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From The Editor

Spring *Has* Sprung, Right?

This time of year in Florida, it's hard to know if spring has reached everyone yet, so I usually ask people before mentioning it. It's my favorite season here because, all too soon, it will be so hot everyone will hibernate inside to be near an air conditioner unless they're literally in the water somewhere. Wherever you are, I hope you are at least enjoying a bit of spring as winter recedes.

Spring brings renewed activity in the food industry around the world. Planting is getting underway as temperatures rise and the gray of winter gives way to the fresh green of newly sprouted seeds. Sadly, I don't think we're going to see that this year in Ukraine, the breadbasket of Europe. Closer to home, the drought-stricken areas surrounding Arizona's Lake Powell mean that California could be in for a rough growing season.

Continued shortages of certain products are the logical expectation given these circumstances. A recent informal poll among food producers showed that nearly 75% of the industry experienced pandemic-related shortages they weren't prepared for, and another 14% indicated they were only partially prepared. Regardless of whether we've seen the worst of the pandemic, it appears we may continue to see shortages that impact our grocery store shelves, so common sense would tell us to stay alert to these disruptions.

On a more practical note, I do need to send a huge thank you all those who have sent me story ideas, topics of concern, new product notices, and corporate updates. Unfortunately, they can too often get buried in the day-to-day work "stuff" and are sometimes overlooked in my already overloaded inbox. To better respond to you, I have added an email address that should help expedite responses. Please email me at fqseditor@pawesta.com going forward, and together we'll work on the topics of the day.

To end on a more upbeat tone, it *is* still a normal spring here in Florida; summer's oppressive heat is still a way off. Of course, that means temperatures in the upper 80s during the day and mowing the lawn every four or five days. May your spring be just as normal as ever, and I look forward to hearing from you more every day.

Patricia A. Wester
Executive Industry Editor

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NEWS & NOTES

FDA Plans to Limit Lead in Juice

FDA has issued draft action levels for lead in single-strength (ready to drink) apple juice and other single-strength juices and juice blends. This move, intended to reduce the potential for negative health effects from dietary exposure to lead, supports the Closer to Zero action plan that sets forth FDA's aim to reduce exposure to toxic elements in baby foods.

In particular, Draft Guidance for Industry: Action Levels for Lead in Juice provides draft action levels of 10 parts per billion (ppb) for lead in single-strength apple juice and of 20 ppb for lead in all other single-strength juice types, including juice blends that contain apple juice.

As part of its commitment in the Closer to Zero action plan to consider the biological effects of exposure to harmful elements in foods eaten by babies and young children, the draft action levels for lead in juice were guided by FDA's interim reference level (IRL) for lead, a measure of the contribution of lead in food to blood lead levels. The agency estimates that establishing a 10 ppb action level could result in as much as a 46% reduction in exposure to lead from apple juice in children. For all other fruit and vegetable juices, establishment of an action level of 20 ppb is estimated to result in a reduction of 19% in exposure to lead from all other juices in children. FDA has issued a lower draft action level for apple juice because it's the juice most commonly consumed by young children.

"As we outlined in the Closer to Zero action plan, the agency is increasing targeted compliance activities as part of our efforts to monitor levels of these elements in foods through the FDA's Total Diet Study, Toxic Elements in Food and Foodware program, and sampling assignments," said Susan Mayne, PhD, director of FDA's Center for Food Safety and Applied Nutrition, in a statement. "In addition, our work in this important area of food safety will progress with advancements in science. For example, action levels may be progressively lowered over time, as appropriate, to make continual improvements in reducing the levels of lead, arsenic, cadmium, and mercury in foods eaten by babies and young children."

FDA is accepting comments on the draft guidance, and manufacturers may choose to implement the recommendations in the draft guidance before the guidance becomes final. FDA will work with manufacturers of these products to encourage the adoption of best practices to lower levels of lead in juice.

Because lead is in the environment as a naturally occurring element and as a result of consumer and industrial products and processes, it is not possible to remove it entirely from the food supply; however, the action levels recommended in the draft guidance document will help limit consumer exposure.

USDA Increases Efforts to Curtail Bird Flu

BY KEITH LORIA

USDA's Animal and Plant Health Inspection Service (APHIS) is taking immediate action to ensure a rapid response to a highly pathogenic avian influenza (HPAI) outbreak in the United States.

Tom Vilsack, Agriculture Secretary, approved the transfer of approximately $263 million from the Commodity Credit Corporation to APHIS to directly support the response, which allows APHIS to continue critical work with state and local partners to quickly identify and address cases of HPAI.

As of May 12, the virus has been confirmed in 29 states, impacting more than 33 million domestic birds, with the latest positive tests coming in Oregon, Washington, Vermont, Alaska, and Oklahoma. The virus was initially detected in a flock of pheasants earlier this year.

Agriculture and avian flu expert Chris Helm, executive vice president of global business at Longhorn Vaccines & Diagnostics, notes that USDA is expanding its surveillance of wild birds with the goal of preventing new cases from entering the poultry population, or at least tracking where new cases appear. This way, the agency can get ahead of any new cases and take action before it's too late.

"Wild birds are the carriers of avian flu and carry it from farm to farm, which is why we're seeing an uptick in avian flu among the U.S. poultry population," he tells Food Quality & Safety. "If the USDA is able to track how the virus is spreading, they have the opportunity to get ahead of any new cases."

(Continued on p. 8)

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This is critical, because the virus kills birds and often necessitates that flocks be culled, which affects the U.S. supply of both eggs and broilers and turkeys. This could lead to inflation on these products and/or scarcity unless the virus is tamped down.

So, testing in both wild birds and chicken and turkey flocks is expanding, and remains a critical part of tracking the spread of the virus and preventing new cases. "Early detection can prevent spread, and we don't want to see the virus jump from bird and poultry to humans, which we saw in the early 2000s," Helm says.

"Highly pathogenic avian influenza is a serious concern for our nation's poultry industry, and we need to continue our nationwide response to minimize the impact," says Jenny Lester Moffitt, USDA's undersecretary for marketing and regulatory programs. "The agency's actions during this ongoing emergency serve to safeguard U.S. poultry and egg producers and reduce the effects of avian influenza on agriculture and trade, while also enhancing readiness for other animal health emergencies.

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FDA Issues Warning Letters to Dietary Supplement Manufacturers

On May 9, 2022, FDA announced that 11 companies were illegally selling adulterated dietary supplements, and proceeded to send warning letters to the companies demanding that they cease this practice.

In the week that followed, one of the manufacturing companies, Glanbia Performance Nutrition, was taken off the list, after it was determined that FDA incorrectly associated them with the products Uplift Max and Shred Her Max. The other 10 companies are Advanced Nutritional Supplements, LLC; Exclusive Nutrition Products, LLC (Black Dragon Labs); Assault Labs; IronMag Labs; Killer Labz (Performax Labs Inc.); Complete Nutrition LLC; Max Muscle; New York Nutrition Company (American Metabolix); Nutritional Sales and Customer Service LLC; and Steel Supplements, Inc.

The warning letters stated that the companies were manufacturing dietary supplements that, in some cases, contained new dietary ingredients not yet FDA approved or included unsafe food additives.

"The companies are receiving the warning letters because they are listing unapproved non-dietary supplement ingredients on their product label and using unsafe non-food product ingredients per their label as well," says Bill Bremer, FDA compliance director for Adroit North America, a food and beverage consulting agency. Both actions constitute the sale of products as dietary supplements that are considered adulterated product by not using approved dietary supplement ingredients, adds Bremer. The use of other non-food grade (GRAS) ingredients results in an additional case of adulteration.

The dietary supplements contain what FDA believes to be ingredients that could potentially cause adverse effects for consumers. Ingredients being singled out in the letters include higenamine, 5-alpha-hydroxy-laxogenin, higenamine HCl, hordenine, hordenine HCl, and octopamine.

The warning letters (classified as 483 reports) allow 15 days for acceptance of the warning and the resolution taken to remove the product from market distribution; however, FDA noted in the letters that it has not evaluated whether the unapproved products are effective for their intended use, are in the proper dosage, have potential interaction with FDA-approved drugs or other substances, or cause dangerous side effects or other safety concerns.

"The FDA will monitor based on the response, while the lack of response will result in more direct response by the FDA," Bremer says. "This is important stuff because there is too much leeway and [there are] too many companies out there making supplements that really don't know how to make an ethically produced and distributed product."

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CDC Launches Center to Improve Outbreak Response

The Centers for Disease Control and Prevention (CDC) has launched the Center for Forecasting and Outbreak Analytics (CFA). CFA seeks to enhance the nation's ability to use data, models, and analytics to enable timely, effective decision making in response to public health threats for CDC and its public health partners.

CFA's work will be focused into three main pillars: predict, inform, and innovate. CFA has begun to build an outbreak analytics team that includes experts across several disciplines who will develop faster, richer evidence to predict trends and guide decision making during emergencies. CFA is hiring expert communicators to regularly share insights with federal, state, and local partners and the public, and will also continue to advance the state of the science of outbreak data, models, and analytics to improve the nation's ability to respond to health emergencies.

Planning for CFA began in August 2021, with initial funding of $200 million from the *American Rescue Plan Act*. So far, CDC has awarded $26 million in funding to academic institutions and federal partners to advance modeling and forecasting methodology.

Fast Food Chains Sued over PFAS in Food Packaging

BY KEITH LORIA

This spring, two separate lawsuits were filed against McDonald's and one was filed against Burger King alleging similar causes of action and seeking similar remedies, part of a growing trend of consumer product cases involving polyfluoroalkyl substances (PFAS).

PFAS, often known as "forever chemicals," are commonly used in food packaging in an effort to prevent leakage. On October 18, 2021, EPA Administrator Michael S. Regan announced a strategic roadmap aimed at significantly reducing the use of the chemicals, including a comprehensive strategy to address the problem.

"While the three cases were filed separately, they all rely in part on third-party testing reports, such as a Consumer Report that supposedly found elevated levels of total organic fluorine in food packaging, which some contend is a measure of PFAS," says Matt Walker, an associate at Lathrop GPM Law Firm in Chicago.

The federal government's actions addressing PFAS in food packaging have largely relied on voluntary phaseouts of certain compounds, but several states have moved to ban the sale of PFAS in food packaging.

The details of the cases are as follows. In April, plaintiff Azman Hussein sued Burger King in the U.S. District Court for the Northern District of California. The class action lawsuit alleges that, while Burger King markets its food as using "real ingredients" with "no secrets" and sustainable packaging, the company was allegedly exposing consumers to harm by using PFAS-coated food packaging.

"The complaint details several examples of Burger King's statements about the safety of its food," Walker says. "The proposed class includes any person in the United States, or the California subclass, who purchased Burger King products. Hussein seeks medical monitoring for the proposed class, in addition to monetary damages and injunctive relief."

In a lawsuit filed March 28 in the U.S. District Court for the Southern District of Illinois, plaintiff Larry Clark alleged that McDonald's Corporation was using PFAS product packaging, contrary to its food safety pledge, resulting in what the lawsuit says is fraud and deceptive business practices. "The plaintiff alleges he purchased products from various McDonald's restaurants in several central Illinois counties, but does not identify any specific franchisees," Walker says.

On March 31, plaintiff Ken McDowell brought a class action against McDonald's Corporation in the U.S. District Court for the Northern District of Illinois, making similar allegations that the products were fraudulently and misleadingly marketed as safe for consumers and environmentally friendly, in violation of federal and state consumer protection laws. "Among monetary damages and injunctive relief, McDowell seeks medical monitoring on behalf of a national class and California subclass," Walker adds.

While the complaints make various allegations of potential human health effects and refer to state and federal regulatory actions to address PFAS, these lawsuits do not bring traditional tort claims for personal injury, says Walker. Instead, they bring claims arising from the misrepresentation of products as safe based on violations of consumer protection and false advertising laws. "Certainly, a judgment in favor of plaintiffs would be detrimental for the industry, but even in the absence of a verdict, the combination of media attention, increasing regulatory pressure, and consumer activism means that the food industry will likely be the target of continuing litigation," Walker adds. ■

Washington Report

FDA's Foodborne Outbreak Response Improvement Plan

An in-depth look at agency's latest effort to improve the speed and effectiveness of outbreak investigations

BY **KEITH LORIA**

Because foodborne disease is a significant public health issue in the United States, FDA recently developed the Foodborne Outbreak Response Improvement Plan (FORIP) to help the agency and its partners enhance the speed, effectiveness, coordination, and communication of outbreak investigations. "Tackling foodborne illnesses faster and revealing their root cause is essential to the prevention of future outbreaks," says Frank Yiannas, FDA's deputy commissioner for food policy and response. "We are confident that these actions outlined in the plan will contribute to bending the curve of foodborne illness in this country by helping to prevent future outbreaks."

The plan is a necessary component of the agency's strategy to ensure that the most effective tools and procedures are being used to streamline outbreak investigations and alleviate the effects of foodborne illness.

Key Areas

FORIP focuses on four specific priority areas in which improvements will have the most impact on outbreaks associated with human food:

1. Tech-enabled product traceback,
2. Root cause investigations (RCIs);
3. Analysis and dissemination of outbreak data; and
4. Operational improvements within the agency.

Yiannas notes that the plan specifically focuses on reducing the time needed to identify contaminated product; gathering and sharing critical investigational findings and recommendations to prevent future outbreaks more quickly and fully; more rapidly identifying a source and providing earlier and more open communications with government partners, industry, and the public; and measuring, streamlining, and continuously improving FDA's performance.

David Goldman, MD, MPH, chief medical officer in FDA's Office of Food Policy and Response, notes that FDA learns something new with each outbreak that occurs and then tries to incorporate that knowledge into its response. "Metrics are being addressed across the entire foods program," he says. "We're looking at a combination of operational and public health metrics—which, together, we intend to translate into faster response, earlier action, and secondary prevention—that are preventing further illnesses during an outbreak."

Craig W. Hedberg, PhD, professor in the division of environmental health sciences at the University of Minnesota in Minneapolis, who conducted an independent review of FDA's foodborne outbreak response processes, notes that FORIP was necessary to address new food safety challenges that continue to emerge and to take better advantage of new developments in public health surveillance methods. "In particular, the development of whole-genome sequencing for bacterial pathogens such as *Salmonella*, Shigatoxin-producing *E. coli*, and *Listeria* provides more information to better identify outbreaks with small numbers of cases, to link cases to food or environmental isolates, and to identify recurring patterns over time that highlight persisting problems that may not have been adequately addressed," he says.

Liz Sertl, senior director of community engagement for GS1 US, a nonprofit standards organization, notes that FORIP is an extension of the work that FDA already has in place with the Food Safety Modernization Act and its New Era of Smarter Food Safety. "FORIP is focused on multi-

state outbreaks that require significant engagement coordinated by FDA's Coordinated Outbreak Response and Evaluation (CORE) Network," she says. "The plan seeks to enhance the speed, effectiveness, coordination, and communication of those outbreak investigations. Ultimately, the plan is intended to complement two of the blueprint's CORE elements, "Tech-Enabled Traceability" and "Smarter Tools and Approaches for Prevention and Outbreak Response."

