to its inherently high separation efficiency and the selectivity of quadrupole MS. This analysis method may conceal several challenges, however.

The first issue concerns the risk of sample contamination during GC-MS analysis, which affects the reliability of the resulting data. Phthalates are ubiquitous in the en-

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vironment so they can easily contaminate samples during preparation and analysis, and potentially be carried over from injection to injection. The use of clean glassware, correct GC consumables, high purity standards, and solvents are crucial for producing data that analysts can have confidence in. Moreover, poorly optimized experimental conditions can cause phthalates to persist in instrument inlets, transfer lines, and ion sources, causing contamination over extended analyses and resulting in false positive results.

A second key challenge is related to the complexity of fatty matrices, such as cooking oils, which are difficult to analyze directly using GC-MS and often require extensive sample clean up procedures prior to injection. Additionally, heavier fractions, like triacylglycerols, can be difficult to elute from the chromatographic column due to their high boiling points. Given these challenges, more robust GC-MS workflows are required to ensure the reliable detection of phthalate contaminants in complex fatty foods.

Lastly, phthalates are characterized by similar molecular structures and physical properties. Many of them produce similar fragment ions and can co-elute if the chromatographic separation is not optimized. The correct choice of capillary column and MS quantification ions are important for the reliable identification of phthalates.

An Advanced GC-MS Workflow

A novel approach has recently been developed that overcomes the challenges of detecting phthalates in fatty foods. The new workflow, which makes use of the Thermo Scientific ISQ 7000 GC-MS system configured with the sensitive Advanced Electron Ionization (AEI) source, has been successfully used for the detection of 13 phthalates in vegetable oil, offering a fast, sensitive, and robust method for phthalates quantification.

To assess the linearity, limit of detection (LOD), and limit of quantification (LOQ) of the new method, vegetable oil samples were spiked with phthalates at three concentration levels (5, 25, and 50 µg/kg). The spiked vegetable oil samples were added to acetonitrile, vortexed, and sonicated before being centrifuged. The supernatant was collected and extracted to dryness, reconstituted into hexane, and subsequently analyzed for phthalates by GC-MS. To minimize the risk of contamination and to handle the high boiling nature of the analytes and the matrix, low bleed and highly inert consumables combined with optimized instrument conditions were used. The method employed polytetrafluoroethylene and siloxane vial closures, bleed-temperature-optimized inlet septa, and used optimized syringe washes, inlet, and MS temperature conditions. The results showed no heavier compound carryover, highlighting the robustness of the method.

Using timed selective ion monitoring (timed-SIM) mode enabled a significant improvement in analytical selectivity and sensitivity over full-scan acquisition, as only data on masses of interest were collected, rather than the full mass range. Thermo Scientific Chromeleon Chromatography Data System software was used to automatically optimize scan rate and dwell time for faster experimental setup and analysis. The system demonstrated selective and sensitive detection of phthalates in complex vegetable oil matrices (Figure 2).

A Better Analytical Approach for Phthalate Testing

The new timed-SIM GC-MS workflow achieved estimated LOQs ranging from 5 to 25 µg/kg, and all 13 phthalates showed excellent linear responses, with an average R2=0.999. An assessment of the recoveries of the pre- and post-spiked vegetable oil samples (across the three 5, 25, and 50 µg/kg spiking levels) returned average recovery values between 80 and 102 percent, well within the required method performance limits. These results highlight the ideal limits of detection achieved by the method, even when studying challenging food samples.

The robustness of the AEI ion source over time was demonstrated by the ion ratio stability being within ± 10 percent over 100 repeated injections of the 50 ng/mL spiked vegetable oil extract. The improved geometry of the AEI source enhanced the ionization efficiency while generating a highly focused ion beam, reducing the risk of source contamination. Thanks to the enhanced sensitivity of the AEI source, the oil extract can be further diluted before injection, or a higher split ratio can be used,

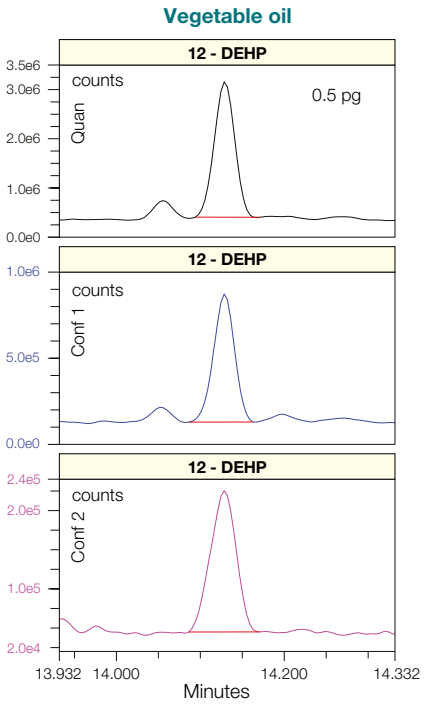

Figure 2: Example timed-SIM chromatogram for DEHP spiked at 5 µg/kg in a vegetable oil n-hexane extract (0.5 pg on-column), demonstrating measurement sensitivity.

maintaining sub-ppb limits of detection, giving more flexibility in sample preparation and lowering the risk of contamination to the GC flow path.

To support the strict limits for phthalate levels in FCMs and food products set by international food safety regulators, robust analytical methods for the reliable detection of phthalates in foods are required. However, the high risk of contamination, critical chromatographic separation, and low vapor pressure of phthalates and triacylglycerols make it challenging to reliably detect phthalates in complex fatty matrices. A new phthalate testing workflow, based on a timed-SIM GC-MS approach and making use of a highly sensitive ion source, shows enhanced sensitivity, selectivity, and routine grade robustness in phthalate analysis. This workflow has been shown to be helpful for laboratories providing food testing to better protect consumers against potentially harmful phthalate exposure, while maintaining adherence to regulatory limits. ■

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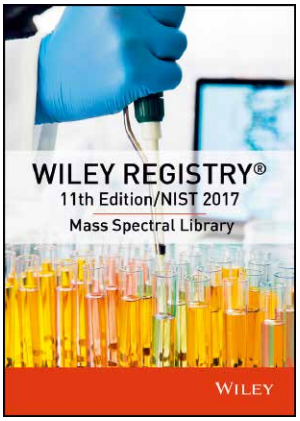

