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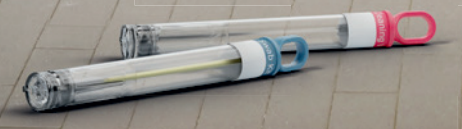

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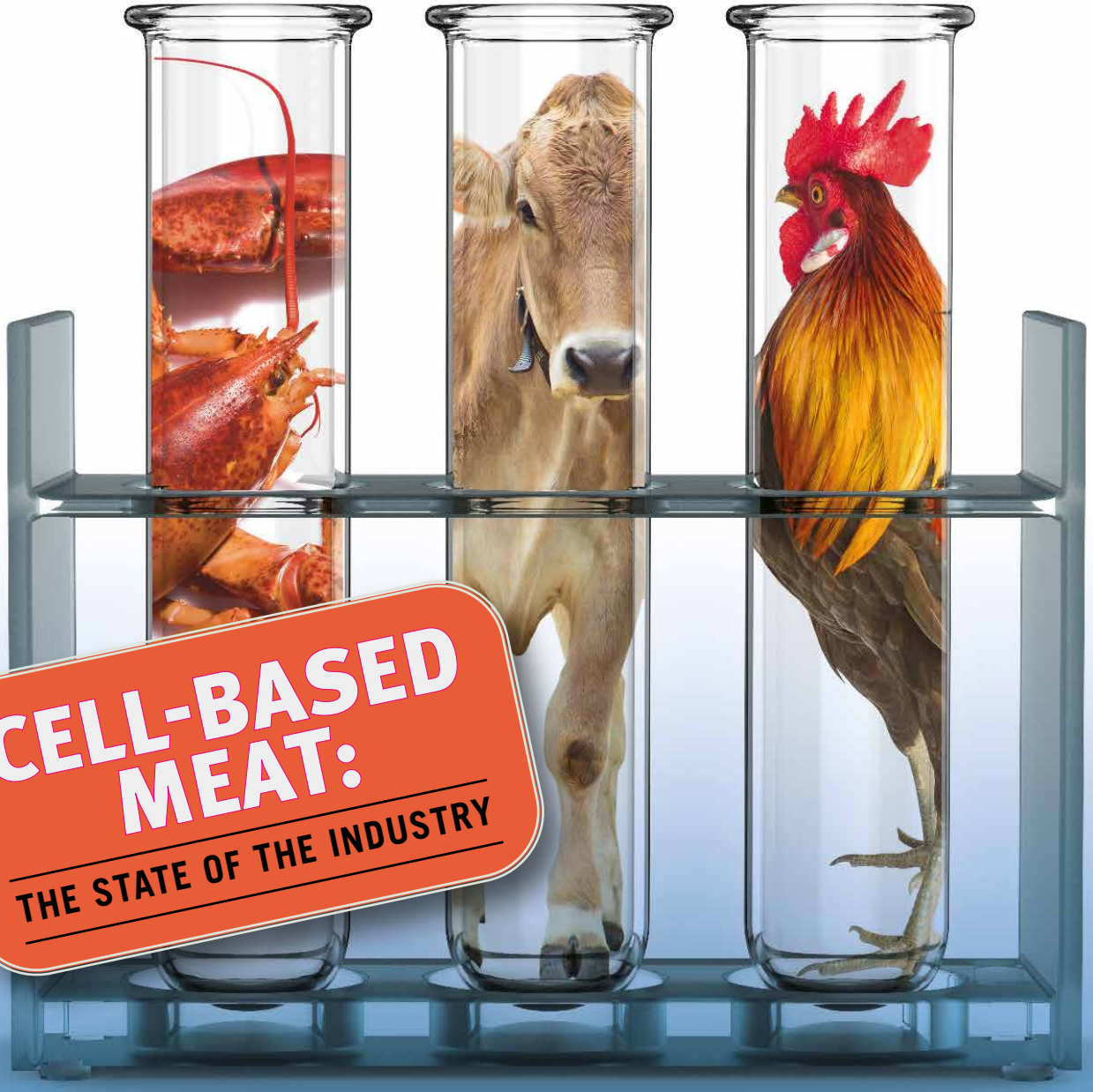
Volume 28 Number 5
OCTOBER / NOVEMBER 2021