The positive impact of this work is made possible, she adds, by using smarter ways of digitizing information to help get to the root cause of foodborne illness more quickly due to the speed of information available. "Data that's identified, captured, and shared in a standardized, digitized manner is key for FORIP, as this enables trading partner collaboration and systems interoperability, and can help members meet the requirements of FDA regulations," Sertl adds.

New Elements of the Plan

FORIP aligns closely with FDA's existing New Era of Smarter Food Safety Blueprint, which was established in 2020. The blueprint includes four core elements, including tech-enabled traceability, smarter tools and approaches for prevention and outbreak response, new business models and retail modernization, and food safety culture.

FORIP includes actionable steps to implement the strategies and principles of the blueprint specifically related to foodborne illness outbreak response. Some of the key components of the plan include reducing the time needed to identify contaminated product, accelerating the gathering and sharing of findings and recommendations, disseminating pertinent information quickly, and—ultimately—raising the bar to continually improve performance in this area. "At the core of all three of these new factors will be technology that helps food manufacturers to determine exactly how to predict, identify, and stop foodborne illnesses from coming to fruition," says Joe Scioscia, VP of sales for VAI, an organization that offers software for tracking and traceability in the food industry. "FORIP's new elements will work to cover all the bases of a potential foodborne illness process, including identifying its origins, detailed analysis, and determining areas of weakness so that distributors can better prevent another incident from occurring."

Being able to rapidly assemble records for shipment of food products through the distribution system to the point of service will greatly increase the speed and reliability of traceback efforts and make it more feasible to incorporate traceback data into the epidemiologic investigations.

—Craig W. Hedberg, PhD

FDA is also trying to improve tracebacks of food items during outbreak investigations by defining data elements that can be tracked electronically without requiring field staff to physically visit every establishment and review documents. Outbreak responses will be sped up by digitizing processes for collecting consumer purchase data and leveraging advanced analytics tools. "Being able to rapidly assemble records for shipment of food products through the distribution system to the point of service will greatly increase the speed and reliability of traceback efforts and make it more feasible to incorporate traceback data into the epidemiologic investigations," Dr. Hedberg says. "Increasing the speed and efficiency of tracebacks and incorporation of traceback data into epidemiologic investigations are critical areas for improvement."

In the plan, there are also detailed steps for systematizing the agency's root RCIs and adopting a continuous improvement approach for food safety operations.

Additionally, FORIP facilitates a streamlined process for analyzing and disseminating outbreak data to the Centers for Disease Control and other regulatory partners. "Many of these additional efforts will increase the amount of information available from outbreak investigation partners and increase the timeliness of the information, so that contaminated food products can be more rapidly identified and removed from commerce," Sertl says.

Measuring Success

FDA is using both performance and outcome metrics to identify the level of success it achieves in reaching its goal of enhancing the speed, effectiveness, coordination, and communication of outbreak investigations. While the individual metrics are important, the true progress indicators will be reduced cases of sickness, hospitalization, and death related to foodborne illness outbreaks.

Scioscia calls FORIP a necessary step forward, both for the safety of food suppliers and distributors working alongside the various touchpoints throughout the supply chain and for consumers at the receiving end. "Without food safety track and trace technologies and plans in place, food distributors cannot identify and remove contaminated food items in time," he says. "The FORIP is necessary for suppliers to gain access to IoT technology and food [enterprise resource planning] ERP applications with AI and predictive analytics, that will help prevent contaminated foods from reaching restaurants and store shelves and getting into the hands of consumers."

According to Yiannas, successfully implementing the series of actions outlined in FORIP will enable FDA to respond more quickly and more efficiently to foodborne outbreaks and reduce the number of foodborne outbreaks that go unsolved in the future.

Dr. Hedberg says that success of FDA's plan will be measured by the increased speed and effectiveness of investigations to identify the source of outbreaks and by the improved ability to provide insights to industry on how they can develop preventive controls based on better understanding of the root causes of outbreaks. "For that to happen, we need time, continued investment in the public health system that supports these efforts, and the continued belief that these efforts matter." ■

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Legal Update

Culture Wars

The onging controversy over labeling laws for cell-cultured meat products

BY **SHAWN K. STEVENS, ESQ.** AND **ELIZABETH PRESNELL, MS, ESQ.**

Cultured meat, also known as cell-cultured meat, is grown in a lab from a few animal cells. Although the meat produced is technically of animal origin, it does not require the growth or slaughter of living and breathing animals. As such, cell-cultured meat is often touted as a more environmentally friendly and humane alternative to traditional animal meat products. With that said, the fact that consumers expect that food labels to be truthful and to include critical information about the origin of their foods, a significant amount of debate has surrounded the issue of how, exactly, these products should be labeled.

To date, cultured beef, chicken, pork, and fish have been created using cell-culture technologies. Because of the variety of products created and the creation method itself, both USDA and FDA could potentially and logically regulate cultured meat, poultry, and seafood products.

As a result, USDA and FDA combined their resources and forged an agreement that defines each agency's role in regulating cell-cultured products. The agencies have determined that FDA will be responsible for evaluating production processes and materials, as well as ensuring manufacturing controls for tissue collection and culturing. Additionally, FDA will retain full regulatory authority over cultured seafood products. USDA will determine which products are eligible for the USDA mark of inspection, and will conduct inspections at locations producing cultured meats eligible for the mark of inspection.

In addition, at the point of harvest of cultured products subject to USDA's Food Safety and Inspection Service (FSIS) oversight, regulatory authority will transfer from FDA to FSIS. Although the agencies have not yet issued guidance as to how this joint regulatory authority will be implemented, it's likely fair to say that cultured meat producers will be expected to comply with both FDA and USDA regulations, and should anticipate inspections and oversight by both agencies throughout various parts of the culturing process.

Reportedly, at this point, neither agency is expected to release additional complex food safety guidance or regulations for the production of cultured meat products. Rather, it is anticipated, at least in the short term, that the production, storage, and distribution of cultured meat products will be subject to existing USDA and FDA food safety regulations.

Labeling

Once these products have been cultured, however, they will be required to carry appropriate labeling. As a result, both USDA and FDA have issued requests for comments on the labeling of cultured meat products. Neither agency has published proposed rules on the labeling requirements, electing instead to hear from the public, industry, and others in response to a number of specific agency questions directed toward determining how these products should be labeled. These questions are focused primarily around the permissible (or impermissible) use of traditional meat and poultry names or descriptors for products that are, in fact, composed of cultured animal cells. The main focus of both agencies' efforts in this area has been, and will continue to be, to ensure that consumers are truthfully and adequately informed about the true underlying nature of the products they are buying and consuming.

Notably, because there is not yet a federal regulatory standard for the labeling of cell-cultured meat products, many states have implemented laws that regulate the labeling or naming of cultured meats. Louisiana has implemented a law that generally prevents cultured meat from being represented as meat or a meat product. Similarly, certain Alabama laws prohibit food products made using cultured animal tissue from being labeled as "meat" or a "meat product." Kentucky, North Dakota, and South Carolina have implemented similar language.

Several other states have also imposed new labeling requirements on both cultured meat and plant-based meat alternatives. Missouri, for instance, has specifically defined "meat" as only portions of an animal carcass, and has prohibited calling cultured meat "meat." The Missouri Department of Agriculture has determined that, when implementing this law, cultured meat products must utilize qualifying language demonstrating that the product is cultured, and this qualifier must be used immediately before or after the product name. Additionally, the agency has indicated that an additional statement must be included on the product packaging indicating that the product was "grown in a lab."

The increasing chorus of differing laws and legal decisions demonstrates the need for, and will likely compel USDA and FDA to adopt, a single set of new and uniform federal labeling regulations.

When these statements are not included, the Missouri Department of Agriculture has stated that the products will be considered misbranded in violation of state law. Arkansas has passed a law that features similar language, with the purpose of protecting consumers from "being mislead or confused by false or misleading labeling" on cultured meat and meat alternatives. Mississippi and Wyoming have passed laws with similar language.

The laws in many states have been challenged by producers of meat alternatives, who claim that the laws are unconstitutional. So far, the Louisiana law has been held unconstitutional as applied to a plant-based alternative product in a Louisiana district court. The state of Louisiana has appealed this decision to the Court of Appeals. Lawsuits by producers are ongoing in several other states, including Oklahoma, Missouri, and Arkansas. The increasing chorus of differing laws and legal decisions demonstrates the need for, and will likely compel USDA and FDA to adopt, a single set of new and uniform federal labeling regulations.

Consumer Understanding

Because the federal regulatory agencies have not yet issued guidance or regulations on how cultured meat should be labeled, producers of these products should use caution to ensure not only that any applicable state laws are followed, but also that consumers understand the true nature of the product they are purchasing.

Notably, research by Hallman and Hallman at Rutgers University has shown that consumers widely understand the meaning of labeling that includes the terms "cell-based" or "cell-cultured." Following the publication of this research in 2020, many industry organizations and consumer protection organizations, including the National Fisheries Institute, the Environmental Defense Fund, the Center for Science in the Public Interest, and the Alliance for Meat, Poultry, and Seafood Innovation, have begun to center communication about cultured meat around the term "cell-cultured." The use of this term would likely satisfy most existing state laws and would additionally provide sufficient details to a consumer to ensure that the consumer understands not only what the product is, but also how it is produced.

In the coming months, and maybe years, both USDA and FDA will work tirelessly to ensure that there is a uniform set of labeling rules governing these products. In the meantime, continue to stay abreast of the agencies' benchmarks and progress. And, if you're motivated enough, you might even consider joining the conversation to help shape the rules in the future. ■

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Allergen Control

Gluten-Free Labeling of Fermented Foods

The implications and impact of FDA's final rule

BY **MELANIE L. DOWNS, PHD,** AND **STEVE L. TAYLOR, PHD**

As of August 2021, finalized rules are in effect for gluten-free claims on fermented and hydrolyzed foods regulated by FDA. If a fermented or hydrolyzed food (or a food containing fermented or hydrolyzed ingredients) bears a gluten-free label, the manufacturer must maintain records demonstrating that the food or ingredient met the FDA definition of gluten free prior to fermentation or hydrolysis and that gluten cross-contact was controlled after fermentation or hydrolysis. While this regulation seems straightforward on paper, challenges remain for food manufacturers trying to interpret the rule for their products. This article reviews the development of the current gluten-free regulations and the impact of the recently finalized rule for fermented and hydrolyzed foods.

Gluten and Celiac Disease

Celiac disease, also known as gluten-sensitive enteropathy, a lifelong condition affecting an estimated 1% of the U.S. population, is characterized by a chronic immune-mediated inflammatory response to the gluten proteins found in certain cereal grains, including wheat, rye, barley, and sometimes oats. The inflammatory process in celiac disease primarily impacts the intestinal tract, creating a chronic malabsorption syndrome unless treated. The symptoms of celiac disease, which are reflective of an inability to absorb nutrients including weight loss, anemia (iron deficiency), bone loss (calcium deficiency), and growth retardation in children, along with nausea, abdominal cramping, and diarrhea.

Gluten is a complex mixture of different individual proteins and includes two major fractions- prolamins (also referred to as gliadins) and glutelins. Individuals affected by celiac disease must strictly avoid gluten-containing foods to prevent serious adverse health outcomes, making establishment of regulatory criteria for the use of gluten-free claims critical to their ability to make safe food choices.

For many years, food manufacturers catering to celiac consumers had been labeling products as gluten free, but there was no established regulatory definition in the U.S. prior to 2013. The development

of the current regulatory structure started with the *Food Allergen Labeling and Consumer Protection Act of 2004*, which required the Secretary of Health and Human Services to issue regulations to define and permit use of the term "gluten-free" for food labels. The final rule for gluten-free labeling of foods under FDA jurisdiction was published in August 2013, with a compliance date of August 5, 2014.

Gluten-Free Regulatory Definition

The gluten-free labeling regulation finalized by FDA and incorporated as 21 CFR 101.91 defines gluten-containing grains as wheat (any species belonging to the genus *Triticum*), rye (any species belonging to the genus *Secale*), barley (any species belonging to the genus *Hordeum*), or any of their crossbred hybrids (e.g., triticale). As illustrated in Table 1 (see below), this definition can encompass many different individual species, particularly when it comes to wheat. The rule also defines gluten as "the proteins that naturally occur in gluten-containing grains that may cause adverse health effects in persons with celiac disease (e.g., prolamins and glutelins)."

With respect to the definition of gluten-free, the rule stipulates that a product bearing a gluten-free label may not contain any of the following:

1. An ingredient that is a gluten-containing grain;
2. An ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten; or
3. An ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten, if the use of that ingredient results in the presence of 20 ppm or more gluten in the food.

Foods that inherently do not contain gluten may be labeled as gluten free if the presence of any unavoidable gluten is less than 20 ppm gluten.

Failure to meet these requirements for a product labeled as gluten free would result in a misbranded product. In addition, the terms "no gluten," "free of gluten," and "without gluten" must meet the same requirements as products labeled "gluten free."

When compliance with the gluten-free rule is based on analysis, FDA indicated it would use a "scientifically valid method that can reliably detect and quantify the presence of 20 ppm gluten in a variety of food matrices, including both raw and cooked or baked products." The reliance on analytical methods for evaluating compliance with the regulation plays a key role in the agency's perspectives on fermented and hydrolyzed foods.

Methods for Gluten Quantification

Several methods have been developed for the detection and quantification of gluten in food matrices, including a few that have been validated as AOAC Official Methods of Analysis. These methods are generally sandwich enzyme-linked immunosorbent assays (ELISAs) that employ different types of gluten-specific antibodies. Sandwich ELISAs can provide sensitive, reproducible, and accurate quantification of intact gluten, but they require multiple intact binding sites to be present on the target protein molecule (see figure 1, p. 16). When gluten proteins undergo partial hydrolysis during fermentation, one or more of the required binding sites may be disrupted, affecting detection.

Competitive ELISA methods, on the other hand, only require one binding site for protein detection. While competitive ELISAs are more appropriate for detection of partially hydrolyzed gluten proteins, accurate quantification remains a challenge. Different fermentation processes and conditions may result in different levels of hydrolysis and different cleavage sites yielding multiple peptides of varying length and immunogenicity. These differences in hydrolysis make it difficult to develop a single ELISA calibrant that will be applicable for accurate quantification of gluten in a diverse range of fermented and hydrolyzed products.

In the preamble to the final rule for gluten-free labeling, FDA indicated that they were unaware of any currently available methods that could reliably detect and quantify the presence of 20 ppm intact gluten in fermented or hydrolyzed foods. They therefore indicated their intent to issue a separate rule for how they would verify the compliance of fermented and hydrolyzed foods.

Gluten-Free Labeling of Fermented or Hydrolyzed Foods

In the final rule, FDA outlined compliance requirements for situations in which a scientifically valid method is not available to quantify gluten because the food is fermented or hydrolyzed or contains ingredients that are fermented or hydrolyzed.