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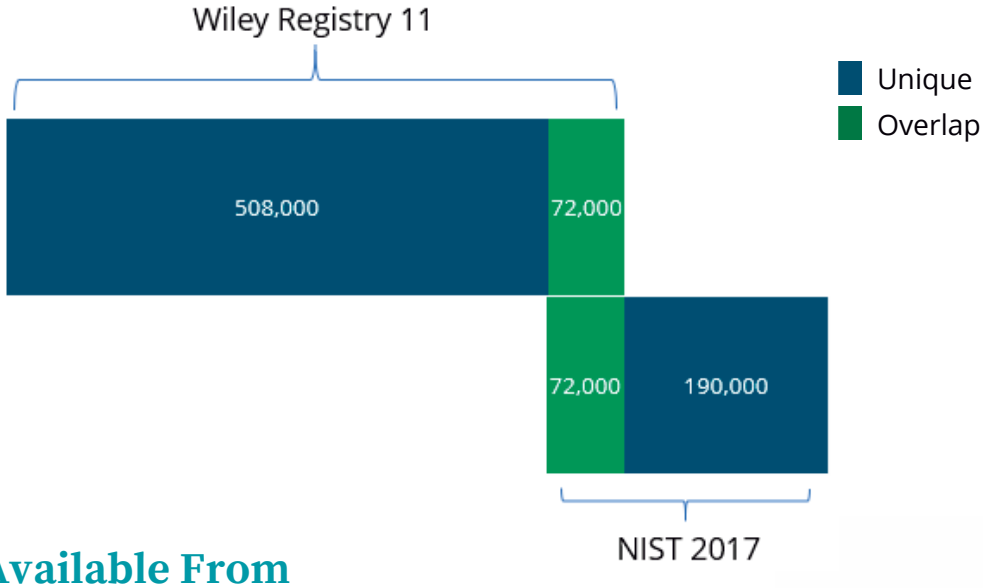

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Keeping Tabs

How microbiology laboratories can validate procedures and routinely verify compliance

BY **DOUGLAS MARSHALL, PHD**

Like high-functioning food manufacturing facilities, high-functioning food microbiology laboratories should conduct a number of validation and verification activities to demonstrate their processes are under control. Similar to how a food manufacturer must develop and validate its FSMA-required food safety plan, food microbiology laboratories also should conduct a hazard analysis, develop preventive controls for hazards reasonably likely to occur, use monitoring to validate preventive controls and for routine verification activities, develop corrective actions when out-of-spec results are obtained, and keep records for all activities. (In this case, a micro lab "hazard" is the risk of cross-contaminating client samples with out of control microorganisms in the laboratory environment.)

To ensure that laboratory test results are accurate, consider the following:

- Does company management have a conflict of interest in testing programs, and are there protocols in place to mitigate such conflicts?
- Are laboratory employees trained in ethical behavior regarding proper sample collection, testing, and reporting?
- Are there written non-conformance policies?
- Are there undue influences that impact test data integrity?
- Are the methods used fit for their purpose?

Well-performing microbiology laboratories are accredited against ISO17025 standards. The standard includes a focus on yearly employee training, a well-documented laboratory quality system, reason, length, and documentation of planned departures, and regular audits. In addition, the USDA provides a laboratory guidance document.

Employees must know the purpose of policies and procedures, the principles of procedures, how to do calculations, understand QC practices, how to keep records, how to correlate test results, and how to keep training documentation. Environmental monitoring can provide useful data points to help validate procedures and routinely verify compliance.

Fit for Purpose

The laboratory physical plant must be fit for purpose. Adequately maintained pest control, lighting, walls, ceilings, and floors are needed. Ensure hot water handwash stations are provided and impervious benchtops for sanitation are used. Air HEPA filtration and positive pressure help prevent laboratory cross-contamination. Regularly conduct air contaminant monitoring and zone environmental pathogen monitoring. Address glove change frequency and adequacy of use. If the laboratory is doing pathogen testing, is it Biosafety Level II compliant?

Individuals trained in proper laboratory cleaning should do laboratory housekeeping on a regular schedule. Care should be taken if these individuals also clean the food facility due to cross-contamination risk. Follow proper standard sanitary operating procedures, with regular environmental monitoring verification conducted for pathogens. Cleaners and sanitizers should be fit for purpose. Check for the presence of cleaning residue on all glassware before use. Keep records of all activities.

All laboratory equipment must also be fit for purpose. Properly maintain such equipment on a regular preventive maintenance schedule and calibrate on a

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routine appropriate for the equipment. Difficult-to-sanitize equipment should have sanitation standard operating procedures detailing such routine. Usual suspects include pipetors, stomachers, auto preps, balances, and glass/plastic ware. Environmental monitoring of this equipment can verify its sanitary condition before use.

Media performance should be routinely checked. Perform productivity, selectivity, and sterility tests on each medium batch. Statistical process control chart use is advised for quantitative testing. The media preparation autoclave needs to be of suitable size to sterilize media batch sizes in use. In addition, do not use the media prep autoclave to decontaminate spent media and contaminated materials. Rather, a separate decontamination room and separate autoclave is preferred.

Media fill volumes should be validated and routinely monitored, including petri plates, dilution blanks, MPN tubes, and slant volume and butt height. Likewise, routinely measure water quality and final media pH. If media sterility is questioned, there may be potential for environmental contamination. Monitoring for this potential will allow for quicker resolution of sterility issues if they occur.

Sample Collection

There are many questions that need to be addressed in regard to sample collection. Have employees been trained on aseptic technique? Samples should be held at the appropriate temperature in impervious sample containers. Upon receipt, are samples and tests adequately described, and are the chosen tests fit for purpose? Are samples fit for analysis—what is sample integrity upon receipt and are they held under adequate storage conditions? What is the potential for sample cross-contamination during handling, and is this potential routinely measured through environmental monitoring?

Is the laboratory accredited to ISO 17025 standards to perform tests? Can lab personnel describe and perform methods? Is the lab capable of performing sample preparation, such as thawing, composite pooling, and experience with difficult matrices (e.g., large samples, complex samples, antimicrobial ingredients)? How is sample uniformity ensured (e.g., mixing by blending, stomaching, by hand)? Is the laboratory using appropriately validated methods (e.g., AOAC, FDA, FSIS, AFNOR, MicroVal), and are they validated for the matrices of interest? Can the lab fully justify and validate using non-standard methods?

Laboratories must have quality control procedures for monitoring the validity of tests. The resulting data must be recorded in such a way that trends are detectable and, where practicable, statistical techniques must be applied to the reviewing of the result. Good laboratory procedures include the use of quality control samples with each sample batch to demonstrate the test worked properly.

Just as self-taught brain surgery is discouraged, don't do the math yourself: Hire a trained microbiologist, and use a sophisticated laboratory information management system to do calculations.

A daily process control system, or the use of a non-pathogenic microorganism sample of a known quantified amount, must be plated on a daily basis for those assays being performed. Positive controls are those that include the target microbe to see if the method is working that day or if there are interfering matrix substances. Negative controls use non-target microbes to assess for method discrimination, while sterility controls use blank samples to ensure that media and materials are sterile.