Food Quality & Safety

FARM TO FORK SAFETY



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From The Editors

Food Regulation by State? Bad Idea

Food processors, handlers, growers, and warehousers in the U.S. must deal with rules enacted by local, state, and federal authorities. In some cases, managing regulations at so many levels can create problems, as the agencies aren't always in line with each other. One example of this state-versus-federal conundrum is the legalization of marijuana by state, a subject that we've examined in *Food Quality & Safety*. At the federal level, cannabis is deemed a dangerous substance; however, it is now legal in many states—a situation that has created a raft of issues.

There have been and remain significant issues concerning the differences between a state's rights and how the federal government might interpret things. This is not new; we've seen this crop up in the food industry time and again. Several years ago, Connecticut and Maine enacted regulations mandating the labeling of genetically modified (GM) foods sold in those states, rules that would have, among other things, been an impediment to interstate commerce. This situation was wonderfully addressed by Don Butte and Jeffrey Whitesell in a 2013 *FQ&S* article called "GM Labeling for Different States?" (available at foodqualityandsafety.com). The authors contend that GM labeling was a violation of the First Amendment and that such actions would violate the Interstate Commerce Clause of the U.S. Constitution. This clause says that states have the right to regulate domestic commerce where there is no federal regulation in the area, but that the exercise of that right cannot impede, discriminate against, or burden interstate commerce.

There is a similar issue looming on the horizon, scheduled to go into effect on January 1. California's Proposition 12 mandates humane raising of pigs, chickens, and calves in the state. The Legal Update article by Shawn Stevens and Joel Chappelle that appears on page 10 of this issue summarizes the legislation. The act says that the animals can no longer be crammed into cages and must have a minimum amount of space. Currently, very few producers meet these requirements, and some estimate that the regulation will increase pork prices significantly and affect husbandry operations in other states, because much of the meat consumed in California is delivered via interstate commerce. Is the regulation a good idea or a bad one? It would seem that enforcement of this proposition violates the issues described in the GM article referenced above.

Additionally, is it really true that the humane raising of calves, pigs, and chickens makes for a happier, healthier, and better-tasting option? I don't know, but there are certainly some negatives that crop up. A 2017 NPR piece detailed the story of a Georgia farmer who set out to raise free-range chickens. Well, guess what? Eagles found that free-range chickens are easy prey and, since bald eagles are protected, the farmer had to obtain the government's blessing to try and control them, without harming the eagles.

Sometimes, you don't get what you hope for.

Richard F. Stier
Co-Industry Editor

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NEWS & NOTES

New Freezing Method Improves Food Quality and Safety

Shifting to a new food freezing method could make for safer and better quality frozen foods, according to a new study by USDA's Agricultural Research Service and scientists at the University of California–Berkeley.

The new freezing method, called isochoric freezing, works by storing foods in a sealed, rigid container, typically made of hard plastic or metal, completely filled with a liquid such as water. Unlike conventional freezing in which food is exposed to the air and freezes solid at temperatures below 32° F, isochoric freezing preserves food without turning it to solid ice. As long as the food stays immersed in the liquid portion, it's protected from ice crystallization, a major threat to food quality.

Isochoric freezing also allows for higher quality storage of fresh foods such as tomatoes, sweet cherries, and potatoes that are otherwise difficult to preserve with conventional freezing.

Another benefit of isochoric freezing is that it also kills microbial contaminants during processing.

The method was first developed to cryopreserve tissues and organs for transplants. Since then, researchers have applied for a joint patent to apply isochoric freezing to food preservation. The research team is now developing the best applications for this technology in the frozen foods industry. ■

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Study: Major Disparity in Safety of Leafy Greens in Low- versus High-Income Areas

BY **KEITH LORIA**

Low-income residents are at greater risk of contracting foodborne illness than those in high-income communities, according to a new study by researchers at the University of Houston in Texas. The study, published last month in the *Journal of Food Protection*, examined the safety and quality of loose-leaf romaine lettuce accessible to low-income populations living in Houston, Texas.