(Continued on p. 16)

Table 1: Examples of gluten-containing grains

Gluten-Containing Grain	Example Species
Wheat (all *Triticum* species)	Common wheat *(T. aestivum)*
	Durum wheat (*T. durum*)
	Club wheat (*T. compactum*)
	Emmer wheat (*T. dicoccon*)
	Einkorn wheat (*T. monoccum*)
	Khorasan (*T. turgidum*)
	Spelt (*T. spelta*)
Rye (all *Secale* species)	Common rye (*S. cereale*)
Barley (all *Hordeum* species)	Cultivated barley (*H. vulgare*)
Crossbred hybrids	Triticale (wheat-rye hybrid)

(Continued from p. 15)

For fermented and hydrolyzed foods, manufacturers must make and keep records adequately demonstrating that all three of the following are met:

1. The food meets the definition of gluten free prior to fermentation or hydrolysis;
2. The potential for gluten cross-contact occurring after fermentation or hydrolysis has been adequately evaluated; and
3. If risks of gluten cross-contact are identified, the manufacturer has implemented sufficient controls to prevent cross-contact during production.

For foods that contain fermented or hydrolyzed ingredients, manufacturers must maintain records demonstrating that the ingredients meet the requirements for gluten-free fermented or hydrolyzed foods.

The particular types of documentation necessary for demonstrating that a food meets the definition of gluten free prior to fermentation should be assessed by the manufacturer. While the rule does not mandate analysis or specific documents, the preamble to the proposed rule does indicate that ingredients are likely to be at different levels of risk for gluten cross-contact and therefore may require different forms of documentation. For example, ingredients derived from commodities such as legumes, grains, or seeds that are susceptible to cross-contact with gluten-containing grains may require different types of documentation than foods that are inherently gluten free and have a low-risk of gluten cross-contact (e.g., fluid milk). In general, examples of documentation include certificates of analysis, analytical test results, and verification of supplier cross-contact management.

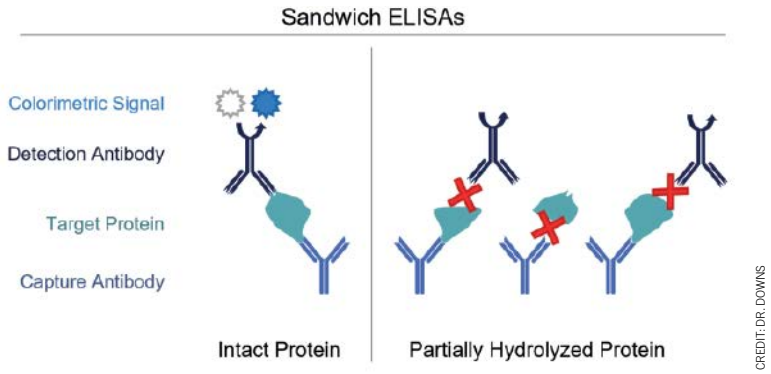

Figure 1: Sandwich ELISAs and partially hydrolyzed proteins.

The final rule for fermented and hydrolyzed foods also contains separate information about gluten-free claims on distilled foods, such as distilled vinegars. Unlike fermentation, which FDA does not consider to be a process that can be validated as removing gluten, distillation is a process that physically separates gluten proteins and peptides from other components based on clearly defined properties. When conducted following good manufacturing practices, distillation will separate volatile compounds (e.g., alcohols) from nonvolatile compounds, including any proteins and protein fragments. As a result, for distilled foods, FDA will use methods capable of detecting the presence of proteins and protein fragments in foods to evaluate compliance with the gluten-free requirements.

Enzymes

In response to comments to the proposed rule, the final rule preamble specifically indicates that FDA declines to exempt enzymes from the requirements that apply to fermented and hydrolyzed foods. When enzymes are produced in a system with gluten-containing nutrient media, FDA expressed concerns about how much carry-

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over of gluten into the finished enzyme product would occur. Given that microbial fermentation processes used to produce the enzymes may also partially hydrolyze any gluten protein present, FDA points to the analytical challenges involved in verifying the subsequent removal of gluten residues from the enzyme product that will result in a final gluten concentration below 20 ppm intact gluten.

Soy Sauce

Soy sauce is a commonly used fermented or hydrolyzed food ingredient that may be derived from gluten-containing grains. Traditional soy sauce is commonly produced from a fungal fermentation of soybeans and wheat. As these types of soy sauce do not meet the gluten-free definition prior to fermentation, they are not allowed to be labeled as gluten free. Certain styles of traditionally fermented soy sauce, including some types of tamari, do not include any wheat in the formulation. If the ingredients used to make tamari meet the gluten-free definition prior to fermentation, then the resulting product could be labeled as gluten free. Lastly, some types of soy sauce do not rely on fermentation but rather use a combination of acid-hydrolyzed soybeans and other ingredients to formulate the product. If all the ingredients meet the gluten-free definition prior to hydrolysis and production, the soy sauce may be labeled as gluten free.

Malt, Malt Extract, and Malt Syrup

Malt is defined in 21 CFR 184.1445 as the "product of barley (*Hordeum vulgare* L.) germinated under controlled conditions." Malt extract and malt syrup are terms both referring to viscous concentrated water extracts obtained from barley malt. FDA has indicated that because malt, malt extract, and malt syrup are derived from a gluten-containing grain and have not been processed to remove gluten, they may not be used as ingredients in foods labeled as gluten free.

Gluten-Free Beer, Wine, and Spirits

In the U.S., beer (malt beverages), wine, and spirits primarily fall under the regulatory authority of the Alcohol and Tobacco Tax and Trade Bureau (TTB). Beers not meeting the definition of a malt beverage, however, are regulated by FDA. Beers regulated by FDA would include those that are not made from both malted barley and hops—for example, beers using substitutes for malted barley such as sorghum, millet, or rice. Often, these beers have been formulated with gluten-free claims in mind, as they are not made from gluten-containing grains. Despite differences in regulatory jurisdiction, FDA and TTB both recognize the same definition of gluten free for fermented and hydrolyzed beverages. For beer or wine to be labeled as gluten free, the ingredients or mash used to make the beer must meet the definition of gluten free prior to fermentation, and controls must be in place to prevent gluten cross-contact after fermentation.

The TTB does, however, allow alternative statements on products fermented from gluten-containing grains (TTB Ruling 2020-2). In certain instances, manufacturers can include the claim that the products are "[Processed *or* Treated *or* Crafted] to remove gluten." If this claim is used, there are additional requirements that must be met:

1. The label must also include the following statement: "Product fermented from grains containing gluten and [processed or treated or crafted] to remove gluten. The gluten content of this product cannot be verified, and this product may contain gluten";
2. The manufacturer must submit a detailed description of the method used to remove gluten and must be prepared to substantiate claims about gluten reduction upon request;
3. Gluten cross-contact must be controlled after treatment to reduce gluten; and
4. No labeling statements are allowed with respect to specific gluten concentrations.

TTB requires pre-authorization of all product labels, and allowable label claims meeting these criteria would be evaluated during that process. For FDA-regulated beers, the final rule indicates that beers not meeting the definition of gluten free are not precluded from using the types of alternative statements recognized by TTB, but the claims must be truthful and not misleading. That being said, FDA does not consider fermentation or hydrolysis itself a process that can be verified as reducing the gluten content of beers made from gluten-containing grains.

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TTB has also indicated that distilled spirits would be allowed to bear a gluten-free claim, and these products would need to comply with the same requirements as distilled products regulated by FDA. Specifically, manufacturers of distilled spirits made from gluten-containing grains must follow good manufacturing practices to prevent introduction of any gluten-containing material into the distillate and must implement controls to prevent gluten cross-contact after distillation. Manufacturers must also be prepared to provide verification of the absence of protein from the distillate and the absence of gluten from any ingredients added after distillation.

Impacts and Future Directions

Given the wide range and diversity of fermented foods and ingredients, the final rule has the potential to impact many products that had previously been labeled as gluten free. Even if the product is inherently gluten free, manufacturers must develop and maintain the required documentation for compliance with the rule.

While FDA has left the door open to enforcing compliance through use of novel gluten quantification methods developed in the future, there are many challenges associated with such an undertaking. Development and validation of a single method capable of quantifying intact gluten equivalents across the wide diversity of relevant fermented and hydrolyzed foods would require substantial time, effort, and resources. ■

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Global Interests

Worldwide Food Habits Under COVID-19

Changes in consumer eating behavior from 2019 through 2022

BY **AURORA A. SAULO, PHD**

During 2020, the first year of the COVID-19 pandemic, American consumers retained their pre-pandemic eating occasions at approximately the same frequency: early morning snack, breakfast, morning snack, lunch, afternoon snack, dinner, after-dinner snack, and late-night meal/snack, according to 2022 research from The Hartman Group. Because most countries isolated from each other and residents were primarily mandated to follow isolation and quarantining practices, those venues with high close-contact activities remained closed or went out of business through most of 2020. Direct person-to-person contacts were severely minimized, almost eliminated. As eat-at-home occasions surged during the pandemic, the number of consumers eating anywhere away from home decreased by about 50% from before the pandemic.

Further, because consumers mostly worked from home, they ate more with others (i.e., family, significant others) during those eating occasions when they would have eaten alone (i.e., for early morning snack, breakfast, morning snack, and lunch) prior to 2020. Consumers also learned to shop more efficiently, especially for dinners, snacks, and meals that they had purchased from food service pre-pandemic. Online shopping and delivery significantly grew in 2020 among all generations except for Gen Z who had often already used digital shopping. But the habit of same-day sourcing stayed. Because of shelter-at-home mandates, about 40% of U.S. consumers cooked at home more often than before the pandemic. They also focused on more expensive foods and ingredients with health and wellness qualities. The trade-up was justified by reduced spending on food and beverages outside the home, fewer options in recreational activities, and travel restrictions. Consumers also had more disposable income, and about 45% also declared that they would continue cooking at home after the pandemic.

But the cooking fun fizzled out quickly in the second half of 2020 as cooking

fatigue set in. Consumers shifted their attention to new cooking methods, culinary skills, and authentic exotic flavors. They ate certain foods on other occasions not traditionally meant for those foods, similar to a "breakfast all day" situation.

Where Are We Now?

Consumer behavior toward COVID-19 around the world seemed to occur in common stages. In the beginning, consumers tried to strengthen their health and immunity through products. They then prepared for periods of quarantining, including hoarding supplies to help them manage those restrictions and any others that might be instituted.

More than two years after the pandemic started, about 48% of consumers remained extremely or very concerned about COVID-19 virus variants, declining from 52% in October 2021, according to research on grocery trends by FMI. By this time, however, other important sources of concern began to surface, such as food prices that were up 4% from early 2021 and supply chain issues that have not adequately addressed out-of-stock items. The consumer price index for all items rose to 8.5% for the year ending March 2022, with the food index rising to 8.8%, according to the Bureau of Labor Statistics.

The number of employees (45%) who continued to work from home full- or part-time remained high, resulting in higher than pre-pandemic levels for at-home eating of mid-morning snack, lunch, and afternoon snack. But the food-at-home index rose 10% for the year ending March 2022, levying economic pressure on work-at-home employees.

In 2019, before the pandemic, eating away from home was highest among Millennials (34%), followed by Gen Z (27%), Gen X (26%), and Boomers (14%). During the first year of the pandemic in 2020, all generations showed a decline in their away-from-home eating occasions. But in late 2021, all generations showed a resurgence, almost to pre-pandemic levels, in away-from-home eating. Gen Z didn't show much change in their away-from-home eating habits during the pandemic, likely because they are the first generation to grow up in a totally digital world and, for them, shopping and ordering online is a normal process.

Due to limited spending opportunities during the pandemic, Millennials, parents, and higher-income households were willing to pay more for food and beverage with higher quality products, more unique flavor, higher integrity in sourcing and processing, and other authentic characteristics that elevated their eating experiences.

Before the pandemic, consumers also were more likely to eat alone (48%) during early morning snack, breakfast, morning snack, and lunch times as they hurriedly prepared to go to work or were already at work. But in late 2021, all generations experienced a decrease in time eating alone except for the Boomers, whose eating-alone experiences remained unchanged at 52%. The Millennials and Gen Z experienced significant drops in time eating alone from pre-pandemic and pandemic levels, and Gen X during pandemic times, perhaps due to a rise in eating as a couple and as a family. Many in these generations also moved back in with family due to financial hardships, causing a decline in time eating alone.

Restaurant Dining

In 2021, approximately 24% of eating occasions took place in or were ordered from a restaurant (including takeout and delivery), surpassing even the 2019 levels. Millennials, Gen X, and parents significantly looked to restaurants to address their need for convenient and healthful meals, often enjoying those meals with others. It was also their way of demonstrating their support for restaurants that were struggling to remain open. In addition, although cooking fatigue quickly set in toward the latter part of 2020, consumers, when they chose to cook, seemed to use higher levels of preparation in 2021 than in 2019. On the other hand, consumption of ready-to-eat foods remained relatively stable during these times, while consumers engaging in little or moderate preparation of food (e.g., stove-top cooking or microwaving) declined. But the food-away-from-home index rose 6.9% over the year ending March 2022, according to the Bureau of Labor Statistics, causing a concern that eating away-from-home eating rates might stall or even decline.

When consumers sourced their food partially or totally from restaurants, it seemed that they intentionally planned to have leftovers. In 2021, about 66% of eating occasions involved all or some leftovers sourced from a restaurant, a number significantly higher than those in 2019 and 2020. For all generations except the Boomers, the number of eating occasions that involved leftovers significantly increased from 2019. From 2019 to 2021, there was a significant decline, from 51% to 34%, in the total number of leftover occasions that did not involve food sourced from a restaurant. It could be that, for consumers, having leftover food sourced from a restaurant (takeout or delivery) has developed into a norm. Besides, consumption of leftovers was a way for them to save and to reduce food waste.

Spending

Due to limited spending opportunities during the pandemic, Millennials, parents, and higher-income households were willing to pay more for food and beverages with higher quality products, more unique flavor, higher integrity in sourcing and processing, and other authentic characteristics that elevated their eating experiences. During those times, many declared that "money is no object" when choosing healthful foods to sustain them during the pandemic.

By mid-2021, food spending was almost equally split between retail and food service, just as it was pre-pandemic. Consumers increased food and beverage consumption more for late night meals/snacks and early morning snacks, perhaps due to their resumption of evening social activities.

(Continued on p. 20)

(Continued from p. 19)

Although consumers reduced their participation in the other eating occasions, there was a significant increase in the average number of categories of food and beverages consumed in late 2021 as compared with 2019. At-home eating significantly declined and eating at work and at restaurants significantly increased, although not to pre-pandemic levels.

After two years of drastically altering their daily lives to survive the pandemic, consumers began to show signs of an eager return to pre-pandemic living conditions in 2022. But the consumer price indices of all items, especially at-home and away-from-home foods started to increase in 2020. To transition back sensibly to the lives they had led before the pandemic, approximately 86% of consumers began to change the behaviors they had developed during the pandemic, according to the FMI survey. They searched for grocery deals (59%), bought store brands (35%), substituted or changed their products of choice (58%), and changed where and how they bought groceries (48%).