In-House Testing?

If you are a food manufacturer, is it wise to do pathogen testing in house? Doing so may be a significant biosecurity risk. Without positive controls, a lab is doing faith-based microbiology. Separate personnel and limit culture access to prevent cross-contamination. Implement policies that govern glove and lab coat use. Understand the risk associated with the lab location in relation to food production. Care must be taken in staging positive control samples in relation to other samples to avoid cross-contamination.

Running a lab requires constant use of measurements that utilize instruments traced to national or international standards. For example, temperature hold precision adequacy is extremely important when doing coliform/E. coli testing at 44.5 or 45.5 degrees Celsius. Sample and media pH values are routinely measured, with precise adjustments sometimes necessary. Pipet and pipetor fill volumes should be periodically calibrated. Balance calibration is necessary to ensure proper sample and consumable weights. Keep records and validation of correction factors.

Integrity of analytical result data should be maintained, and laboratory information management systems secured through password protection. For physical records, labs need a hand error correction policy. To protect against unauthorized access, back up data and log off unattended computer terminals. Scrutinize results for correlation with other results and analyze all lab QC before result release.

Math errors are a common problem. Quantitative microbiology is difficult! Dilution problems are challenging! Counting rules are insanely complicated! Just as self-taught brain surgery is discouraged, don't do the math yourself: Hire a trained microbiologist, and use a sophisticated laboratory information management system to do calculations. Regularly check performance by subscribing to a check sample proficiency program. Use prepared culture pellets to make spiked controls.

A records retention program should include how to identify, collect, record, index, file, and access records. Additional information on record storage, maintenance, and destruction must be available.

Procedure Challenges

In a world that's far from perfect, laboratories will make mistakes, or a client will challenge results. Lab errors can happen, so a full discussion of the occurrence with the client is best. Such complaints should have a formal recording structure that details who is responsible for dealing with complaint or error. The document should detail how to conduct a root cause investigation, identify the cause of the failure, detail corrective and preventive actions,

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The Heat Is On

Hot air sterilization can ensure food packaging is bacteria free

BY **JASON SANDERS**

Packaging materials play an important role in food processing. Organizations spend a great deal of time identifying the right packaging for their products and processes. From bottling to food packaging, end users want to ensure they are operating efficiently in order to provide consumers with a quality product. Even when choosing the right packaging for the product and process, issues can still arise. One of the problems that can occur is the bacteria that reside within packaging materials.

Manufacturers take the necessary steps of sanitizing produce or introducing various wash methods to clean food products. While these are helpful measures, bacteria can be hidden and grow in the packaging materials, causing harm in many ways. Some examples of bacteria found in packaging include *E. coli* and *Salmonella*. Failing to remove bacteria can reduce a product's shelf life, causing unnecessary waste. Also, bacteria can produce harmful side effects on consumer health, and even death, if not removed entirely from the packaging process. In order to minimize any issues with the end product, manufacturers use sterilization to remove harmful pathogens from the process.

Hot Air Sterilization Processes

Sterilization end users rely on different methods to ensure that harmful bacteria are eliminated from equipment and packaging. Sterilization, which can be used on metal, glass, or porcelain, can have cycle times lasting up to 30 minutes. One of the methods utilized in the sterilization process is hot air, which achieves precise temperature regulation and safe process control. Not only can end users achieve a repetitive process, but it is also environmentally friendly and nontoxic. Two examples of hot air implementation would be static and forced hot air.

With static air, end users introduce hot air from a location near the bottom of a tunnel or an enclosure and let the heat dissipate toward the top. An example of static hot air implementation would be a hot air oven or autoclave for pasteurizing glass jars and tin cans. While this method does provide a level of sterilization, it is not an effective solution for a couple of reasons. The first is that the temperature profile will not be uniform, meaning that certain surfaces will receive more heat than others. The second reason is that it will require a longer dwell time for the heat cycle, which may have a significant impact on product quality. This means that packaging companies will not be able to get the necessary throughput required to meet manufacturing demands.

With forced air, hot air is introduced by a compressed air source or blower system. An example of forced hot air implementation would be dry sterilization for beverage filling processes. This is a preferred method for a majority of the end users for a couple of reasons. With forced air, you get better temperature uniformity within the process, which allows the heat to be evenly distributed over the product. Forced air also decreases the necessary dwell time in the process, which can reduce manufacturing process time.

Hot Air Sterilization Benefits

In industrial beverage filling systems, hydrogen peroxide (H_2O_2) is used in combination with hot air. First the containers are pre-heated using air heaters to get the surface temperature of the container to approximately 140 degrees Fahrenheit. In the next step, H_2O_2 is evaporated at around 392 degrees Fahrenheit. To ensure the vapor doesn't cool down while flowing to the nozzle, double-walled tubes are used.

These tubes are heated from the outside to avoid the cooling down of the vapor. To heat the tubes, hot air is blown into them. This hot air is typically generated by electric air heaters due to the precise temperature control those heaters offer. Nowadays, many companies are using hot air recycling systems, such as the Leister RBR blower and DF-R air heater combination, to help improve the efficiency of dry aseptic decontamination systems.

This vapor is sprayed into the containers and settles at the inner surfaces of the container. Important for this method is a full coverage without any blind spots to be able to kill all spoiling organisms inside the container. In bottle decontamination systems the surfaces above the neck ring are exposed to the vapor as well.

This process is necessary to ensure complete sterilization of all surfaces that will be in contact with the product. After approximately 4 seconds, the H_2O_2 residuals are dried out with hot air to ensure a maximum residual level of less than 0.5 ppm H_2O_2. This so-called "dry sterilization" offers some advantages: Dry aseptic is cost efficient, has a small footprint in the aseptic filling machine, generates zero waste, and doesn't need sterile water rinsing.

To assess such systems, sterility tests are performed at every new installation using H_2O_2, peracetic acid, or steam in accordance to various equipment testing standards. To make sure the sterilization process is efficient, test germs like *Bacillus atrophaeus* and *Bacillus subtilis* SA 22 are used. For steam, the test germ is *Geobacillus stearothermophilus* NCA 1518. All surfaces of the packaging material in contact with product will be exposed to the test germs. The contaminated packaging material is then exposed to the sterilization systems of a filling machine using H_2O_2, peracetic acid, or steam. After the decontamination is completed, the log reduction rate has to be at least 10-5 for aseptic systems.

One of the methods utilized in the sterilization process is hot air, which achieves precise temperature regulation and safe process control. Not only can end users achieve a repetitive process, but it is also environmentally friendly and nontoxic.