The researchers purchased fresh greens from five different retailers in both low- and high-income socioeconomic status areas over a six-month period. The samples underwent reverse transcription polymerase chain reaction testing for pathogen contamination. The investigators found a disparity between the microbial quality and safety of the produce accessible to low-income communities and those collected from the high-income areas.

While both communities saw positive results for *Staphylococcus aureus*—38% of samples in high-income areas tested positive for the pathogen and 87% tested positive in those collected from low-income areas—no other pathogens were found in the produce sampled in the high-income areas. Greens collected from the low-income areas tested positive for *E. coli* O157:H7 (4%), *Salmonella* spp. (53%), and *Listeria monocytogenes* (13%).

The research also showed that romaine lettuce in low-income communities had higher levels of spoilage microorganisms, fecal contaminants, and pathogens.

While the study did not identify why the disparity exists, the researchers theorize that it could be because of time and temperature abuse of produce, potential cross contamination at various stages in the supply chain, or challenges and differences in the supply chain contributing to contamination. ■

USDA Invests $700 Million to Provide Relief to Farm and Food Workers Impacted by COVID-19

USDA has announced that $700 million in grant funding will be available through the new Farm and Food Workers Relief (FFWR) grant program to help farm workers and meatpacking workers with pandemic-related health and safety costs. Additionally, the agency has set aside $20 million of this amount for at least one pilot program to support grocery workers and test options for reaching them in the future. The new program is funded by the Consolidated Appropriations Act of 2021 and is part of USDA's Build Back Better efforts to respond to and recover from the pandemic.

The program will provide relief to farm workers, meatpacking workers, and frontline grocery workers for expenses incurred due to the COVID-19 pandemic. This relief is intended to defray costs for reasonable and necessary personal, family, or living expenses related to the COVID-19 pandemic, such as costs for personal protective equipment, dependent care, and expenses associated with quarantines and testing.

The application period will likely be open through mid-November 2021. For more information, visit the FFWR webpage at www.ams.usda.gov/services/grants/ffwr or contact ffwr@usda.gov. ■

Washington Report

The Food Labeling Modernization Act of 2021

The bill would require a standard front-of-package nutritional label and a clear definition of the term "natural"

BY **KEITH LORIA**

The Food Labeling Modernization Act (FLMA) of 2021, an update of legislation originally introduced to Congress in 2018, was presented to the House and Senate in August. As written, the bill would require FDA to establish a standard front-of-package labeling system for all FDA-regulated food products. In August 2021, lawmakers introduced an update to the legislation.

The 2018 version of the FLMA required nutrition information on labels to be displayed, including nutrition facts, ingredients, and allergen information. The updated version encourages the use of substitutions for overconsumed nutrients, such as sodium, and also requires that labels provide information to consumers regarding caffeine content and gluten-containing grains.

Laurie Beyranevand, director of the Center for Agriculture and Food Systems at Vermont Law School in South Royalton, notes that the proposed law differs from existing law in that it seems to reflect a more holistic approach to thinking about claims on labels. For example, currently, a producer can include a claim of high fiber on the package of a product that may also contain a lot of sugar, but the high fiber claim could suggest to a consumer that the product is more healthful than it actually is. "This bill seems to try to correct some of those issues and requires more front-of-package disclosures for foods that don't promote healthy dietary patterns," Beyranevand tells *Food Quality & Safety*. "It also seems to help to line up some of the food label issues with the recommendations in the dietary guidelines. One of the biggest changes is the requirement for a front-of-package labeling system to improve consumer understanding of the nutritional composition of the foods they're purchasing."

The lawmakers who authored the bill contend that consumers should be able to quickly and easily comprehend the new labeling system as an indicator of a product's contribution to a healthy diet without requiring them to have specific nutritional knowledge. "This bill will bring much-needed clarity to food labels so Americans can make informed, healthy decisions for themselves and their families," said Sen. Richard Blumenthal (D-Conn.), one of the co-sponsors of the bill. "Today's food labeling standards do not provide adequate information that consumers need to make healthy lifestyle decisions."