According to the Expert Panel of the Forbes Business Council, consumers today are or will be better informed and more participatory, make purchase decisions "on-the-go," use text messages via social media, demand consistent quality and volume of products, and prefer businesses that address ESG mandates (environmental, social and governance practices). They will also require businesses to be more customer-centric providing personalized and high-quality customer service. These characteristics will allow them to wade comfortably through the pandemic.

Other Countries

There do not seem to be studies on the eating behavior of consumers in other countries that report the same categories as those included by The Hartman Group and FMI, but there is a systematic review of longitudinal studies conducted by Gonzalez-Monroy and colleagues and published in the *International Journal of Environmental Research and Public Health* to compare eating behavior changes pre- and post-pandemic. Of the 826 studies these researchers initially gathered, 23 longitudinal studies passed their planned screening process. There were five studies from Italy, four from China, two each from Australia, Spain, United Kingdom, and Japan, and one each from the United States, India, Brazil, France, Poland, and Canada. Only adults older than 18 with no comorbidities were chosen, but they found specific subgroups of people with diabetes mellitus, young obese people, and others in vulnerable situations. The group was relatively young, with a mean age of 24.2 years.

The researchers confirmed the existence of changes in eating behavior during the pandemic. Because people stayed mostly at home during these times, the researchers reported that consumers cooked more and "showed a more frequent intake of food, an increased consumption

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of ultra-processed food and a higher caloric intake due to a more frequent alcohol consumption." People in the specific subgroups also "appeared to increase the daily amount of food eaten" with a reported "significant increase in the amount and frequency of unhealthy food products." Younger people showed "a lower adherence to healthy diets such as the Mediterranean Diet" "due to an increased intake of food, a preference for snacks and a lack of fruit and vegetables intake." The researchers concluded that their systematic review showed "changes in eating behavior, which may have become less healthy during the pandemic." They advocated the use of government-supported preventive interventions and social actions to promote healthy eating habits with a focus not only on food intake but also on alcohol consumption.

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Will There Be More Changes in Eating Behavior?

Consumers worldwide changed their eating behavior during the pandemic. Some changed to strengthen themselves to ward off the coronavirus by eating what they considered healthful foods. Others changed the frequency of eating at different eating occasions. And others, probably due to anxiety and uncertainty, changed by overeating and increasing their alcohol consumption. Will these changes significantly and permanently alter our daily lifestyles? And, how will consumers consequently react? ■

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Cannabis Corner

Cannabinoid Additives

Five different categories of additives for cannabis-infused foods, and their impact on the end product

BY **JESSE STANIFORTH**

As more and more U.S. states legalize cannabis for medical or adult use, the words "cannabis infused" have become common to describe cannabis-infused edible and drinkable products. But these products aren't infused with the cannabis plant or flowers; rather, they're infused with the active compounds the plant produces.

These compounds are usually cannabinoids—tetrahydrocannabinol (THC), cannabidiol (CBD), and lesser-known compounds such as cannabigerol (CBG) and cannabinol (CBN). Sometimes, these products can also contain terpenes, the aromatic compounds that give cannabis its strong odors.

Infusing foods with cannabis is primarily a process of infusing foods with cannabinoid additives, which, for food purposes, are broadly broken down into five different categories of products: crude oil/cannabutter, Rick Simpson Oil (RSO), cannabis distillate, cannabinoid isolate, and activated hash rosin (ice hash or bubble hash).

Crude Oil

Cannabinoids are waxy and do not dissolve in water, but they dissolve readily in oil, particularly when heated. This is the most basic means of removing cannabinoids and other active ingredients from the cannabis plant itself. No matter what cannabis additive an infuser uses, the process always begins with crude oil, sometimes known as "cannabutter" because it was originally made using butter as an extraction medium. Whether it's made using butter, coconut oil, or another carrier oil, crude oil is a simple extraction

accomplished by soaking cannabis flower in heated oil over a long period of time.

Tabitha Fritz, owner of edible producer Fritz's Cannabis Company, which is based in Etobicoke, Ontario, Canada, began her career as an edibles maker using crude oil. In 2015, the Canadian Supreme Court had just legalized medical edibles, and Fritz and her husband set out to develop their own line of products. "Crude oil is decarboxylated [heated to make the THC active] dried flower, infused into an oil carrier using heat and time," Fritz says. "We were buying [cannabis plant trimmings] from a medical shop for $200 a pound, and we would run it into coconut oil ourselves in our slow cooker."

The product is variable, based on the quality of the source cannabis, and naturally only those cannabinoids present in the plant will be extracted into the oil. Aromatic terpenes may also be extracted into oil, but because they begin boiling off at 70 degrees, they can only be maintained in a low-temperature crude oil extraction.

The first problem with crude oil, Fritz says, is the difficulty of charting the potency of the end product. "When we first got our products tested," she says, "we had been guesstimating the dosage on our product based on comparable products in the market. We had literally no idea. So when we got our products tested at the first lab that was available to consumers, we found out that what we had been marking as 125 mg was coming in at like 20 mg." After this, the company put all of their products through testing, and realized their original calculations were way off.

These were the early days of Canada's "grey market"—the period between the legalization of medical cannabis and the overall legalization of adult use products. Fritz informed her customers about the mistake through an Instagram post and changed the labels on her products. At the same time, she began mixing crude oil with distillate for more precise potency measurements.

That wasn't the only problem with crude oil. For Fritz, who eventually opted to use primarily distillate and isolate in her products, there was also the question of flavor: "It's full of plant matter," she says, referring to the high concentration of lipids, fats, and waxes left over in crude oil. "It greatly affects your taste."

But there's one aspect in which crude oil can't be beat—it's the cheapest way to extract cannabinoids into an additive suitable for food.

For a new breed of consumers who want edibles that taste like cannabis, there's a developing demand for products made with more traditional cannabis extracts, which are first derived from the plant and then decarbed to activate their cannabinoids.

Rick Simpson Oil

In the early days of medical cannabis, Rick Simpson Oil (RSO), a concentrated cannabis oil process named for its founder, became popular among medical consumers. Bao Le, DC, a chiropractor-turned-CEO of cannabis and edibles producer Hhemp, based in Hayward, Calif., first encountered RSO while he was seeking medical cannabis remedies for his 3-year-old son, who suffered from severe seizures.

He says the process for creating RSO is essentially to "put a hot iron" to buds. This melts off trichomes—the resinous deposits containing cannabinoids—into a thick extraction that can be made less viscous by mixing with a carrier oil.

RSO is good as a delivery mechanism for high-potency extracts—but that's also one of its major limitations.

David Sela, PhD, is an associate professor at the University of Massachusetts Amherst's Department of Food Science. He says that RSO has been around for a while, and it was always used before the proliferation of medical marijuana, medical cannabis, and legalized recreational cannabis. "Everyone has their proprietary artisanal preparation," he says. "Some people put the buds into the preparation, while some people put in a lot more plant material."

The advantage for many medical patients is that RSO is extremely potent, possibly more than 80% cannabinoid. However, for food producers aiming for gummies with 5% to 10% THC, Dr. Sela suspects that RSO might be too strong. "RSO might be overkill for whatever kind of product someone's trying to make," he adds. "It's highly enriched and high in cannabinoids."

For those seeking sheer potency, distillate products are usually more desirable than RSO.

Distillate

In producing cannabis edible and drinkable products, everything starts as plant matter, says Dr. Le, "You extract it [and] you get crude," he adds. "You can either use that or refine the crude oil to make what they call distillate." Distilling cannabinoids involves using heat and other refining processes to cook impurities—waxes and other plant material—out of crude oil. "That distillation or distillate is really just a refined crude oil that you get from plant," Dr. Le says.

Dr. Sela agrees. "A distillate is going to take the raw source material—the buds from the cannabis sativa plant—and then it's going to distill crudely your major cannabinoid of interest. It could be CBD, but there are also going to be other cannabinoids coming in as well. And you're going to also have other terpenes too. So maybe you could enrich that for 80% CBD, but you're also going to have some minor cannabinoids there."

This means distillate can be a "full spectrum" product, containing not just a single isolated cannabinoid such as CBD or THC, but a variety of compounds believed to work together in creating "the entourage effect,"a combination of cannabinoids and terpenes working together to accomplish more than any one could do on its own. Crude oils and RSO are naturally full spectrum, but once crude oils are refined, they can lose some of their range.

"There are a lot of very passionate cannabis chefs out there who want what you call broad-spectrum and full-spectrum products," Dr. Le says. "Full spectrum in the [cannabis] world means that there's everything in the plant. Broad spectrum is isolation of less minor cannabinoids and more of the major ones. If I'm a chef that's more organic, I want full spectrum, because I want everything that's squeezed out of that plant."

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For Fritz, distillate was just what she needed to help raise the potency, and reliability, of her edibles. After she discovered she'd been misstating the potency of her products, she moved to pair crude oil with whatever distillate she could find since, unlike crude oil, distillate can't be made at home.

Thus, an edibles manufacturer who uses distillate needs to find a reliable supplier—and expect a jump in price. Fritz ballparks that distillate costs about twice as much as crude oil. "Distillate is going to be quite a bit more potent than your crude oil would have been, but you're paying more to have a cleaner product."

Even with a much cleaner product, there can also be flavor issues with distillate. Not cannabis's traditional skunky or piney flavors, but chemical flavors brought to the fore by concentration. "It can be quite bitter; a lot of it has to do with how well refined it is," says Fritz. "You can end up with a little bit of the plant matter left in there, and some lipids, and they can have a very bitter taste." Even well-refined distillates, she adds, can have undesirable flavors—such as those similar to the taste of fish or scotch tape.

Isolate

The most concentrated form of commercially available cannabinoid additives is an isolate, sometimes called a single-compound extraction, which removes as many impurities from the cannabinoid as possible, until almost nothing remains but the cannabinoid in question.

Isolates are particularly useful in states that have strict rules about the presence of THC in products, says Dr. Sela. A completely purified product means a producer who bakes with CBD doesn't risk inadvertently adding THC to their goods, while also allowing for a marketing strategy boasting of CBD purity.

Isolates (along with distillates) are also one basis for the emerging range of cannabinoid nanoemulsions, which are cannabinoids altered in a lab to make the isolate powder water soluble and much more quickly absorbed by the body; however, even in non-emulsion form, isolate is the most expensive process of all, and removes many of the flavors people associate with cannabis. This plays into an uncomfortable split in the world of cannabis consumers. "You have a part of the industry that loves the organic medicinal smell, touch, and taste of cannabis," Dr. Le says. "They're not going to mask it with peppermint, or lavender, or orange. And then there's also the other culture side, where they don't want it to taste like cannabis. They don't want to smell it. They don't want to eat it and burp it up later and smell like weed."

This split is, at least for the moment, irreconcilable. "There are a lot of people in the industry who figure, 'If I don't taste that it's cannabis, then it's probably not in it,'" Dr. Le says. "And then there are other people who figure, 'I don't want to taste it, but I want to feel it.'"

Activated Hash Rosin

An important consideration in the case of edible cannabinoids is that they are not pharmaceutically active. In order for THC-A to become the THC well known for its mind-altering characteristics, it must first go through a process called decarboxylation—a fancy way of saying it must be heated to a certain temperature for a period of time. The same is true of CBD, which occurs in the cannabis plant as CBD-A and is also created through decarboxylation ("decarbing").

Crude oils, and thus most cannabinoid additives, begin with decarbed cannabis, so heating the product to activate the cannabinoids is not a concern. However, for a new breed of consumers who want edibles that taste like cannabis, there's a developing demand for products made with more traditional cannabis extracts, which are first derived from the plant, and then decarbed to activate their cannabinoids.

To make what's known as ice hash, a producer agitates dry cannabis flour in ice water in a series of buckets with screens of decreasing mesh size. The cannabinoid-rich trichomes freeze and break off from the plant to fall through the screens. "Trichomes are full of cannabinoid and terpenes," Fritz says. "Once you have ice hash, those trichomes, you have to decarboxylate it. We use a long process at the lowest temp possible to retain as many terpenes as we can."

Though the process is labor intensive, the end result is a cannabinoid additive that gives consumers the familiar flavor and odors of cannabis without the bitter byproducts of distillation. For the time being, Fritz offers one hash rosin-based edible alongside four other products made with distillate and isolate. In a production landscape dominated by distillate and isolate, ice hash is proving popular enough that some major edibles producers have begun offering ice hash products.

After all, the legal cannabis market is barely a decade old in its most established states, and consumers are still in the process of figuring out what they want. ■

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How to Manage Food Waste

Redistributing and upcycling food waste can help your bottom line, and reduce global hunger

BY MARY BETH NIERENGARTEN

Businesses and organizations that have pledged to reduce food loss and waste by 50% in their operations by 2030 were honored in October 2022 at a Food Loss and Waste event sponsored by the Environmental Protection Agency (EPA), FDA, and USDA. Designated "2030 Champions" for their public commitment to fulfill the 2015 goal set by EPA and USDA to cut food waste in half by 2030 (as part of the United Nations' 2030 Sustainable Development Goals), the businesses honored included food companies such as Kellogg's, Kroger, General Mills, Tyson, and others.

Cutting food waste is increasingly seen as a critical component of addressing what remains a sorry blight worldwide in 2022: global hunger. This concern is highlighted in the Zero Hunger Challenge set by the United Nations that lists the adaption of all food systems to eliminate loss or waste of food as one of the five key elements to end hunger and eliminate all forms of malnutrition globally. In the U.S., the EPA Food Recovery Hierarchy prioritizes the redistribution of food to hungry people as one of the top preferred strategies that companies can take to prevent and divert wasted food.

The need for this redistribution is uncontested given the staggering number of people in the world who don't have enough food to eat. According to the Food and Agriculture Organization of the United Nations, up to 811 million people worldwide face hunger. In the U.S. alone, the Food Research and Action Center says that 38 million people, or 11.8% of the population, struggle with hunger. Furthermore, these numbers are based on 2020 estimates, numbers that undoubtedly rose during the pandemic, and more are increases expected due to the war in Ukraine.

Comprising between 30% and 40% of the food supply in the U.S., food waste through redistribution and, more recently, upcycling, is an increasingly attractive way for food manufacturers and processors to redirect more of their surplus toward beneficial aims such as hunger relief while at the same time making their processes more efficient and cost effective.

Redistribution is an increasingly attractive way for food manufacturers and processors to redirect more of their surplus toward beneficial aims such as hunger relief while, at the same time, making their processes more efficient and cost effective.

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Among the incentives for companies to participate in food redistribution are laws protecting against liability, technologies to help with the safe distribution of goods from facility to donor site (either directly or via distributors), and expanded policies in the U.S. and abroad that are moving toward restricting food waste.

Easing Safety Risks

Jackie Suggitt, director of capital, innovation, and engagement at ReFED, a nonprofit organization that provides data-driven solutions to eliminate food loss and waste in the U.S. food system, characterizes redistribution of food waste as a "very easy sell" for companies not already participating in sustainability issues. "There is a great business case for just about anyone who is looking at food waste to improve the bottom line financially," she says, citing the cost savings to a company by reducing inefficiencies such as waste.