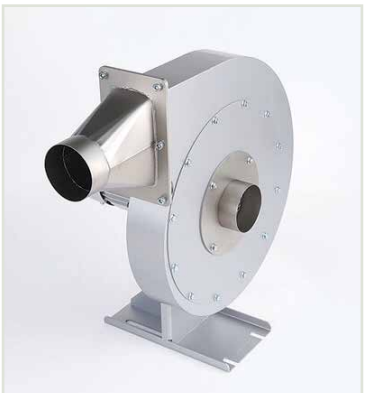
Even though there are many dry sterilization systems in use today, there are alternative sterilization solutions that can be implemented with hot air. While the beverage carton industry is dominated by dry sterilization systems, the majority of aseptic bottle filling systems in the market utilize peracetic acid (wet aseptic) to sterilize the inside and outside of the bottle.

Steam sterilization is mainly used for bottling applications that involve glass packaging. One side effect of this sterilization method is the moisture generated on the surface of the bottle. Not removing this residual moisture can lead to issues with coding, labeling, and bacteria growth. In order to remove this moisture, manufacturers locate hot air products and high-volume blowers on bottling lines before coding and labeling in order to achieve a dry surface on the outside of the bottle; it can also be used to dry the inside of the bottles as well. This method is referred to as a hot air knife.

With the hot air knife process, bottlers mount high pressure blowers and air heaters directly on the manufacturing line. In order to concentrate the airflow to the surface of the bottle, a special type of nozzle is utilized to direct airflow. This nozzle blows a curtain of air, which provides a level of evaporation as the bottles run down the line. Since the high-pressure blower and air heater can be regulated from a control system, this allows for a repeatable process that provides a clean, dry bottle, and can be documented for validation purposes.

The use of air heaters and blowers for the sterilization process provides many benefits for the end user. The air heaters and blowers can be integrated into sterilization equipment with ease by simply sending a signal to obtain the desired output temperature. This allows for repeatability for the end user that can help remove pathogens, improve product quality, and minimize waste. The repeatability also assists in the validation process of the sterilization system. With these added benefits incorporated into the process, manufacturers can have confidence in knowing that they have removed harmful bacteria from their end products.

For food packaging processes, it is essential to take the necessary precautions to ensure that packaging has been thoroughly sterilized. Whether a bottling application or food packaging process, hot air can be used as the driver for the sterilization process to deliver a quality product that is consumer friendly. The end result is a product that is produced in an efficient manner that is safe for consumption. ■



Hot air recycling systems, such as the Leister RBR blower and DF-R air heater combination, help improve the efficiency of dry aseptic decontamination systems.

Sanders is a product specialist with Leister Technologies, LLC, a partner member of the Control System Integrators Association (CSIA). Contact him at Jason.Sanders@leister.com.

Traceability Done Right

License plates can help food suppliers keep track of their products and quickly identify any food safety issues

BY **TRAVIS SMITH**

Traceability requirements are costly. The financial risks and costs associated with food safety are increasing due to trade wars and retaliatory uncertainty. The stakes are rising for food suppliers in a landscape of continuously evolving food safety challenges, technologies, and regulations. An increasingly complex food chain with many touch points and value-added products has increased the potential points of contact and opportunities for contamination. It has also increased the complexity of traceability.

Often, the requirement for lot traceability drives manufacturers to incur a higher cost than anticipated. By avoiding additional labeling during receiving and finished goods creation, effective, lean processes are implemented; on the receiving side, food manufacturers leverage barcodes coming in the door. If that is not possible, license plate (LP) barcodes can be used to meet the traceability requirement without labeling each case or component. Advanced technology allows for reliable traceability throughout the food supply chain and enables faster identification of food safety issues.

License Plates and Food Production

WithoutWire Inventory Sciences defines a license plate number as any object that holds items. Although LPs are associated with containers, they do not need to represent a physical entity, such as a box. Food safety and operations managers define an LP as a collection of items enabled for tracking, transacting, and nesting.

LPs have specific functionality to support detailed chain-of-custody requirements; they identify how to receive, store, and pick material by LP as well as viewing on-hand balances. Traceability challenges vary from basic queries of accurate inventory on hand, location of inventory, where it was sourced (including country of origin labeling). Additional information must include where inventory was moved throughout the day. Automating this data ensures the right mix of SKUs based on history and compliance issues.

Single-scan functionality results in 99 percent-plus accurate data and adds value throughout the supply chain as well as downstream for the customer. Organizations must be able to track inventory expiration dates and eliminate physical errors to improve accuracy and order fulfillment. As more retailers enforce compliance, distributors will now be equipped with the tools needed to reduce the risk of rejected shipments. Standardized electronic traceability across the supply chain will allow each handler to support internal traceability solutions.

The Industrial Internet of Things (IIoT) supports traceability to course-correct business performance. Access to these advanced analytics allows food scientists to identify and remove suspect product from the marketplace as soon as possible to safeguard public health. Simultaneously, product not implicated in an outbreak can stay on the market, and business can return to "normal" as soon as possible.

Single-scan functionality results in 99 percent-plus accurate data and adds value throughout the supply chain as well as downstream for the customer.

The Case for License Plate Traceability

When it comes to finished goods, license plates and item and IIoT barcodes are both options that reduce the total number of scans. When creating goods with an expiration date, it is best to automatically set the expiration date with an item-level, shelf-life setting. Proper planning, along with smart item tracking, drives the difference between making or losing money.

A collection of inventory items or "license plates" reduce scans for any operation.

Because QC/QA professionals can view LP contents in real time, the LPs can be used to perform transactions, print labels and reports for referencing container contents, and track nested LPs (for example, cartons on a pallet). Inventory control is tightly managed for packing, unpacking, consolidating, splitting, and updating LPs. Shelf-life settings auto-generate expiration dates upon receiving and finished-good production, allowing food safety leadership to take advantage of GS1 barcodes during receiving for rapid data collection.

LP inventory avoids over-labeling products. A Global Trade Item Number (GTIN) will identify the "manufacturer" (the owner of the brand that appears on the product case) and the type of product inside that case. This information will appear in both human-readable form and in a machine readable GS1 barcode. The GS1 barcode provides each trading partner in the supply chain with the ability to scan and maintain the encoded information. The GTIN is a globally unique product identification number based on GS1 global standards. These product identification standards are time tested and market proven, having been used in grocery stores for more than 40 years in the form of Universal Product Code (UPC) barcodes.

The cost of traceability technology tools is significantly lower than the violation of regulatory non-compliance. Understanding the risks of food safety incidents, the costs associated with them, and risk mitigation strategies are increasingly important for profitability and long-term economic sustainability. As always, traceability is the first line of corrective action and integral to meeting the Hazard Analysis Critical Control Points requirements. ■

Smith is the CTO and founder of WithoutWire Inventory Sciences, providing supply chain-based consulting and product strategy for a variety of industries. Reach him at traviss@withoutwire.com.