Significant Changes

Shawn K. Stevens, a food industry attorney with the Food Industry Counsel, a food law firm based in Milwaukee, Wisc.,

notes that consumers are increasingly concerned about their health and their nutrition, and that's reflected in the food products on the grocery shelves today. "We see it playing out on television, with commercials focusing on eating healthy and eating clean, and around the dinner table, with families being more conscientious about what we're all putting in our body," he says. "Congress is looking to help this trend along."

According to Stevens, the bill looks to better create a standardized symbol that displays calorie information in relation to serving size, as well as information on saturated and trans fats, sodium, added sugars, and any other nutrients that are strongly associated with public health concerns.

Additionally, the new legislation would require that information appear on all products that bear a nutrition label directly on the principal display panel in a prominent design that contrasts with the packaging to make it easier for consumers to see and read. "I don't see any reason why consumers shouldn't be able to see how many calories are in a product," Stevens says. "It would speed up the shopping process and push food companies to look for ways to develop lower-calorie foods, which would be good for everyone."

One change that is seeing some blowback from industry, and could hold up passage of the bill, is the notion of creating a system of warning symbols for package fronts of foods that have certain nutrients deemed to be of "lesser nutritional value," such as saturated fats, salt, or sugars. "What's referenced are warning symbols like a stoplight, and I think that's a dangerous or slippery slope in that for some people, consuming extra sugars could be a good idea," Stevens says. "I don't think the government needs to be in a place to mandate warning labels on products that contain ingredients that have been in products for the history of time. And even worse is this proposed signaling system that would rank foods based on their overall health value. It seems like a little bit of over meddling."

And with the pandemic resulting in an increase in the number of people shopping online for food, the need for nutritional information requirements that are available at the online point of sale has also grown.

Defining "Natural"

If passed, the new bill would also require FDA to define the term "natural," which many believe would be very helpful for the industry. "The industry has been asking the FDA to define 'natural' for quite some time," Stevens says. "The FDA initially expressed some interest in going down that road [in the original FLMA] but decided to take a pause because it is a loaded term and [it's] difficult for people to agree about what the term means. This is a breath of fresh air to see Congress looking to provide some clarity."

> One of the biggest changes is the requirement for a front-of-package labeling system to improve consumer understanding of the nutritional composition of the foods they're purchasing.
>
> —LAURIE BEYRANEVAND

Joel S. Chappelle, a food industry attorney also with the Food Industry Counsel, notes that the proposed rules governing the term "natural" are contentious; for years, regulators, industry, consumers, and commentators have sparred over the definition of the word. Despite the back-and-forth, no consensus has emerged, because "natural" is a diffuse term with an expansive breadth of meanings. "The FLMA's proposed solution is to require a regulated definition based on consumer opinion surveys, which we already know will not produce a consensus, and public comment, which the FDA has been soliciting for years," Chappelle says. "The bill would also require labels with the term 'natural' to prominently explain what the term does and does not mean."

Beyranevand agrees that the bill's attempt to address the definitions of "natural" and "healthy" is important, but is also difficult to put into practice in a way that captures the full range of meanings consumers associate with these terms. "It would be more beneficial to empower FDA to more stringently regulate potentially misleading claims, given the gravity of the public health crisis posed by diet-related disease," she says.

Deceptive Marketing

A criticism of the original 2018 legislation was that it allowed marketing practices that could mislead customers. The updated bill looks to target trends in marketing that confuse consumers attempting to compare food products and would require new guidelines for the use of the word "healthy."

"It requires products making claims about healthy ingredients like fruits, vegetables, and whole grains to list the amount per serving or include percentages of these ingredients," Beyranevand says.

The pandemic provided an opportunity for many to reconsider the food system, and the bill is an important step toward providing better and clearer information about food products to consumers. "If this bill was ever to have traction, now appears to be the time," Beyranevand says. "Currently, poor nutrition is the leading cause of illness in the U.S., and data demonstrated that those suffering from diet-related disease had worse health outcomes from COVID-19 than those who didn't."