According to data provided by ReFED, food manufacturers generate among the lowest annual percentage of food waste

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among all the sectors involved in the food supply chain (from producers to investors) given the built-in efficiencies already in place in manufacturing systems; however, current data showing that manufacturing generates about 10.6 million tons of surplus food highlights the fact that more can be done to reduce waste. Of the waste generated, most is due to byproducts and production line waste (91.4%), followed by buyer rejections (6.6%) and unshipped finished product (2%). By product, dairy and eggs make up the largest surplus (41.6%), followed by dry goods (28.8%) and produce (18.4%).

One major challenge for manufacturers in redistributing goods, particularly products requiring refrigeration such as dairy and eggs, is maintaining the cold food chain. "If I'm a producer and want to donate a product from point A to point B, I need to ensure that the right temperatures are maintained throughout the entire distribution of the product," says Suggitt.

To help with this issue, she cites technologies such as time temperature indications (TTIs) that can be attached to packaging or products to prove that the cold chain has been protected throughout the distribution chain. Other technologies, such as modified atmospheric packing (MAP), can help ensure that produce stays fresh and is not compromised during transit.

Although manufacturing companies donating their excess produce is not a new concept, Suggitt sees a shift in more manufacturing and processing companies forming direct relationships with global food banks and redistribution organizations. "The standard model most manufacturing companies have in their minds is that a producer produces a product, it goes to a retail store, and if it doesn't sell, the product gets donated," she says. "The model is not new, but I think it is continuing to improve and expand."

Forming a direct relationship with a donor site, she suggests, eliminates some of the safety risk of the product (particularly those needing refrigeration) by reducing the number of intermediary channels and people handling the product. For example, she underscores the challenge of transparency in ensuring the cold chain has been maintained when moving a product such as milk. Transparency may be easier to maintain with a direct distribution from manufacturer to the food donation site rather than when two or three parties are involved in moving the product.

Feeding America, a nonprofit with a network of 200 food banks and 60,000 partner food pantries and meal programs that directly engage with food processors and producers, underscores the importance of food safety and said it adheres to strict food safety protocols based on guidance from a number of organizations including the Association of Food and Drug Officials (AFDO). "If refrigerated or frozen product is being donated, the cold chain must have remained intact throughout the process of pulling the product and staging it for donation pick-up," according to a statement from the organization. The organization lists additional food safety issues such as damaged or open products, inaccurate food product label information, and cross contamination that may occur when the donations are handled. "Donated product must have consumptions shelf life remaining on the product, and enough time to ensure that the product can be picked up, received into a food bank's or partner food pantry's inventory system, and then made available for charitable agencies to order for neighbors relying on their food distributions," a Feeding America spokesperson tells *Food Quality & Safety*.

If you follow all the safety rules and you believe the donated food to be safe, what happens if the consumer gets sick? On that front, there are quite strong protections for businesses and nonprofits to help distribute that food.

—Emily Broad Leib

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Liability Protection and Tax Incentives

Closely tied to food safety concerns are liability concerns that can act as barriers for manufacturers and processors who may otherwise be willing to participate in redistribution of food, according to Emily Broad Leib, faculty director at the Food Law and Policy Clinic and deputy director of the Center for Health Law and Policy Innovation at Harvard Law School in Boston. "It is really complicated how food safety regulations and fear of liability relate to one another," she says.

Leib emphasizes that food safety issues are about following regulations for food safety—that is, to ensure that food meets the safety standards of health inspectors. Liability issues are quite different and pertain to what happens if a consumer gets sick after

eating redistributed product, even if all safety rules are followed. "If you follow all the safety rules and you believe the donated food to be safe, what happens if the consumer gets sick?" she asks. "On that front, there are quite strong protections for businesses and nonprofits to help distribute that food."

Upcycling

Upcycling is the use of product that normally would be discarded as waste for various reasons, such as product that does not meet the specifications for retail sale, or natural byproducts (such as spent grain from brewing or whey from cheese) of a product from the manufacturing process. These byproducts are taken off the manufacturing line and repurposed as either an animal or human food product for sale.

Participation in upcycling by companies both small and large has exploded over the past couple of years. Unlike redistribution of food waste, upcycling food instead of discarding it as waste provides an additional revenue stream for businesses.

A number of new participants have joined the trend as the process has grown in popularity. A few examples of companies that upcyle are:

- **Barnana** repurposes bananas into banana-based snacks (barnanan.com).
- **Seconds** repurposes pulps and peels from carrots into crackers. (www.seconds.nyc).
- **NetZero**, which uses its proprietary equipment and technology platform to repurpose spent grains from distilleries and breweries into grains for products such as cereals, seasonings, and flour; the company also repurposes eggshells into calcium and collagen protein (netzero.us).

U.S. Donation Resources for Food Manufacturers

1. **Harvard Law School Food Law and Policy Clinic**
   - Food Safety Regulations & Guidance for Food Donations: A Fifty-State Survey of State Practices, 2018; available at chlpi.org.
   - Tax Deduction for Food Donation: A Legal Guide; available at chlpi.org.
   - A Global Food Donation Policy Atlas; available at atlas.foodbanking.org.
2. **U.S. Environmental Protection Agency**
   - Reduce Wasted Food by Feeding Hungry People; available at epa.gov.
3. **ReFED**
   - Scaling Food Recovery and Hunger Relief; available at refed.com.
   - Resources to Help Get Food to the People Who Need It; available at covid.refed.com/resources.
   - Roadmap to 2030: Reducing U.S. Food Waste by 50% and the ReFED Insights Engine; available at refed.org/uploads.

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Federal legislation called the *Bill Emerson Good Samaritan Food Donation Act* provides comprehensive liability protection for food donors and nonprofits as long as they believe the food is safe and was donated in good faith, says Leib. States, she adds, all have a version of a liability protection as well, and protection under any of these state laws can't offer less protection than under the federal law. "Congress has enshrined this protection because they believe that when we have safe, edible food, it should be donated," she says.

Along with strong liability protection, further incentives to participate in donor programs are the federal and state tax incentives given to businesses for redistributing their excess food or waste. Leib underscores the strong federal benefits that allow companies that redistribute excess food to claim a deduction that is larger than the deduction allowed for donating money or other goods.

Under the enhanced tax deduction, companies can claim the lesser of either two times the basis value of the donated food (or the price you paid to acquire the ingredients) or the basis value of the donated food along with half of the food's profit margin. "Companies need to look at how much they spent acquiring the raw ingredients and how much they would sell the product for to come up with these two amounts and then claim the lesser of the two," she says. Additional state-level tax credits are also available in about 10 states, she adds.

A Sound Strategy

Businesses and wnonprofits worldwide are increasingly participating in the redistribution or upcycling of their food waste. Guidance on food safety issues, along with favorable liability protections and tax incentives offer businesses strong incentives to participate, as does the social investment of taking a resource (food waste) and making it available as edible food for the millions of people who go hungry each day.

Making food production and processing more efficient by cutting waste and the cost of managing waste is a sound business strategy, and the social benefit of helping to feed people is good business sense. The U.N. goal of cutting food waste in half by 2030 is well on its way and may be achieved with the participation of more businesses and organizations in this shared venture of better managing food waste. ■

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Pest-Free Dining

Tips to keep rodents out of your restaurant

BY **JENNIFER BRUMFIELD, PHD, BCE**

As temperatures rise and strict pandemic regulations begin to lift, you may notice an uptick in foot traffic entering your restaurant. During these times, customers may not be the only visitors scurrying in for a good meal. The same elements that bring in customers can also, unintentionally, invite in unwelcome guests. If you're not careful, your restaurant can easily become a dining destination for pests.

These tormentors reproduce rapidly, and small populations become full-blown infestations in very little time. Rat feeding habits are destructive, and through their gnawing, defecation, and nesting behaviors, the structure of infested buildings can be compromised. Your customers may also be harmed, because rodents are responsible for the transmission of many diseases. That is why it's important to have an expert complete regular inspection of all areas of your restaurant; however, there are also steps you can implement to help prevent infestation and maintain a rodent-free restaurant.

Food storage. Food for humans is also food for rodents, so it's important to store your goods so that rodents cannot easily access them. Dry goods should be kept in sealed metal or glass containers to prevent contamination. Fruits and vegetables should be stored in refrigerators; if they are in a walk-in refrigerator, they should be at least six inches off the ground and at least 12 inches away from walls to allow easy inspection for rodent evidence and effective placement of rodent control devices. Be sure to check your local regulations on storage requirements. Ensure proper ventilation in your food storage spaces to keep moisture down, which discourages pest activity as well.

Dispose of cardboard. Remove these objects from your kitchen area. The material attracts rodents, which tend to chew them up and use the shredded pieces in their nests.

Seal openings. Due to their body shape, rodents are capable of squeezing through spaces that appear to be much too small for them: Rats can fit through holes the size of a quarter, and mice can fit through ones the size of a dime. All holes should be sealed to help prevent entry and reentry of rodents.

Keep garbage cans and dumpsters clean and secure. Waste from the restaurant is most likely what is attracting rodents. Once they discover food outside, they will go inside to search for more. It is essential to cover trashcans and dumpsters with tight-fitting lids to avoid piquing their appetites. Accessible trash also nourishes a rodent population, allowing their numbers to grow and increasing foraging activity around your building. Keeping trash areas clean is also crucial to keeping any type of exterior bait programs successful.

Maintain a clean workspace. Any scraps, crumbs, or odors will attract unwanted rodent attention. A clean environ-

ment minimizes temptation and reduces the risk of disease. Cleaning up clutter will help prevent pest harborage areas. Rodents look for places to nest and breed, and can multiply rapidly when sufficient food, water, and shelter are available. Do not overlook storage areas and closets where clutter can gather, and clean out boxes, papers, and unused items regularly.

Take care of your landscaping. Regular upkeep, such as mowing and trimming around your restaurant, can help make the outside less inviting to rodents. Remove tall weeds, grass, and ground cover such as ivy, juniper, and liriope from around the exterior to keep rodents from hiding or burrowing near the building, lying in wait to sneak in.

Unfortunately, many times restaurant owners do not realize there is a problem until it is too late. These tricky pests often go unnoticed as they penetrate packaging by either chewing or squeezing through weak points and gaps. Aside from compromising your restaurant's image and reputation, these visitors can contaminate food products. Additionally, these pests can transmit diseases such as E. coli, Salmonella, and Trichinae. Infestations can rapidly spread to different products, eventually harming the customer and your business. It is best to get ahead of a rodent infestation if you can. Being proactive with your pest control measures can save you a lot of headaches and money.

Existing Rodents

Here are five signs that indicate you have an existing rodent issue:

1. **Droppings**: Rodents leave behind a lot of droppings. Seeing these capsule-like pellets around your business should raise a red flag. Rodent droppings are not only unsanitary; they can transmit diseases. Make sure your employees take the appropriate precautions by wearing gloves and an OSHA-approved respirator during the removal process and disinfecting the area with disinfectant spray.
2. **Nests**: Rats and mice build nests from shredded material, like paper, cloth, and cardboard. They are usually found in dark areas like crawl spaces, between walls, and in garbage dumps.
3. **Burrows**: While some rodents prefer to scurry along the roof, others take refuge underground. If that is the case, their nests may be hidden in burrows. Rats and mice can create elaborate underground tunnels or excavated holes.
4. **Grease marks**: Rodents are so dirty that their bodies leave behind grease marks as they travel along walls. Darker grease stains generally indicate heavier activity in that area. Take note of grease marks and inform your pest control professional, who can strategically place rodent traps along frequently traveled paths.
5. **Gnaw marks**: With teeth that never stop growing, rodents can literally take a bite out of your business by causing expensive structural damage. Look for chew marks in walls, insulation, wires, flooring, pallets, and products.
6. **Noises**: Keep an ear out for any scratching, nibbling, or squeaking inside walls, under floorboards, and behind appliances or furniture. Rodents are generally more active at night than during the day, so this is the best time to listen for any noises.
7. **Ammonia smell**: Rodents urinate as they travel, rather than in isolated puddles. This means the routes they frequent can smell extremely unpleasant. The strong scent, which is "ammonia-like," tends to hang around even after the rodents have been removed. Also, the closer you are to the infestation, the more pronounced the smell will be.

Because food products can be an open invitation for unwanted visitors such as mice and rats, it is important to have a pest control expert develop a long-term rodent control plan for you.

Planning

When it comes to keeping rodents out of your restaurant, monitoring and regular sanitation should be part of your maintenance routines. Additionally, educating yourself and your staff on pest management best practices will help with the overall business in the long run. Remain steadfast in monitoring for new or increased pest activity to help keep rodents out and customers in.

Food sitting on shelves for longer periods of time has left many restaurants vulnerable to heightened pest activity, especially rodents. Stored products such as flour, spices, and other dry ingredients are easy for these pests to access, which opens up the potential for thousands of dollars of damage to goods and threatens inspection compliance. Be sure to rotate all food products on a "first in, first out" schedule to ensure that each stock spends as little time on the shelves as possible, and no one stock is sitting on the shelf longer than others of the same item.

Long-Term Planning for Pest Control

Because food products can be an open invitation for unwanted visitors such as mice and rats, it is important to have a pest control expert develop a long-term rodent control plan for you.

This plan should include:

Site inspection. Know where your restaurant stands by ordering a comprehensive inspection of your business. During this stage, experts will be able to identify rodent activity, potential entry points, and attractants.

Sanitation. An expert is professionally trained to offer detailed guidelines and recommendations to help eliminate attractants and maintain a clean environment.

Ongoing monitoring and maintenance. A pest control company will monitor your property on a regular basis and inspect all treatment products to ensure effectiveness and make adjustments as needed.

Baits and traps. If necessary, a combination of traps and select baits can be used to monitor and help control rodent populations.

Do not wait until you already have a rodent infestation. Taking a preventive approach and educating yourself on the best management plan for your restaurant are keys to maintaining a pest-free environment. ■

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Spring and Summer Pest Prevention

These months are peak seasons for the risk of pests in your food facility | BY CINDY MANNES

Warm temperatures spur an uptick in pest activity, making the spring and summer months peak seasons for pest threats. The abundance of food, water, humidity, and places to hide in food processing facilities make them the ideal sanctuary for pest populations, which means it's imperative that proper pest control be a top priority for food processing facility managers.

Threats

Understanding the pests that frequently invade food processing facilities and the threats they pose can help facility managers identify and address any issues that may arise before an infestation has a chance to take hold. Food processing facilities present the perfect conditions for various pests, including rodents, flies, cockroaches, and stored product pests, such as Indian meal moths and merchant grain beetles to thrive thanks to an abundance of food, shelter, and moisture. In the spring and summer, food processing facility structures are also susceptible to termites.

These pests can cause serious issues for food processors because they contaminate food with their droppings and are known to spread many diseases to humans, including *E. coli* and *Salmonella*. Rodents are also known for chewing through wiring, which can result in electrical fires and damage to essential machinery. While pantry pests do not transmit disease, they can still infest ingredients, resulting in the contamination of food products made in these facilities. The main threat posed by termites is their ability to cause extensive property damage. They cause $5 billion in property damage in the United States each year, which can be extremely costly to your business.