Tackling Food Waste *(Continued from p. 12)*

"If consumers could trace how long ago and where their meat was slaughtered, packaged, and distributed, or if they could see what date their milk was produced and which farm it came from, they may reconsider throwing away food that is safe to eat, reducing waste," ABB's Simonis says.

A Comprehensive Approach

Everyone, from governments, to food processors, manufacturers, and packing providers, to wholesalers, retailers, and consumers can play a role in reducing food loss and waste, according to recommendations from the World Resources Institute aimed at halving food loss and waste by 2030.

The report, released in August, recommends that packaging manufacturers expand use of coatings and resins to extend shelf life and make available a wider variety of resealable options. Researchers could develop innovative products from perishable items, such as fruits and vegetables, to promote whole food utilization, it stated, and policymakers could support standardized date labeling practices and increase investment in agricultural research to reduce post-harvest loss.

But this isn't to suggest that governments, including the U.S., have been idle. The USDA and EPA, for example, have run programs to reduce food loss and waste since at least 2013, when they launched the U.S. Food Waste Challenge. Thus far, the project has signed up more than 4,000 businesses, schools, and other organizations.

For years, the USDA's Agricultural Research Service has been funding and conducting research on new technologies to reduce food waste. Some of the innovations include development of a fruit- and vegetable-based powder to inhibit spoilage of fresh-cut produce, active packaging to extend fruit and fresh-cut produce shelf life, and development of an optical analyzer to help growers assess crop maturity and quality to determine optimal harvest time and post-harvest handling/processing procedures.

Meanwhile, companies large and small are developing better approaches to reducing food waste. Chicago-based startup Hazel Technologies, for one, is developing sachets that can be dropped into bulk crates of fruit and vegetables to inhibit formation of ethylene, and triple the amount of time produce stays fresh. ■

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Much Ado About ... (Continued from p. 14)

dramatic effect on lowering the mean concentration of psychrotolerant spore-formers in simulated half-gallons. "Specifically, our what-if simulations of lowering the refrigeration temperature from 42.8 degrees Fahrenheit to 39.2 degrees Fahrenheit indicated that only 9 percent of half-gallons of milk would be spoiled (greater than 20,000 cfu/mL) by 21 days when stored at to 39.2 degrees Fahrenheit, compared with the initial 66 percent of half-gallons spoiled by 21 days when stored at 42.8 degrees Fahrenheit," he relates. "This translates to an extension of average shelf life (time to reach greater than 20,000 cfu/mL) by nine days by lowering the storage temperature from 42.8 degrees Fahrenheit to 39.2 degrees Fahrenheit.

"If a milk plant is well run and if there is no post-pasteurization contamination, the high temperature/short time (161 degrees Fahrenheit for 15 seconds) shelf life can be expected to be 24 to 30 to 35 days if milk is refrigerated at less than 39 to 40 degrees Fahrenheit," Dr. Wiedmann points out.

DNA fingerprinting through whole-genome sequencing is now helping scientists to better understand and decrease spoilage organisms in milk, Dr. Wiedmann adds. That's a good thing, he says, because pictures of spoiled food, including milk, are often posted on social media. "Pictures of off colors and spoilage issues can be damaging to the food industry," he emphasizes, mentioning his related collaborative research published in 2019 that used whole-genome sequencing of nine *Pseudomonas spp.* bacteria isolates to determine the cause of blue and gray pigments in cheese and milk, respectively. ■

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Quenching India's Thirst (Continued from p. 25)

The company also hires licensed experts to provide pest control based on denying entry, food, and shelter, and destroying intruders. The service must follow approved environmentally safe chemicals rules set by the corporate business.

Reducing Defects

Hindustan Coca-Coca has an all-surface electronic bottle inspection system that can automatically detect and reject defective returnable glass bottles. It looks for defects like foreign bodies, residual content from washing, and chipped bottle necks. The inspection system uses high-frequency cameras and infrared high-frequency rays to detect faults. Advanced microbiological analytical equipment ensures that the juices produced are free from a microbiological load.

To improve hygiene, the company has installed air-handling units in manufacturing areas. It also fumigates those areas. All manufacturing entrances and sensitive areas are controlled by biometric access, which helps with contamination, and all entrances have air curtains to prevent cross-contamination from the outside to the inside of the filling or process area. All of the air curtains are interlocked with the door openings.

Hindustan Coca-Cola says all these measures have resulted in zero product recalls and declining consumer complaints.

For its total food quality and safety program, the company has created a cross-functional food safety team that includes production, quality, safety, environment, maintenance, human resources, and administration. The team meets at least twice monthly to discuss progress and loopholes.

Last year, the company received the Confederation of Indian Industries Appreciation award for its food safety diligence and compliance.

And as the company stated in its award application: "Our innovation projects have challenged the status quo, have helped build capabilities, and have driven our long-term growth." ■

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Small Company, Big Impact (Continued from p. 29)

The recent transition to a sanitizer tablet allows for a more consistent solution of sanitizer in 150 and 200 parts per million, an improvement over the previous process in which inconsistent amounts of bleach were used to make a solution. The tablets have improved swab results for all zones and decreased counts for all the company's finished products.

Before using the tablets, the bacteria counts for finished products were well below critical limits but still high. Using the sanitation tablets, the finished product counts are 100 percent consistently <10 cfu/g for bacteria. Additionally, *Enterobacteriaceae*, *Listeria*, and *Salmonella* counts are consistently <100 cfu/g for environmental monitoring.

Endangered Species Chocolate says its investments in quality assurance and safety measures have been rewarded in its financial return.

Customer satisfaction is up, and complaint rates are down. The complaint rate for 2018 was 0.0002 percent and is projected at 0.00003 percent for 2019, the lowest rate in five years.

Sales also rose 38.9 percent over the past five years, which the company attributes to increased efforts in quality and safety. The sales increase directly supported its ability to purchase new technology and create efficient processes focused on quality and safety.

Endangered Species Chocolate says it complies with regulations. During

the first FDA inspection of its satellite warehouse, the warehouse passed with 100 percent compliance. The company also adheres to Food Safety Modernization Act guidelines at both production and warehouse facilities, and to Canadian regulations for all products sold in Canada.

The company says that while it strives to stay compliant with all food safety and quality regulations, it is also focused on its sustainability mission, including adding efficiencies to its production and cutting packaging and other waste.