If Passed

Some food producers are concerned about having to reconfigure their product labels and, potentially, product composition as a result of the law, if passed; however, what the bill would mean to companies would depend on what regulations the responsible agencies ultimately drafted. For example, the bill mandates reformatting the ingredient list "as necessary to assist consumers in maintaining healthy dietary practices."

"It is difficult to know how reformatting an ingredient list would assist consumers to maintain a healthy diet," Chappelle says. "At a minimum, it would mean huge cost increases, more lawsuits, more consumer confusion, and ostensibly enormous labels, as would be necessary to accommodate an explanation of what 'natural' does and does not mean."

There is currently no timeline on possible passage of the bill. ■

Loria is a freelance writer based in Virginia. Reach him at freelancekeith@gmail.com.

Legal Update

Will Californians Be Able to Bring Home the Bacon in 2022?

The state's Proposition 12 dictates humane treatment of farm animals; opponents say the law could lead to food shortages and increased food pricing

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

A food-related legal controversy has returned to the news in California as the deadline looms for businesses to comply with a new law. Proponents of the law, the state's Proposition 12, argue that it will reduce the occurrence of animal cruelty, while opponents argue the law will lead to—among other things—increased bacon prices and food shortages. Ultimately, it remains to be seen how the law will affect the meat industry and California consumers, but given the enormity of the California market, the changes are likely to lead to widespread downstream effects and could eventually serve as a national model.

On November 6, 2018, California voters overwhelmingly approved California Proposition 12. The law, known as the Prevention of Cruelty to Farm Animals Act, aims to reduce animal cruelty by phasing out certain methods of farm animal confinement and enacting stricter regulations relating to animal raising conditions. Although the act became law nearly three years ago, its provisions did not all take effect immediately. Some of the most contentious requirements are scheduled to take effect at the end of this year. Since becoming law, the act has survived numerous legal challenges from opponents who contend the law will decimate the pork industry and lead to skyrocketing prices.

Generally, the law establishes new minimum requirements governing the amount of living space farmers must provide to egg-laying hens, breeding pigs, and calves raised for veal. Under the previous law, animals only had to have sufficient room to turn around freely, lie down, stand up, and fully extend their limbs.

The Legislation

Under the law, beginning January 1, 2022, egg-laying hens must be raised in a cage-free environment with at least as much usable floor space as required by the 2017 edition of the United Egg Producers' Animal Husbandry Guidelines for U.S. Egg-Laying Flocks: Guidelines for Cage-Free Housing. For breeding pigs, the space requirements will increase from 20 square feet of floor space to 24 square feet. As for veal calves, the law mandates (since 2020) that they be given at least 43 square feet of space.

Due to jurisdictional limitations—California cannot regulate out-of-state farmers—the farm requirements are only enforceable against California farmers. So, to prevent businesses from simply sourcing out-of-state products, the act also bans California businesses from selling eggs, uncooked pork, or veal derived from animals raised in violation of the act's requirements. Put differently, the requirements of Proposition 12 apply to covered products sold in California, irrespective of whether the subject animals were raised on farms in California or elsewhere. So, for example, a breeding pig confined in another state must be housed in compliance with Proposition 12 if her offspring will be sold for human consumption in California.

One key exception to the law is that it generally does not apply to foods that use eggs, pork, or veal as an ingredient or topping. Additionally, any inventory of shell eggs, liquid eggs, or pork products that are in stock prior to January 1, 2022, can remain in stock and do not need to be discarded if

they were derived from animals raised in violation of the confinement standards.

Because the act regulates matters potentially subject to federal preemption, the drafters had to take care not to overstep. In simple terms, the Constitution's Interstate Commerce Clause states that Congress has the power to regulate commerce among the several states. For example, the definitions of commercial "sale" and "farm" exclude transactions where physical possession of liquid eggs is taken at USDA Food Safety and Inspection Service (FSIS)-inspected plants. Nevertheless, any subsequent sale of noncompliant eggs is prohibited because the exemption attaches to the FSIS-inspected plant, but not the liquid egg product itself.