Pest Prevention

The most important step managers can take to ensure their facility is protected from pest threats is partnering with a licensed pest control company to perform regular inspections and implement an integrated pest management (IPM) plan. IPM is a holistic and customized approach to pest control that comprises three steps: inspection, identification, and treatment to help ensure that commercial facilities are clean, compliant, and pest free. By enlisting the help of a professional, you can rest assured, knowing your facility is well protected from pests year-round, allowing you to instead focus your time on delivering quality products safely and efficiently.

In addition to recommending that mangers partner with a professional, the National Pest Management Association recommends that they add the following steps to their maintenance checklists to protect their facilities from pests:

- Ensure employee kitchens and eating areas are clean by wiping down countertops and sweeping floors to remove crumbs and residue from spills;
- Vacuum and clean all areas regularly, including offices, hallways, lobbies, and public bathrooms;
- Routinely check under sinks and machinery for areas of moisture, and repair any leaky pipes or clogged drains;
- Store all food products in sealed containers, and organize empty boxes to prevent harborage areas;
- Keep trash in sealed containers inside the building and remove from the facility regularly. Ensure dumpsters are far away from any building entry points;
- Inspect the exterior of the building to ensure there are no entry points; pay close attention to areas where pipes and utilities enter the building, and seal any gaps or cracks in the foundation;
- Install door sweeps on exterior doors to seal the gap between the floor and the door where pests can enter;
- Remove debris from gutters and direct water away from the building through properly functioning downspouts, gutters, and splash blocks; and
- Ensure that grounds surrounding the facility are properly maintained, because overgrown vegetation can attract pests to the property.

The spring and summer seasons are exciting times of year that can quickly be ruined by a pest infestation. Help keep your employees and products safe this season and year-round by following these tips and working with a trained pest professional. ■

Mannes is senior vice president of public affairs for the National Pest Management Association (NPMA).

Food Defense and Emerging Threats

Do you know the risks?

BY **NEIL COOLE**

Since the onset of the pandemic and the subsequent disruptions felt throughout the world, the food, beverage, and retail industries have responded to this challenge admirably by ensuring that shelves were stocked and people could continue to enjoy the food and drink they love, from the comfort of their homes. The industry has also embraced innovation and technologies like never before, not only to meet the growing demand from regulations and consumers but also to deliver increased cost savings brought about by process improvements arising from the use of smart devices, autonomous robots, and sensors.

While this digital transformation has certainly supported some great examples of positive innovation and disruption throughout the industry, it has also highlighted the pressing need to connect the dots between food safety and information security. We have all seen the headlines over the past few years about food, beverage, and retail organizations falling victim to a cybersecurity attack that takes their systems offline, preventing them from functioning, and holds them ransom for a Bitcoin payment.

How Does Food Safety Intersect with Cybersecurity?

This is a question that is frequently asked and understandable throughout the industry. The short answer? Everything.

Consider the consequences a cybersecurity attack on an organization: The attacker has access to everything within the organization that is connected by technology, including HACCP controls, processing temperatures, metal detectors, product labels, and expiration dates. This is now a real food safety risk. The attackers' intention may not always be economically motivated, and if the organization is unaware of the attack, then allergens can be easily removed from a label, expiration dates altered, critical control points adjusted, and the list goes on. Let us also consider the regulatory consequences to an organization from the loss of control of their operating systems; it would be impossible to access any records or reports if FDA or any other agency requires access to them.

How to Improve Your Food Defense Plans

The first step is understanding the context of food defense, and how it—directly and indirectly—affects all parts of an organization, including the physical security of a facility, the vetting of staff and visitors, IT infrastructure and use of technologies, purchasing and procurement decisions through to food technology, and process engineering. When most organizations introduce their Threat Assessment and Critical Control Points (TACCP) team, who are responsible for their food defense program and plans, it is typically made up of only their food safety and quality colleagues. The challenge is that food defense goes beyond the safety

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Testing

How to Simplify Mycotoxin Testing

Newer testing technologies for these toxins can be helpful amidst the impact of the "Great Resignation" on the food industry | BY PATRICIA JACKSON

The Great Resignation began sweeping through U.S. workplaces in 2021, resulting in nearly 48 million workers quitting their jobs, according to an April 2022 article in Mashable. Surveys of workers revealed that their top reasons for leaving were better pay, improved benefits, a new career direction, or a better working environment. Nearly 30% of the U.S. workforce was impacted, and the trend continues into 2022 with no clear indication of when, or how, it might ease, according to 2022 research from Statista.

In addition, challenges involving supply chains, transportation, and price pressures are forcing food manufacturers to develop creative solutions that not only serve their immediate production needs but enable greater resiliency in the face of future challenges.

Food safety testing has often followed a predictable pattern: Regulatory, industry, and trade drivers may influence where and how testing takes place, but food manufacturers have long been proactive in developing strategic and tactical approaches to ensuring that food and beverages are nutritious and safe to consume. A closer look at the role that food safety holds across the food manufacturing life cycle can help identify areas in which small changes can significantly improve operational efficiency and worker satisfaction while maintaining the highest product quality and safety standards.

When a worker shortage and employee retention are hurting production as they are today, food processors may want to take a harder look at food safety testing technologies and methods that are easier on the bottom line and safer and easier for new workers to use.

Identifying Mycotoxin Contamination

Produced by naturally occurring soilborne molds, mycotoxins are highly toxic metabolites found in most field, orchard, and vine-grown crops (see Table 1, p. 35). Heat stable and persistent, mycotoxins remain on crops after they've been harvested, stored, and processed. In fact, the United Nations Food and Agriculture Organization (FAO) has estimated that 25% of the world's food crops are contaminated with mycotoxins. Recent studies suggest that contamination is more complex and involves the presence of multiple mycotoxins in a single raw material.

Aflatoxins are among the most widely known and highly regulated mycotoxins. Produced by *Aspergillus flavus* and *A. parasiticus* molds, aflatoxin B1 is classified as a Group I carcinogen by the International Agency for Research on Cancer (IARC). Additional mycotoxins of food safety importance include fumonisin, ochratoxin A, patulin, ergot alkaloids, alternaria, deoxynivalenol (DON), nivalenol, zearalenone, and the combination of T-2 and HT-2. Each mycotoxin, or family of toxins, carries a unique toxicity profile, and regulatory guidelines are reflective of the intended use for the product. For example, the EU regulatory limit for aflatoxin M1 in milk products is 0.05 parts per billion (ppb); however, milk used to manufacture infant formula must follow a much stricter limit of 0.025 ppb.

The type or level of mycotoxin contamination varies with each crop season; therefore, having a process in place for screening can help identify high-risk raw materials, suppliers, and geographic regions. Severe weather patterns, warm and humid storage conditions, or even late crop planting may contribute to the severity of mycotoxin contamination.

Once a mold begins producing toxin, the contamination may remain highly localized to a very small area within a crop field or in a "hot spot" inside a storage bin. A single grain or nut kernel may constitute 100% of the aflatoxin contamination in each lot or shipment, for example, indicating the need for thorough inspection and careful sampling, especially at harvest.

In regions where environmental conditions (such as high heat or humidity) are favorable to mold growth, vigilance is key. Routine "upstream" monitoring is common, helping quality managers to identify and reject unsafe raw materials before they are allowed on site for storage or processing. Once mycotoxins enter the processing stream, the risks of cross contamination or further toxin production by the resident mold are always present.

Table 1. Mycotoxins commonly detected in food and agricultural products.

MYCOTOXINS	AFLATOXINS B1, B2, G1, G2, M1	DEOXYNIVALENOL	FUMONISINS B1, B2, B3	OCHRATOXIN A
Selected Molds that Produce Toxins	*Aspergillus flavus, Aspergillus parasiticus*	*Fusarium graminearum*	*Fusarium verticillioides*	*Aspergillus ochraceus, Penicillium verrucosum*
Foods Susceptible to Contamination	Maize, groundnuts, nuts, cottonseed, copra, spices, milk, wheat, oats, barley, and rice.	Maize, wheat, barley, malted barley, and oats.	Maize and other cereal grains	Maize, wheat, barley, beer, oats, sorghum, dried vine fruits, wine, coffee, and cocoa.
Health Effects	• Liver cancer and damage. • Immunosuppression. • Decreased milk and egg production.	• Damage to digestive tract, bone marrow, spleen, reproductive organs. • Weight loss, vomiting, and feed refusal.	• Cancer in rats. • Brain decay in horses. • Lung congestion in pigs • Human esophageal cancer.	• Kidney damage and cancer. • Immunosuppression • Skin and oral lesions in livestock and humans. • Alimentary toxic aleukia in humans. • Considered 10x more toxic than DON. • Negatively impacts reproduction, fetal development, and the health of newborns • Causes feminization in animals at 1 ppm.

Table 2. Lateral flow strip tests have come a long way and are highly sensitive, as these data from a 10-minute multi-toxin test procedure show.

	LIMIT OF DETECTION	TEST RANGE
Aflatoxins (B1, B2, G1 & G2)	2.0 ppb	0-300 ppb
Fumonisin (B1, B2 & B3)	0.2 ppm	0-100 ppm
Deoxynivalenol (DON)	0.25 ppm	0-16 ppm
Ochratoxin	2.0 ppb	0-30 ppb
Zearalenone	0.1 ppm	0-5 ppm
T-2/HT-2	10 ppb	0-800 ppb

Food recalls or litigation due to mycotoxin contamination can be costly; the average recall costs the food industry between $5 and $10 million/incident, including insurance claims, legal representation, brand, and immediate and long-term business losses. The upstream detection of mycotoxins in raw materials also enables food manufacturers to find alternative markets for an ingredient that may not be suitable for their application but may be just fine for animal feed formulation.

Advancing Testing Technologies

The Food Safety Modernization Act (FSMA) generated an upsurge in the use of rapid testing technologies. FSMA's focus on prevention has enabled more food companies to better understand where mycotoxins come from and to manage the mycotoxin contamination of raw materials before they reach the processing facility. Early detection, combined with the unique challenges of our shifting workforce, creates the need for technologies that are simple enough to be used by staff with or without technical training or expertise. Adopting simpler test procedures that don't require organic solvents and that are helped by automated data management are key factors that improve productivity, worker satisfaction, and safety, while giving the food manufacturer a leg up in meeting their own sustainability objectives.

Traditional mycotoxin testing methods are showing their age for a number of basic reasons. Some call for organic solvents, such as methanol, to extract toxins for analysis, which is what makes water-based test methods very attractive. Other methods, like ELISA, rely on employees handling the actual toxins and hand pipetting prior to sample analysis, risking exposure. Proper storage and disposal of unused testing supplies is also a consideration.

Fewer steps reduce error, bringing greater accuracy and better overall performance to screening tests.

As we know, not all mycotoxin testing takes place in the field. Sometimes it's necessary to send samples for confirmatory testing to an analytical laboratory where trained lab technicians test for mycotoxins on analytical instrumentation including high performance liquid chromatography (HPLC), ultraperformance liquid chromatography (UPLC) and liquid chromatography-mass spectrometry/mass spectrometry (LC-MS/MS). These techniques can be automated to detect and quantify as many as one hundred mycotoxins in a single run. Effective onboarding and retention of new laboratory staff members may require investing in up-to-date instruments or methods, exploring service plans, or upgrading data handling software. Investments like these create an environment where employees are encouraged to learn, grow, work, and hopefully build a career.

Building for the future is always a good plan. There is an incredible opportunity amid the Great Resignation to pause and take a closer look at the technologies we use for food safety testing, and how they impact the employee experience. When our teams and the testing technologies they depend on work well together, food safety testing can deliver the most value. ■

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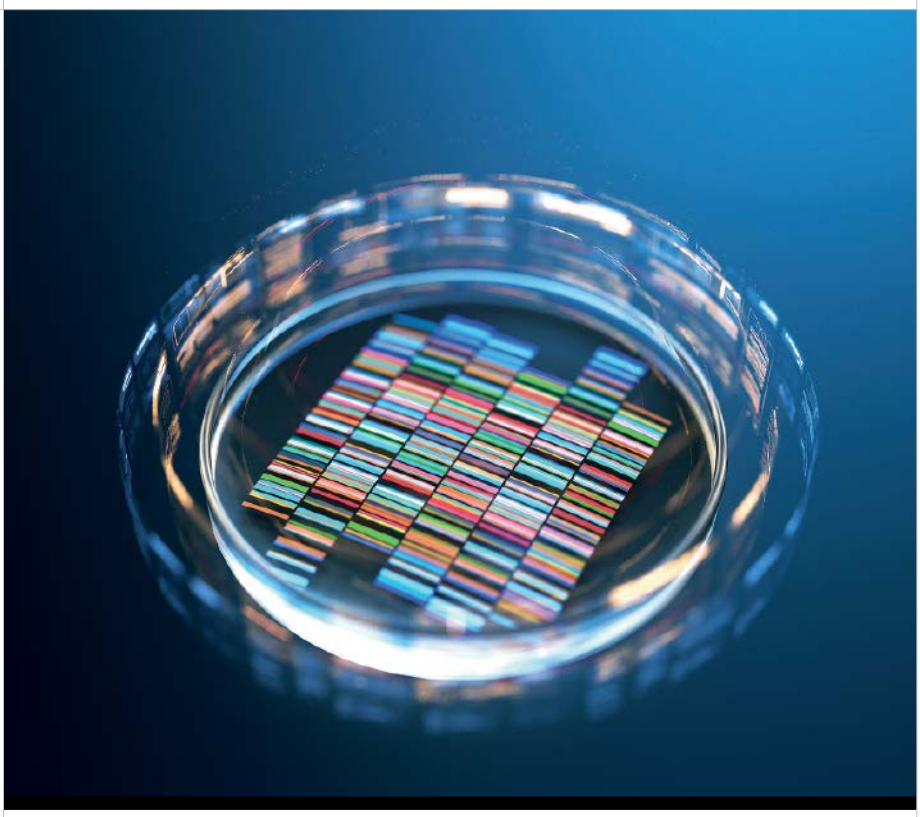
In The Lab



How Advances in Food Testing Technology Have Helped Fight COVID-19

Several technologies developed for the food industry were applied and adapted by SARS-CoV-2 testing laboratories

BY **ANDREW LIN, PHD**

Over my two-decade career as a food microbiologist, I have seen a dramatic shift in the methods used to detect foodborne pathogens—from conventional microbiology techniques to molecular methods. Developments in these molecular technologies have led to wider access and shorter testing times, allowing public health agencies and food manufacturers to ensure a safer food supply.

Having started my career at FDA, I have seen firsthand the significance of rapid methods in minimizing the scale and impact of foodborne outbreaks. Access to in-house molecular testing has helped manufacturers monitor the bacterial load in their facilities and allowed them to perform environmental mapping to identify areas in which to focus sanitation efforts. As part of a quality assurance program, increased testing for microorganisms has helped companies spot trends and intervene before issues grow out of control. The passage of the Food Safety Modernization Act (FSMA), which declared that environmental monitoring and finished product testing are a part of a robust food safety system, is an open endorsement and recognition of the benefits of testing by public health agencies.

With the recognition of the importance of pathogen detection, molecular methods have continued to be developed to improve testing. Initially, immunological and nucleic acid amplification testing methods were developed for more rapid, sensitive, and specific results, but these methods were mostly used for screening for the presence or absence of pathogens. Additional tests were needed to confirm the presence of potential pathogens and to characterize the microorganisms more deeply.