"ESC validates our commitment to sustainability and verifies our purchase of clean renewable energy to match 100 percent of ESC electricity consumption," says Troyer, who was instrumental in the company's recently achieving a Green-e certification for renewable energy use. ■

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A Common Language *(Continued from p. 44)*

the form of monographs and identity standards. Each standard includes specifications, the methods needed to determine if a sample of the substance meets these specifications, and any reference materials that are required to implement these methods.

FCC monographs and identity standards have several sections (see Figure 1). The first section provides general information such as the name of the substance, synonyms, the chemical formula, the chemical structure (if relevant), CAS number(s), INS numbers, and a qualitative description of the substance. This description can include information on how the ingredient is produced and how it should be stored. An identification section includes tests that can be used to determine if a sample of the substance is what it claims to be.

These tests use many analytical techniques, including chromatography and spectrophotometry, and include in detail all the information needed to run each test. Each test is accompanied by acceptance criteria, which may, for example, include a spectrum or a table of high-performance liquid chromotagraphy (HPLC) peak retention times. An assay section includes analytical tests to determine purity.

In addition to determining overall purity, each standard provides information on tests and acceptance criteria for relevant impurities. In this context, impurities include both organic and inorganic substances, such as heavy metals or residual solvents. Finally, tests for marker compounds and for properties that can affect functional quality (such as moisture content) are found in the specific tests section.

Because the utility and applicability of the analytic methods are critical for ensuring that FCC standards are practicable, many of the methods in the FCC are developed or evaluated by USP laboratories. This evaluation is carried out using multiple samples of the substance obtained from different sources. The lab ensures that the methods work as intended for each specific substance and that they are adequately described. In some cases, validated methods from recognized authorities such as the Joint FAO/WHO Expert Committee on Food Additives, International Organization for Standardization, or AOAC International have been adapted for use in the FCC. In other cases, FCC methods have been adopted by these other organizations.

The test methods described in a standard may require the use of well-characterized materials as reference materials, calibration standards, or system suitability standards to ensure accurate results. A reference material, for example, can be used to generate an HPLC chromatogram for comparison with a chromatogram from a test substance analyzed using the same equipment and reagents to allow identification and quantitation of analytes of interest. The use of these materials meets the requirement of ISO17025:2017 Section 7.7 on ensuring the validity of results by "use of reference materials or quality control materials."

The Importance of Standards

There are several reasons why the wider application of technically sound standards is critical for developing improved information systems to support transparency and traceability in the food supply.

First, as discussed above, standards ensure the use of consistent terminology at all steps in the production process, a fundamental requirement for effective communication. Second, standards ensure consistent expectations for product identity and quality for all participants in the supply chain. Third, standards provide a verifiable physical underpinning for the information contained in food-related data systems (such as a blockchain). This is extremely important because the value of a data system is limited by the quality of the information that it contains. The food industry makes and sells physical materials in the form of ingredients and foods. Electronic records are like paper records in that they can become inconsistent with the physical materials that they purport to represent. Standards that include specifications and test methods provide the tools needed to ensure accurate correspondence between records and materials.

Public standards for foods, food ingredients, and for all substances used in food production play a critical role in protecting the integrity of the food supply. Standards support commerce, help combat fraud and adulteration, and facilitate transparency and traceability. Unfortunately, many individuals and companies in the food industry are not aware of these standards or mistake information on a supplier certificate of analysis for standard information. Others use part of a standard, such as the specifications, but not the methods needed to assess adherence to the standard. Understanding where to find standards and what they contain is an important skill for mitigating business, quality, and legal risks in an increasingly interconnected and interactive world. ■

Dr. Gendel is the senior director for food science for the FCC, which is published by the United States Pharmacopeia. He has over 30 years of experience in food safety and policy. Reach him at steven.gendel@usp.org.

NEW PRODUCTS

Dual Detectable Material to Help Food Processors Mitigate Contamination Risks

Rexnord has announced a new Dual Detectable material for select KleanTop and TableTop conveyor belts. The new material, which can be detected in both metal and X-ray machines, offers an additional safeguard for food processors against product contamination. In addition to its dual detectability, the material comes in a unique blue color, making it easier for food processors to identify it on their production lines. Rexnord's Dual Detectable material is offered in the KleanTop and TableTop series products, including belting and attachments where applicable. **Rexnord, www.rexnord.com**

Grain Sourcing System

The new SureTrack PRO ingredient sourcing system enables processors to easily source quality grain that meets their exact specifications, including monitoring inventories and tracking deliveries to ensure that plants are always up and running. The system digitally connects processors, merchandisers and grain buyers with farmers to simplify the process of sourcing and managing grain used in food and beverage production, pet food manufacturing and restaurant operations. The system enables processors to access a robust grower network, know exactly what they are receiving before it is delivered and get an in-the-bin look at the condition of their contracted grain. This network of 3,200 grower participants fuels the traceability of about 700 million bushels of grain in the SureTrack PRO system, including corn, soybeans, barley, wheat, and other commodities. **AGI SureTrack, www.suretrackpro.com, 855-293-5607**

Water-Based Laminating Adhesive

Ashland introduces Purethane A2018 adhesive, the latest development in water-based laminating adhesive technology specifically designed for metalized film adhesion.

Purethane A2018 joins Ashland's growing portfolio of high-performing laminating adhesives for food packaging where improved metal adhesion and enhanced clarity are required. Purethane provides high metal adhesion for moderate-to-high levels of moisture, temperature, and chemical resistance. **Ashland Global Holdings Inc., www.ashland.com**

Multiscan Metal Detector

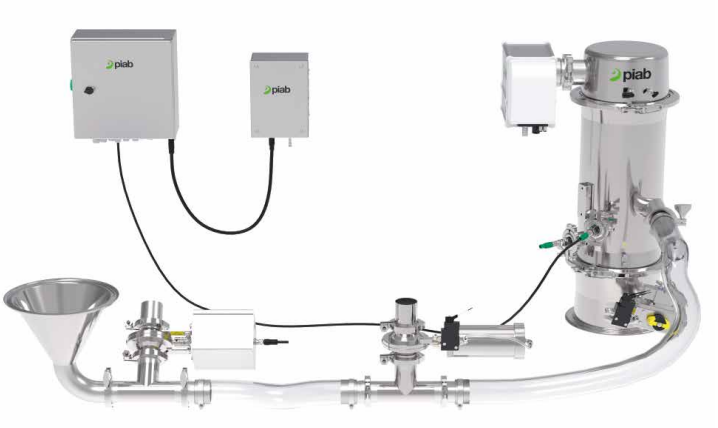
A new scanning multi-frequency metal detector is designed to enable food manufacturers and food quality managers to improve productivity and maximize factory floor space by combining the benefits of multiscan metal detection technology with accurate weight control. The Thermo Scientific Sentinel 3000 multiscan metal detector is the smallest model in the line of Sentinel metal detectors and mounts on the frame of Thermo Scientific VersaWeigh and Versa GP checkweighers. The Sentinel 3000 detector is the first multi-frequency metal detector specifically designed for metal detection-checkweighing combination systems in food production, providing users with improved functionality and performance in a smaller footprint than typically required with two pieces of equipment. By integrating the detector onto the checkweigher frame, the need for an external metal detector conveyor is eliminated. New harmonized Versa checkweigher software incorporates the capability to operate the checkweigher and metal detector from one screen and is designed to improve usability and reduce training time. **Thermo Fisher Scientific Inc., www.thermofisher.com/sentinel3000**