Compliance

The penalties for violations of the law can be severe. Violations of the law are chargeable as misdemeanor offenses, punishable by a fine of up to $1,000, imprisonment in county jail for up to 180 days, or both. Moreover, violations of the sales ban also constitute acts of "unfair competition" under California's Unfair Competition Law (UCL). Each violation of the UCL is punishable by a fine of $2,500.

Notably, civil actions for injunctive relief and restitution under the UCL may be initiated by anyone who has suffered an injury and has lost money or property because of the unfair competition. Because injured parties can bring claims—in addition to the Attorney General, district attorneys, and certain county and city attorneys—it will be especially important for businesses to ensure that the products they source are compliant with the law. Given the severity of the potential consequences, those transacting business in covered products should immediately work to gain a clear understanding of the legislation's requirements and vagaries.

Generally, businesses can achieve compliance by obtaining written certification that the products they are selling originated from animals housed in accordance with Proposition 12 confinement standards. In turn, any companies that sell covered products in California should take immediate action to ensure that their suppliers are compliant and can provide certifications to that effect.

Additionally, it may be useful to procure sufficient reserves to work through the anticipated product shortages and price hikes that are widely expected when the new requirements take effect.

The law provides a defense for sellers who relied in good faith upon written certification by their suppliers that meat and egg products comply with new confinement standards. Thus, as long as there is a good faith effort to comply with the law, companies conducting business in California will have a defense.

> Ultimately, it remains to be seen how the law will affect the meat industry and California consumers, but given the enormity of the California market, the changes are likely to lead to widespread downstream effects and could eventually serve as a national model.

Unfortunately, while the broad strokes of the law have been set in stone for years, the finer details, in terms of specific regulations, have yet to be published. The California Department of Food and Agriculture said that, although the regulations are not quite finished, the key rules will not change. In turn, companies will want to closely track any new developments that may affect their ability to comply with the regulations.

Challenges

Despite the challenges that some farmers are likely to face when enacting the changes necessary to comply with the law's requirements, this is far from the biggest challenge the industry has faced. In the last 25 years, the meat industry has faced a litany of extraordinary tests and, in each case, has managed to adapt. In fact, the meat industry has undergone a series of tectonic shifts, opponents of which have claimed would be the death knell for the industry. Yet, because of the remarkable ability the industry has shown to adapt, the opposite has proven true.

By most metrics, meat is safer and more plentiful than ever before. The number of recalls is down, the number of outbreaks is down, and the industry continues to thrive. This is a testament to the hard-working people in the industry who have continued to adapt and overcome, no matter the challenge. Certainly, this law will present significant challenges to many who produce our food. But, at the same time, we are sure that the industry will continue to innovate and adapt to meet the challenge. Likewise, we have no doubt that Californians will continue to bring home the bacon. ■

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Allergen Control

The FASTER ACT

Beginning in 2023, sesame and sesame-derived ingredients will need to follow all FALCPA labeling requirements

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

On Friday, April 23, 2021, President Biden signed the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2021 into law. The law contains two main components. First, sesame is added as a major food allergen, marking the first official change to the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) since its passage. Second, the FASTER Act requires reports on selected food allergy topics to be delivered to Congress, including those on how to establish and implement criteria for future updates to the list of major food allergens.

Sesame seeds (*Sesamum indicum*) are an oilseed crop, with yellow, white, red, brown, and black varieties grown for various food ingredients. Sesame seeds are approximately 50% fat, 23% carbohydrate, 18% protein, 4% ash, and 5% water. In 2019, the estimated global production of sesame was 6.5 million metric tons; the top producing countries were Sudan, Myanmar, India, Tanzania, Nigeria, and China. Sesame-derived food ingredients can include whole seeds, oils, flours, and pastes (commonly referred to as tahini).