Technologies such as pulsed field gel electrophoresis (PFGE), multi-locus variable-number tandem repeat analysis (MLVA), multi-locus sequence typing (MLST), and whole-genome sequencing (WGS) provide higher resolution in distinguishing strains of bacteria to match food, clinical, and environmental isolates in outbreak investigations, to track pathogens within a facility, and to identify sources of contamination. Taken together, many techniques have been useful in ensuring food safety, but biotech companies that develop tests still strive for the holy grail: a rapid, low-cost, sensitive, and specific method for detection with strain-level resolution that is easy to use and does not require extensive expertise and training for those performing the test or analyzing data.

Next Generation Sequencing

One promising candidate to achieve these goals is next generation sequencing (NGS). With the establishment of GenomeTrakr in 2014 and PulseNet's adoption of WGS in 2016, genomic data has been widely adopted as a common language across a network of government, academic, and private industry laboratories. The availability and accessibility of high-quality, genome-wide data makes NGS incredibly powerful in strain-level resolution of microorganisms for many users. An additional advantage of NGS is the generation

of millions of sequencing reads to provide redundancy in the detection of multiple targets, which increases accuracy and minimizes false positive and false negative results.

While NGS can provide these benefits, sequencing workflows can be complex and laborious, requiring many hands-on steps in sample preparation, amplification, library preparation, and loading sequencing flow cells. These workflows are not easily performed by novices; they require expertise and training, both in performing assays and in interpreting data. Many experts had been skeptical about the possibility that NGS could ever be used for routine detection and characterization of pathogens in foods because of these challenges. These predictions may have proven true if not for the application of automated robotic systems and data analysis pipelines to simplify NGS. Minimally trained technicians can load an automated NGS platform, walk away, and view curated results after the analyses are done. Analytical software can interpret NGS data to simply provide answers to the questions asked, without requiring the user to have a deep understanding of bioinformatics and genome assemblies.

Fully automated sequencing platforms are now in heavy use and battle tested in the food industry. Automated NGS assays have been approved by the Association of Analytical Chemists (AOAC) and USDA's National Poultry Improvement Plan (NPIP). In addition, the technology is becoming prevalent in the poultry industry, providing detection, speciation, serotyping, and similarity analyses for environmental, in-process, and finished goods testing. These automated NGS systems provide high-throughput NGS testing to accommodate hundreds of samples, improve robustness by reducing user errors, increase consistency, and free up the technician's time for other duties.

Similarities Between Food Testing and COVID-19 Testing

The global COVID-19 pandemic has faced many of the same issues that the food industry faces with pathogen testing. Assays for detecting SARS-CoV-2 needed to be rapid, sensitive, and accurate, similar to food pathogen detection assays. Time to results, important for foods with limited shelf lives, for which results are needed before releasing goods to markets, are now important for SARS-CoV-2 testing, to prevent release of infectious individuals into susceptible populations. Highly sensitive assays with ultra-low limits of detection, important for food testing, in which illness can occur when even a single cell is ingested and multiplies, is now important for SARS-CoV-2 testing, because individuals in early or late stages of infection with low viral loads but could still infect others.

Accuracy is of paramount importance, because false positive and false negative results can be disastrous. In food testing, false positive results may cause economic loss when uncontaminated foods are recalled, and false negative results may allow unsafe foods to reach the public. Similarly, for SARS-CoV-2 testing, false positive results may lead to uninfected individuals being mistakenly quarantined with infected patients, and false negative results may increase the chances of SARS-CoV-2 carriers infecting others.

Just as NGS provided solutions to critical challenges in food pathogen testing, it has also been contributing to unmet needs in SARS-CoV-2 testing. The world recognized the need to better track and trace SARS-CoV-2 through the human population when scientists observed that the virus mutated and was able to spread more easily. Thus, genomic sequencing was integral for identifying new variants of concern (VOC) and variants of interest (VOI), identifying hotspots of spread to mitigate outbreaks and providing crucial information in developing diagnostics and therapeutics, among other vital functions, so that scientists could better monitor and track the evolution of the virus. Global and national SARS-CoV-2 genomic repositories began to grow—e.g., Global Initiative on Sharing Avian Influenza Data (GISAID) and National Center for Biotechnology Information (NCBI) and, similar to GenomTrackr and PulseNet, allowed for communal access to the data in hopes that answers to fighting this virus might lie within the genomic code.

Concerns over the complexity, hands-on time, training, and expertise required to perform and analyze data that the food testing industry faced were also concerns for SARS-CoV-2 testing. In fact, the Wall Street Journal reported that 58% of the clinical laboratories surveyed struggled with staffing, in part because of the education and training needed to perform laboratory analyses. Here, again, the solution applied in food testing—the application of automated robotic systems—provided the solution to the challenges facing public health labs. Automated robotic systems reduced both the workload and the expertise and training needed, making NGS possible for these short-staffed and overworked public health laboratories.

Industry Intersections

Food microbiologists and clinical diagnostics laboratories have aimed to answer the same basic question: Is there an infectious agent present that can be harmful to people? For years, researchers have been applying advances in biotechnology to improve methods for answering that question. Now, we strive to answer that question with more and more resolution: How harmful is it? Is it related to other harmful pathogens? Where did it come from? Is it getting more dangerous with time?

Having worked the past couple of years to make NGS solutions for the food testing market, I have witnessed the power that higher-level resolution NGS data provides to answer these questions, as well as the challenges involved in making this technology more widely available and accessible. Public health labs, having seen these same benefits, are now striving to expand WGS analysis of SARS-CoV-2 specimens. Fortunately, the roadmap of applying automated robotic systems to NGS, already proven in the food testing industry, has been easily applied and quickly adopted by SARS-CoV-2 testing laboratories.

This technology—first developed in food testing laboratories—is now in use in public health laboratories nationwide, giving scientists crucial insights to fight this global pandemic. In return, advances in streamlining SARS-CoV-2 NGS workflows are now being explored to improve food pathogen NGS methods, further demonstrating the cumulative benefits of applying technological advances across industries. ■

Lin is a staff scientist at Clear Labs, a provider of automated, next-generation sequencing platforms for diagnostics. Reach him at andrew.lin@clearlabs.com.

Automated Food Manufacturing

How a certified system integrator can help you upgrade your facility's technology

BY **KEITH MANDACHIT, PE**

Since the 1940s, when food manufacturing was significantly slowed in favor of war production, technological innovations have tremendously increased the speed, efficiency, quality, and production of food. New technologies continue to hit the industry on a regular basis.

But what happens if a wave of new technology has not quite hit your production line? Aging equipment in food manufacturing is often commonplace, as production managers and operators too often embrace the "if it isn't broke, don't fix it" line of thinking. Charged with increasing output and amplifying regulation but with no budget to adjust either, many food manufacturing plants struggle to keep up with demand, even as their equipment ages.

Strategy

Among the list of things that keep most manufacturers up at night is the need to make upgrades a priority; that concern ranks at the same level as shipping, safety, macroeconomics, and competition, according to a 2018 article in *Businessing Magazine*. The fact is that keeping a strategic lens on upgrades and proactively asserting the necessity to make changes before a catastrophic failure within a food plant threatens to shut down operations is the wiser bet to make as a manufacturing leader; we've seen it in action more than once or twice. Let's face it, technology moves at warp speed, so the need to upgrade is ever present in order to keep up with the pace of business today.

A Case Study in Automated Control Systems

Industrial control systems integrator Huffman Engineering partnered with a large food manufacturing plant to help design and automate control of their corn milling process, upgrading the control system along the way. The biggest plan for this project included a mechanism to increase mill throughput by way of two pieces of groundbreaking equipment, including a vertical degerminator. But they didn't stop there: This particular food manufacturer had an eye to the future and knew enough to plan ahead. Preparing the control system for additional equipment allowed for future expansion without the additional cost of re-programming the control system down the road. This way, when budget dollars were freed up and allowed for these next steps, the re-engineered system would decrease downtime and provide a smooth transition to strong production.

This is how they did it.

A control system upgrade for the equipment provided controls and system integration for new and repurposed equipment as part of the upgrade. This large food processing plant installed two new pieces of equipment in the corn mill to increase capacity and efficiency in the corn milling operation.

Engineers with extensive expertise can be innovative in creating solutions that allow new equipment to sit alongside existing transfer equipment (only slightly modified) to facilitate the increased throughput in an operation (in this case, corn milling). Throughout this particular project, the electrical installation of equipment was integrated to both the programmable logic controller (PLC) and

human machine interface (HMI) to talk to the automated start and stop sequences and load-on and load-off conditions. Critical alarms for the new and modified equipment were included in the end of the production process. These technical integrations allowed operators in the manufacturing plant to visually sound alarms when processing wasn't going as smoothly as intended, calling their attention to systems that might need to be fixed.

As with many food processing customers, key performance indicators ultimately tie back to greater efficiency, less downtime, trust, and innovative sharing of ideas along the way. No upgrade comes without a few bumps along the way, but valuable lessons learned can now be passed on to other teams to make sure the transfer of knowledge can help additional projects to run more smoothly.

What we do know is that a trusted partnership with open communication and teammates willing to do the heavy lifting will get the job done every time. In our manufacturing experience, here are just a few tips for upgrading automation at food plants that we find lead to success.

1. **Collaborative control.** Being a valuable teammate is crucial to success in automation, and leaving egos at the door must be step one. When it comes to automation, it's often not adequate to work only with operators, IT professionals, or safety experts on complex systems requiring a multitude of steps. A collaborative system integrator, specifically one certified in machine safety, should be adept at trying to simplify the complex, allow disparate systems to talk to one another, and protect the safety of the operators. Specifically, an integrator skilled in bringing people together to find a solution is helpful as well. For example, many make the mistake of assuming that operators are also controllers. While incredibly talented in their own right, no one should assume all operators also understand how to apply controls. Likewise, control integrators need to listen to and learn from the operators, understanding their end goal and how their daily job roles will be impacted by any changes proposed. Collaboration among all the talent in the room always makes a better product.

Submersion in the environment allows engineers to look at all aspects of a machine and environment to produce the best, safest results.

2. **Open communication.** Communication is key to success. Conversation should be initiated to ensure that everyone is on the same page when it comes to expectations and the end result of a project. Throughout the design, build, and implementation stages, topics should include the scope of what is working, what is not, and what success looks like to the customer. Alongside great communication, documentation of that communication and buy-in is also vital—especially in highly regulated industries such as food production. Version control and documentation allows for quality standards to be met and proven throughout an engineering project. Even as projects are completed, making sure operators understand the changes and any new modes of operation, along with detailed documentation, will ensure that everyone from operations to IT, safety, and management feels that the project is a success.
3. **Safety first.** With any food or beverage production line, food quality standards are imperative. Ensuring that an integrator is well versed in those standards must be a priority. At the same time, attention to the safety of the consumable product should always be paired with the need to ensure that the manufacturing floor and environment are properly equipped with safety features. Often, safety controls (hardware) are "used" but installed improperly in conjunction with other elements of the production line, be they human or machine. Having a certified machine safety expert on hand ensures the safety of not only the equipment operation, but also that of your most precious resource—your employees.
4. **Onsite visits cannot be replaced.** If we have learned nothing else during the pandemic, we have learned the value of technology, remote learning, and communication. When it comes to system design, though, while the value of being able to work with systems and equipment on site can be enhanced with pictures, videos, or virtual calls, they should not be seen as replacements. Submersion in the environment allows engineers to look at all aspects of a machine and environment to produce the best, safest results. Pictures and other media sources should be used primarily for documentation and as reminders of a specific piece of technology, because engineers juggle multiple job sites. Expedient and efficient success comes with preparation, and the very best kind is on site so that engineers can get a feel for every aspect of the environment and modify designs accordingly, with all pertinent information.

Success

As food manufacturers delve into the world of upgrading existing and aging equipment, their best bet is to consult with a certified system integrator. The benefits of getting it right the first time, with an eye toward growth into the future, will define success for a company. With cyber security concerns, food shortages, and environmental and climate factors impacting agriculture around the world, now is the time to upgrade manufacturing facilities. The race to get ahead in food manufacturing, with an eye laser focused on high quality, expedient and efficient production, isn't slowing down.

To really propel a company into the future and maintain excellence, rely on the expertise of certified control system integrators with knowledge of hardware, software, manufacturing processes, and FDA regulations. Subject matter experts in design, development, installation, and education should not be underutilized, and prioritizing upgraded facilities now will pay off in the end.

They may even help you sleep better at night. ■

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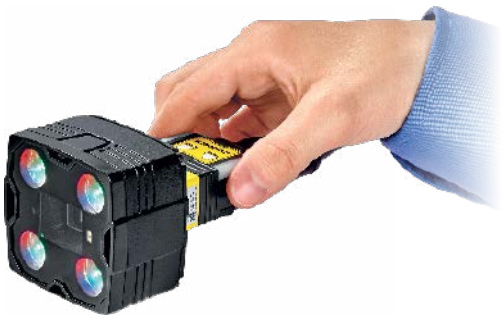
NEW PRODUCTS



Vision System

Cognex Corporation has released the In-Sight 2800 series vision system. In-Sight's EasyBuilder interface guides users through the application development process step-by-step. The combination of deep learning and traditional vision tools gives users the flexibility to solve a broad range of inspection applications; operators select the tool designed to deliver the highest possible accuracy for their task. Tools can be used individually for simple jobs or chained together for more complex logic sequences. The toolset also includes ViDi EL Classify. Using as few as five images, this powerful classifying tool can be trained to identify and sort defects into different categories and identify parts with variation. The system also offers a wide variety of accessories and field-changeable components to help users adapt to changes. **Cognex, cognex.com/in-sight-2800.**

Food-Grade Hydraulic Fluid

Renewable Lubricants introduces Bio-Food Grade Hydraulic Fluids, environmentally friendly food-grade hydraulic fluids. The fluids are multifunctional, biosynthetic lubricants that contain ingredients that are classified GRAS, making them good for applications with incidental food contact in and around food processing equipment areas. They may be used on food processing equipment as a protective anti-rust film, as a release agent on gaskets or seals of tank closures, and as a lubricant for machine parts and equipment in locations in which there is a potential exposure of the lubricated part to food. Available in 5-gallon pails, 55-gallon drums, 275- and 330-gallon totes, and bulk, the fluids are readily biodegradable, renewable, more fire resistant, and EPA and ISO 1400 compliant. These patented biobased hydraulic fluids are formulated to perform in high- and low-pressure hydraulic systems that require anti-wear, anti-rust, anti-oxidation, anti-foam, and demulisibility properties. **Renewable Lubricants, Inc., info@renewablelube.com, renewablelube.com.**

Industrial Control System

The latest enhancement to the PowerFlex 6000T drive now accepts up to 13.8 kV primary voltage, nearly twice the input voltage, in a footprint that is only 2310...3010 mm (7.58...9.87 feet) wide. The drive can be applied to 3...4.16 kV applications with high voltage input built in. Additionally, high-voltage feeds can be directly connected to the drive from the main distribution line without additional step-down transformer or substation equipment. The compact A-Frame design works for new and retrofit industrial applications in IEC markets where industrial space is a premium, specifically for high-voltage primary installations. The drive is engineered for managing motor control for demanding applications in heavy industries. **Rockwell Automation, rockwellautomation.com.**

Metal Detector

The Interceptor DF metal detector inspects low profile, high value foods vertically and horizontally, concurrently. The metal detector uses a dual electromagnetic system to help eradicate small metal contaminants that are hard to identify with a conventional single-plane detector. The detector can be customized to different aperture sizes and uses multiple coil sets to drive the electromagnetic fields in different directions for optimum detection sensitivity. It can also be used to inspect small, thin packages of conductive products such as cheese and deli meats. To ensure ease of use across mixed product lines, the detector has the capability to learn and recall the signature of any given product with just one pass. It also uses automatic product tracking and data capture

software; these electronic records can then be viewed, filtered, and exported. **Fortress Technology, fortresstechnology.com.**

(Continued on p. 42)

Now serving a fresh new website

We've updated our website to make it easy to reach must-read information that impacts food safety professionals.