Power Transmission Belt

Timken Belts announces the introduction of their new Carlisle Super Arc belt specifically designed for live/powered roller conveyor drives commonly used in warehouse or product loading and shipping industries. The new Super Arc belts have a special fabric clutching cover that provides just the right amount of slip and grip between the belt and roller—enough friction to turn the rollers that move the product down the conveyor, and enough slip to reduce heat and wear from misalignment. Multiple layers of small diameter polyester cord allow the belt to flex laterally around the arc of the conveyor (up to 90° corners), while still providing exceptional strength. Made of a highly engineered rubber compound that supports the cord, Super Arc belts offer superior flexibility and performance while retaining excellent flex life. **Timken Company, www.timken.com**

NeoSpectra-Scanner for In-Field Material Analysis

Si-Ware Systems has built a handheld material analysis scanner around its NeoSpectra spectral sensor, for those companies and developers who want a tool with immediate onsite detection and quantification of contaminants in samples, at the molecular level. Food processing QA is a key market for this device. The technology is already being used for soil analysis, and for feed scanning on farms to determine nutritional conformance. The near infrared range of the NeoSpectra-Scanner is versatile enough for on-site agriculture, food, and industrial use, and Si-Ware hopes it will further drive the mobile technology into a range of new markets. It's easy to configure, in a five-step process. **Si-Ware Systems, www.si-ware.com, 818-790-1151**



Vacuum Conveyer

Piab's Changeover Champion vacuum conveyor piFLOWp SMART enables users to save time when changing from one material to another, increasing the productivity of their operations. Changeover that would take one hour in a conventional vacuum conveyor takes only 10 minutes in the company's new vacuum conveyor. piFLOWp SMART is a self-optimizing vacuum conveyor targeted primarily at industries handling many different materials or those in which frequent changes need to be made. This makes the conveyor ideally suited for producers within the food and pharma sectors, where its full changeover potential will have great impact, saving time and money. With each new conveying cycle, the piFLOWp SMART will prove its name, using machine learning to automatically tune the process by configuring and optimizing a flawless flow of materials, set at the correct rate. **Piab, www.piab.com**

Subfreezing Dryer

Ingersoll Rand has introduced its new dryer technology, the Subfreezing Dryer. The Subfreezing Dryer is the world's first dryer that provides -4 degrees Fahrenheit pressure dew point at 70% lower energy costs and 40% smaller footprint than that of traditional desiccant dryers. Ingersoll Rand's new Subfreezing Dryer is compatible with oil-flooded rotary compressors, oil-free rotary compressors, centrifugal compressors and reciprocating compressors. **Ingersoll Rand, www.IngersollRandCompressor.com**

Chromasens Machine Vision Camera

Multispectral imaging now enables the extraction of several wavelength bands during automated vision inspections, and is proving to be far more accurate than traditional RGB (Red Green Blue) cameras in detecting invisible color flaws. Of this new breed of multispectral cameras, the Chromasens' truePIXA line-scan camera stands out, especially in the real-time color measurement of food, organic materials, pharmaceuticals and printed materials. The Chromasens' truePIXA features 12 spectral selective sensors that simultaneously scan an object within a spectral data range of 380nm to 730nm in twelve individual color channels instead of just three (RGB). The resulting high-contrast spectral images provide precise space-resolved spectral measurements of the whole image and in arbitrary areas of interest. Exceptionally versatile, the camera permits measurements on RGB, CIE-L*a*b*, and spectral reflectance with high stability and excellent repeatability. Plus, with up to 3,500 pixels per channel and 21.1 kHz line frequency, it achieves optical resolution up to 60 µm/pixel at speeds up to 6 meters per second. **Chromasens, www.chromasens.com**

News & Notes *(Continued from p. 10)*

Among patients who traveled to Mexico, 87% reported eating beef and 63% reported eating soft cheese, most commonly queso fresco, a cheese typically made with raw, unpasteurized milk from cows or goats.

Among those who did not travel to Mexico, 29% reported eating Mexican-style soft cheese and 93% reported eating beef.

In September 2018, the outbreak strain was detected in samples from a steer at a slaughter and processing plant in Texas; in October 2018, it was detected in a mixture of queso fresco and Oaxaca soft cheese purchased in Tijuana, Mexico; and in November 2018 and March 2019, the outbreak strain was detected in beef samples at two Texas slaughter and processing facilities.

Among patients with treatment information, 75% received antibiotic therapy,

but 33% received an antibiotic to which the outbreak strain was resistant or showed decreased susceptibility.

"For patients with invasive *Salmonella* or with risk factors for invasive disease, prompt antibiotic treatment is indicated," Dr. Plumb said. "When giving antibiotics, it's important to test to make sure that the antibiotics given will work in a particular patient. If a patient is suspected to have the outbreak strain and needs antibiotics, it's important for clinicians to know that some of the commonly recommended antibiotics may not work, and alternative injectable antibiotics may be needed."

He added, "There are measures that you can take to prevent infection with the outbreak strain. If you eat beef, make sure that the beef is cooked to a safe internal temperature, using a food thermometer. Ground beef, including hamburgers, should be cooked to at least 160 F, and steaks and roast to at least 145 F. After cooking, it's best to wait for three minutes before cutting or eating beef."

"If you eat soft cheese, make sure that the label says, 'Made with pasteurized milk,'" he said.

—By Will Boggs, MD, Reuters Health

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SCIENTIFIC FINDINGS

For access to complete journal articles mentioned below, go to "Food Science Research" in the October/November 2019 issue at foodqualityandsafety.com, or type the headline of the requested article in the website's search box.

ARTICLE: Detection of Spicy Compounds Using the Electronic Tongue

The sensory evaluation of foods containing spicy compounds provides challenges due to their trigeminal innervation and associated sensory fatigue. Thus, for the routine evaluation of spices, a need exists for rapid and objective methods of analysis; the electronic tongue (e-tongue) provides a potential solution. The objective of this study was to evaluate the ability of the e-tongue to distinguish among spicy compounds at varying concentrations. Due to the diversity of spicy compounds, seven spicy compounds were selected: capsaicin, thymol, piperine, zingerone, p-cymene, menthol, and eugenol. For each of these compounds, a low concentration (1.427 × 10−5 to 0.85 mg/L), medium concentration (2.854 × 10−5 to 1.49 mg/L), and high concentration (0.0133 to 30.5 mg/L) were analyzed by the e-tongue. For each compound, the e-tongue discriminated among the concentrations with discrimination indices between 72% to 84%. Based on the responses of the e-tongue sensors, the samples formed three clusters. Cluster 1 contained menthol, eugenol, and p-cymene, cluster 2 contained capsaicin and thymol, and cluster 3 contained piperine and zingerone. Same-different sensory testing was completed on a representative sample from each cluster. Untrained consumers (n = 80) distinguished among the three clusters, verifying the clusters identified by the e-tongue. **Journal of Food Science, Volume 84, Issue 9, September 2019, Pages 2619-2627.**

ARTICLE: Cold Plasma-Mediated Treatments for Shelf Life Extension of Fresh Produce: A Review of Recent Research Developments

Fresh produce, like fruits and vegetables, are important sources of nutrients and health-promoting compounds. However, incidences of foodborne outbreaks associated with fresh produce often occur. This review summarizes recent developments of cold plasma technology and associated activated water for shelf life extension of fresh produce. An overview of plasma generation and its physical-chemical properties as well as methods for improving plasma efficiency are first presented. Details of using the technology as a nonthermal agent in inhibiting spoilage and pathogenic microorganisms, inactivating enzymes, and modifying the barrier properties or imparting specific functionalities of packaging materials to extend shelf life of food produce are then reviewed, and the effects of cold plasma-mediated treatment on microstructure and quality attributes of fresh produce are discussed. Future prospects and research gaps of cold plasma are finally elucidated. The review shows that atmospheric plasma-mediated treatments in various gas mixtures can significantly inhibit microorganisms, inactive enzyme, and modify packaging materials, leading to shelf life extension of fresh produce. The quality attributes of treated produce are not compromised but improved. Therefore, plasma-mediated treatment has great potential and values for its application in the food industry. **Comprehensive Reviews in Food Science and Food Safety, Volume 18, Issue 5, September 2019, Pages 1312-1326.**

ARTICLE: Functionality of Freeze-Dried Berry Powder on Frozen Dairy Desserts

In the present work, the use of different freeze-dried berry powders as stabilizers to avoid the melt-down of frozen desserts was investigated. Samples were prepared using 3.5% freeze-dried berry powder (strawberry, raspberry, blackberry, and blueberry) and compared with a control containing no berries. The addition of strawberry or raspberry powder completely prevented the meltdown of the frozen desserts. These samples retained their original shapes once the ice crystals melted. Blackberry powder prevented the melting of the frozen desserts, but the foam structure collapsed and lost its original shape. The incorporation of blueberry powder did not prevent the melting of the frozen desserts. The blueberry samples showed phase separation with a fraction of clear serum. Freeze-dried strawberries and raspberries could be used to replace stabilizers in the production of "clean label" and nutritionally enhanced ice creams. Also, the production of frozen dairy desserts that do not melt at ambient temperature will allow the creation of complex structures using new technologies, such as 3D printing under ambient conditions. **Journal of Food Processing and Preservation, Volume 43, Issue 9, September 2019, e14076**

(Continued on p. 62)

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ARTICLE: Natural Antifungal Peptides/Proteins as Model for Novel Food Preservatives

A large range of ingredients for food and food products are subject to fungal contamination, which is a major cause of destruction of crops, exposure of animals and humans to invasive mycotoxins, and food spoilage. The resistance of fungal species to common preservation methods highlights the necessity of new ways to increase the shelf life of raw material for food and food products. Antimicrobial peptides and proteins (AMPs) are essential members of the immune system of most living organisms. Due to their broad range of activity and their stability to commonly used food processes, they represent promising alternatives to traditional preservatives. However, despite the growing number of reports of potential food applications of these AMPs, the number of approved peptides is low. Poor solubility, toxicity, and a time-consuming extraction are hurdles that limit their application in food products. Thanks to a deep understanding of the key determinants of their activity, the development of optimized synthetic peptides has reduced these drawbacks. This review presents natural and synthetic antifungal peptides/proteins (AFPs), effective against food-related fungi, with particular emphasis on AFPs from plant sources. The design of novel antifungal peptides via key elements of antifungal activity is also reviewed. Finally, the potential applications of natural and synthetic AFPs as novel antifungal food preservatives are discussed. **Comprehensive Reviews in Food Science and Food Safety, Volume 18, Issue 5, September 2019, Pages 1327-1360.**

Keeping Tabs (Continued from p. 50)

and validate effectiveness. If the issue is serious or a common reoccurrence, conduct a reassessment of lab standard operating procedures along with routine verification. If a client insists on retesting, a subsequent negative pathogen test result does not negate a previous positive. Because samples may not be uniformly homogenous and the analyte in question may not be uniformly distributed in a lot, an out-of-spec result is not always associated with laboratory error. Clear articulation is needed to justify retesting.

Because environmental monitoring is an effective assessment tool to determine if the laboratory environment is fit for purpose, testing for pathogens and amplicon in the pathogen handling portion of the lab will provide data points showing how the risk of cross-contamination is being managed. Eurofins advocates using a zone approach to laboratory environmental monitoring programs.

For example, lower-risk areas in the lab include media preparation and materials supply storage. The sample reception area can be greater risk if samples are high count or have a history of pathogen detections, such as sponges, swabs, or raw meats and poultry. In such cases, designated sample receiving and sample preparation areas should be used and considered higher risk.

Because the goal of a food micro lab is to cultivate large numbers of microbes (indicators, spoilers, or pathogens), downstream areas where such high-count materials are handled should be considered high risk. For example, plate counting, enrichment transfers, pathogen detections, positive control handling, and waste disposal are considered greatest risk. Indicator (aerobic plate count, coliform count, *E. coli* count, *Enterobacteriaceae* count, yeast and mold count) environmental sampling may show surfaces in the laboratory that have been poorly cleaned and sanitized. Direct swabbing of employee hands, gloves, and lab coats can inform personal hygienic practices and conformance.

The value of laboratory environmental monitoring program testing is most realized when clients blame the laboratory for out-of-spec results, including elevated indicator counts or positive pathogen detections. One major way to rebut such claims is to rely on routine laboratory quality control data points. Such data can help argue that laboratory cross-contamination is not the mostly likely cause of the out-of-spec result. ■

Dr. Marshall is chief scientific officer at Eurofins Microbiology Laboratories, Inc. Reach him at 970-217-6854.

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