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Food Quality & Safety
FARM TO FORK SAFETY

WILEY

(Continued from p. 40)

Poultry Processor Trays

TekniPlex Consumer Products has launched a line of 100% PET processor trays offering premium product display while addressing common packaging challenges prevalent in the poultry industry, particularly in higher-end products such as those labeled organic, non-GMO or sustainably sourced. The trays are made of 100% PET and contain up to 50% postindustrial recycled content. They also are 100% recyclable. The trays are designed to survive the rigors of the case-ready environment and are shatter-resistant even in harsh, cold environments. During a year-long production campaign with a poultry processor, the trays showed no signs of cracking or breakage throughout the supply chain. The trays use a technique called hidden rim technology, which prevents the overwrap film from tearing and creates freight and shipping efficiencies. Because the trays pack denser, customers can

increase shipping volume per truck, reducing the number of truck trips needed. In the poultry test example mentioned above, the rim technology also yielded a 30% reduction in the number of worker hours needed to unload trucks. They are available in clear (natural), translucent, and opaque colors. **TekniPlex Consumer Products, tekni-plex.com.**

Droplet Size Analyzer

Bruker Corporation has launched the minispec Droplet Size Analyzer 2.0 in its minispec nuclear magnetic resonance (NMR) portfolio. Based on time domain (TD)-NMR technology, this launch offers a non-invasive method to support texture and stability analysis in food applications. The analyzer offers improved droplet size distribution analysis in food matrices, giving manufacturers important information about the shelf life and textural properties of their products. New parameters have been added for emulsions with unimodal distribution where a lognormal distribution is assumed. In the new multimodal fitting, a regularization technique is employed without assuming any shape for the distribution. **Bruker Corporation, bruker.com.**

Remote Monitoring System

The Sensert remote monitoring and alert system uses your existing sensors. A variety of sensors can be hardwired directly to the base unit or wirelessly connected via the remote I/O for true wireless, remote, online capability. Sensor data is monitored in real time and alerts are triggered based on customizable thresholds, configurable through a mobile app or web portal. Each channel can be configured for a high and low threshold value as well as custom alerts. The system works with any commercially available 0-20 milliamp, 4-20 milliamp, 0-5 volt, or 0-10 volt sensors. It is engineered to monitor sensors in critical processes and provide alerts to the user in numerous environments. It can monitor a vast range of conditions including level, temperature, pressure, flow, and current, as well as vibration and presence of voltage. **ATC Diversified Electronics, sensertio.com.**

Avian Influenza Disinfection Solution

PurOne has EPA-registered efficacy against every major animal pathogen, including a 1-minute kill claim for the Avian Influenza Virus. It is also biodegradable with the lowest toxicity rating, a 0/0/0 HMIS, and a neutral pH. The primary ingredient in PurOne is NaDCC, which creates a natural HOCl solution when mixed with water. The tablet concentrate ensures accurate dilution to the correct strength for cleaning and disinfecting interior or exterior surfaces, floors, and equipment. PurOne requires minimal PPE and can be applied using microfiber cloths and mops or EvaClean's disposable wipes system. Because PurOne is a versatile broad-spectrum chemistry, it can replace nearly a dozen other cleaning, disinfecting, and deodorizing products that are unnecessary or unsafe. This approach not only helps reduce chemical exposure but simplifies procedures and elevates sustainability. **Evaclean, evaclean.com**.

of the product and requires collaboration throughout departments within the organization, including security, human resources, operations, procurement, IT, and marketing.

Your Food Defense Team

You wouldn't phone your IT colleagues to discuss a food safety risk or regulatory requirement. In the same way, the food safety and quality department(s) are not fielding calls from colleagues to discuss the cybersecurity features of a wireless smart device; however, envision the potential risks and vulnerabilities to an organization in which the food safety and quality department(s) has introduced new smart devices to improve pest control measures, such as a wireless bait box or wireless sensor directly connected to the organization's central operating systems. This is one real-life example of a food manufacturer that was affected by a cybersecurity attack; the attacker sat in a nearby parking lot and searched for wireless connected devices without sufficient security protection to gain access to an organization and its systems. Would your current food defense team be able to address a risk like that? Knowledge is key to an effective food defense program, and the shared knowledge and experience of a diverse team will empower the organization to protect itself from the growing number of cybersecurity attacks on the food, beverage, and retail industries.

As the food, beverage, and retail industries continue to innovate and embrace new technologies, they must also keep an eye on emerging industry threats.

Emerging Threats

As the food, beverage, and retail industries continue to innovate and embrace new technologies, they must also keep an eye on emerging industry threats, in particular the creative approaches that attackers are adopting to successfully attack food, beverage, and retail organizations. Food safety and quality professionals should know the importance of food defense, what it means, and why it is an essential element of an effective food safety management system. ■

Coole is director of Americas, food and retail supply chain, at BSI, a standards and regulations organization based in the U.K. Reach him at neil.coole@bsigroup.com. To access BSI's PAS 96:2017, "Guide to Protecting and Defending Food and Drink from Deliberate Attack," visit bsigroup.com.

SCIENTIFIC FINDINGS

For access to the complete journal articles mentioned below, go to "Food Science Research" in the June/July 2022 issue at foodqualityandsafety.com, or type the headline of the requested article in the website's search box.

Innovations in 3-D Printing for the Food Sector

3-D printing is a neoteric technology that can make existing food value chains client-desirable and sustainable by providing on-demand food production, enabling automated food personalization, and minimizing food wastage. It can address food scarcity in countries where affordable and fresh ingredients are inaccessible by integrating nutrient-rich substrates, probiotics, bioactive compounds, and functional ingredients into complex fabricated foods. The global food processing industries are endorsing 3-D food printing technology to make production more efficient and self-reliant, anticipating a compound annual growth rate of approximately 55%. This review paper provides a holistic outlook of the technology beginning with the various techniques utilized for 3-D printing and printers available in the market. Substantial raw ingredients used for printing and the components in the future precision and personalized foods are discussed. The pros and cons of this technology along with its potential applications and future perspectives of 3-D food printing are also evaluated. ***International Journal of Food Science and Technology*. 2022; 57:3326-3332.**

Improving Freezing Time and Quality of Frozen Fruits and Vegetables through Ultrasound

Freezing is widely used for the preservation of fruits and vegetables (FVs). Whereas the conventional freezing method presents low process efficiency in frozen FVs. Ultrasound application is used as a supplementary technology to improve the freezing process of FVs. This reviewed paper shows the cavitation effect of ultrasound and the effect of ultrasound application on freezing time and the physicochemical quality of frozen FVs. The cavitation effect of ultrasound in the freezing process was described in detail. Compared with conventional freezing, ultrasound application in freezing of FVs can shorten the freezing time, and improve physicochemical quality including drip loss, color, firmness, chemical compositions (ascorbic acid, total phenolic and anthocyanin), as well as microstructure. Therefore, the results of these studies illustrated that ultrasound is a potential technology to enhance freezing efficiency and retain the quality of FVs during freezing. ***International Journal of Food Science and Technology*. 2022; 57:3352-3360.**

Near-Infrared Techniques for Fraud Detection in Dairy Products

Dairy products are an important part of the food industry, and their consumption is expected to grow in the next 10 years. Therefore, the authentication of these products in a faster and precise way is required for the sake of public health. This review proposes the use of near-infrared techniques for the detection of food fraud in dairy products

as they are faster, nondestructive, environmentally friendly, do not require sample preparation, and allow multiconstituent analysis. First, we have described frequent forms of food fraud in dairy products and the application of traditional techniques for their detection, highlighting gaps and counterproductive characteristics for the actual global food chain, as longer sample preparation time and use of reagents. Then, the application of near-infrared spectroscopy and hyperspectral imaging for the detection of food fraud mainly in cheese, butter, and yogurt are described. As these techniques depend on model development, the coverage of different dairy products by the literature will promote the identification of food fraud in a faster and reliable way. ***Journal of Food Science*. 2022;87:1943-1960.**

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Biocontrol Applications in Preharvest and Postharvest Environments

Increasing concerns toward food safety and public health have rendered the use of synthetic chemicals in agricultural environments unacceptable. A shift toward biologically safe approaches has been considered a preferred strategy within the food handling chain and has received increasing attention over the past years in managing undesirable microbial growth. Although several studies have looked at the mode of action of most antagonists, the manipulation of microbial communities in food safety has not been fully explored. Very little is known about the effect of microbial diversity and composition in developing a healthy environmental approach for pathogen management in the farm to fork continuum. In view of the progress made in recent years in metagenomic technologies, information generated should be used to develop a dynamic approach that will consider a comprehensive approach involving environmentally friendly strategies in dealing with food losses caused by microbes to ensure food safety. Thus, this review includes information on the latest biocontrol applications to suppress undesirable microbial growth and extend fresh produce shelf life along the farm to fork continuum. The role of recent trends related to the potential of microbiomes in food safety and quality is further discussed. The use of physical treatments against pathogen growth is also highlighted. ***Journal of Food Safety*. 2022:42:e12957.**

High-Pressure Processing of Fish and Shellfish Products

Seafood products have been one of the main drivers behind the popularity of high-pressure processing (HPP) in the food industry owing to a high demand for fresh ready-to-eat seafood products and food safety. This review provides an overview of the advanced knowledge available on the use of HPP for production of wholesome and highly nutritive clean label fish and shellfish products. Out of 653 explored items, 65 articles published from 2016 to 2021 were used. Analysis of the literature showed that most of the earlier work evaluated the HPP effect on physicochemical and sensorial properties, and limited information is available on nutritional aspects. HPP has several applications in the seafood industry. Application of HPP (400–600 MPa) eliminates common seafood pathogens, such as Vibrio and Listeria spp., and slows the growth of spoilage microorganisms. Use of cold water as a pressure medium induces minimal changes in sensory and nutritional properties and helps in the development of clean label seafood products. This technology (200–350 MPa) is also useful to shuck oysters, lobsters, crabs, mussels, clams, and scallops to increase recovery of the edible meat. High-pressure helps to preserve organoleptic and functional properties for an extended time during refrigerated storage. Overall, HPP helps seafood manufacturers to maintain a balance between safety, quality, processing efficiency, and regulatory compliance. Further research is required to understand the mechanisms of pressure-induced modifications and clean label strategies to minimize these modifications. ***Comprehensive Reviews in Food Science and Food Safety*. Published May 31, 2022 online ahead of print. DOI: 1541-4337.12977.**

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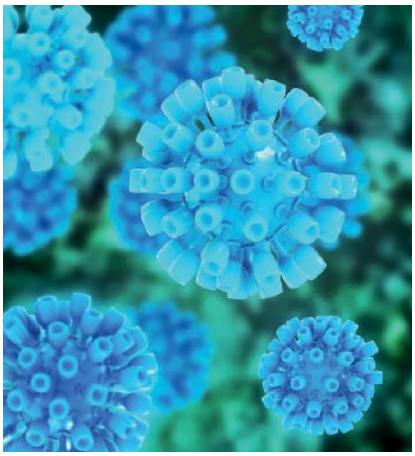
Novel Methods of Viral Control

Food- and waterborne viruses, such as human norovirus, hepatitis A virus, hepatitis E virus, rotaviruses, astroviruses, adenoviruses, and enteroviruses, are major contributors to all foodborne illnesses. Their small size, structure, and ability to clump and attach to inanimate surfaces make viruses challenging to reduce or eliminate, especially in the presence of inorganic or organic soils. Aside from traditional wet and dry methods of disinfection using chemicals and heat, emerging physical nonthermal decontamination techniques (irradiation, ultraviolet, pulsed light, high hydrostatic pressure, cold atmospheric plasma, and pulsed electric field), novel virucidal surfaces, and bioactive compounds are examined for their potential to inactivate viruses on the surfaces of foods or food contact surfaces (tools, equipment, hands, etc.). Every disinfection technique is discussed based on its efficiency against



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viruses, specific advantages and disadvantages, and limitations. Structure, genomic organization, and molecular biology of different virus strains are reviewed, as they are key in determining these techniques effectiveness in controlling all or specific foodborne viruses. Selecting suitable viral decontamination techniques requires that their antiviral mechanism of action and ability to reduce virus infectivity must be taken into consideration. Furthermore, details about critical treatments parameters essential to control foodborne viruses in a food production environment are discussed, as they are also determinative in defining best disinfection and hygiene practices preventing viral infection after consuming a food product. ***Comprehensive Reviews in Food Science and Food Safety*. 2022;21:904-941.**

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Mexico Association for Food Protection Annual Meeting
Virtual Event
Visit amepal.com.

9-10
Turkish Food Safety Congress
Istanbul, Turkey
Visit foodsafetycongress.org.

12-14
Summer Fancy Food Show
New York, N.Y.
Visit speciatlyfood.com.

JULY 2022

10-13
FIRST Annual Expo and Virtual Experience
Chicago, Ill.
Visit ift.org/events.

July 29-Aug. 3
IAFP
Pittsburgh, Penn.
Visit foodprotection.org or email info@foodprotection.org.

AUGUST 2022

Aug. 22-Sept. 1
AOAC Annual Meeting and Exhibition
Scottsdale, Ariz.
Visit aoac.org/annual-meeting-exposition.

OCTOBER 2022

17-19
Cannabis Quality Conference and Expo
Parsippany, N.J.
Visit cqcexpo.com.

19-21
Fresh Food, Packaging and Susainability Summit
Clemson, S.C.
Visit sonocofreshsummit.com.

19-21
Food Safety Consortium Conference and Expo
Parsippany, N.J.
Visit foodsafetyconsortium.org.

23-26
Pack Expo International
Chicago, Ill.
Visit packexpointernational.com.

NOVEMBER 2022

2-4
Dairy Practices Council Annual Conference
Bloomington, Minn.
Visit dairypc.org/dpc-conferences.

JANUARY 2023

15-17
Winter Fancy Food Show
Las Vegas, Nevada
Visit speciatlyfood.com.

MARCH 2023

28-30
SIAL America
Las Vegas, Nevada
Visit sialamerica.com.

MAY 2023

8-11
Food Safety Summit
Rosemont, Ill.
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