Sesame is also known to cause food allergies and can be responsible for serious and life-threatening allergic reactions in sensitive individuals. The prevalence of sesame allergy varies around the world, with relatively higher prevalence observed in the Middle East, Israel, and Australia and lower prevalence observed in North America and Europe. Recent estimates in the U.S. indicate a convincing self-reported sesame allergy prevalence of approximately 0.2% in both adults and children. In comparison with the prevalence of other food allergies reported in the same studies, allergy to sesame is less prevalent than reported allergies to current major allergens (peanuts, tree nuts, wheat, soy, milk, crustacean shellfish, egg, fish) and molluscan shellfish. The allergenic potency of sesame is broadly similar to other seeds and nuts. The VITAL 3.0 reference dose (the ED01, or the dose expected to elicit reactions in the 1% most sensitive sesame-allergic individuals) is 0.1 mg total sesame protein. For comparative purposes, the sesame ED01 is the same as hazelnut, but higher than cashew and walnut and lower than peanut. The proteins in sesame seeds that have been identified as allergenic are predominantly seed storage proteins, as is also the case with tree nuts and peanuts.

In several regulatory jurisdictions around the world, including Canada, the EU, and Australia and New Zealand, sesame has been a priority food allergen for many years, with corresponding labeling requirements. In the U.S., sesame was not originally considered a major allergen in the context of FALCPA, but labeling of sesame or sesame ingredients was still required for many products in which such ingredients were used. For example, whole sesame seeds used as an ingredient were required to be labeled as such. However, sesame paste might have been declared as tahini, thus requiring sesame-allergic consumers to know that tahini was made from sesame. Additionally, when other forms of sesame (i.e., not whole seeds) were used, there were selected instances where those ingredients could be labeled as "spice" or "flavor." The FASTER Act sought to remedy some of the potential confusion and improve labeling clarity by requiring sesame-

derived ingredients to be subject to the same labeling regulations as other major food allergens.

The Amendment and Implications for FSMA

The FASTER Act amends Section 201(qq) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (qq)) to read:

(qq) The term "major food allergen" means any of the following:

(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame.

The amendment to include sesame as a major food allergen is effective as of January 1, 2023. With this change, sesame and sesame-derived ingredients will need to follow all FALCPA labeling requirements. Specifically, all sesame and sesame-derived ingredients must be declared as sesame either in the ingredients list or in a "Contains" statement. If a "Contains" statement is used, all major allergen ingredients must be included. As noted above, one common sesame-derived ingredient used in foods is sesame oil. While FALCPA does exempt highly refined oils derived from allergenic foods from labeling, much of the sesame oil used in food production is not highly refined and is therefore not exempt from labeling. FALCPA does not provide a specific definition of highly refined oils, but industry best practice would indicate that processing should include refining, bleaching, and deodorizing. Sesame-derived ingredients must also be declared by their common or usual name; tahini may still be used on the ingredient list but sesame must appear either parenthetically or in a "Contains" statement.

In addition to direct changes in FALCPA requirements, the inclusion of sesame in the definition of major food allergens also has implications for the Food Safety Modernization Act (FSMA). The FSMA Final Rule for Preventive Controls for Human Food includes the following definition: "*Food allergen* means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act." With the FASTER Act amendment, sesame will also be considered a major food allergen in the context of FSMA. As such, manufacturers will need to include sesame in food safety plan hazard assessments and will need to have preventive controls in place for the ingredient, if undeclared sesame is identified as a potential hazard.

Allergen Management

Given that sesame has been considered a priority allergen in other regulatory jurisdictions for many years, there are tools and resources available to aid in sesame allergen management. Commercial detection methods for sesame are available in multiple formats, from several different kit manufacturers. Enzyme-linked immunosorbent assay (ELISA) methods are available for the detection and quantification of sesame in ingredients, processed food products, and environmental samples. The sesame ELISA methods, like other allergen ELISAs, are generally most appropriate for use in centralized or third-party laboratories due to the equipment and expertise required. Rapid methods, including lateral flow devices (LFDs), are also available for sesame. LFDs are easy to use, require minimal equipment, and are good options for detecting allergen-specific residues from equipment swabs and rinse waters when conducting allergen change-over validation studies. For selected situations where confirmatory analysis may be required, commercial PCR methods are also available for sesame detection.

> Manufacturers will need to include sesame in food safety plan hazard assessments and will need to have preventive controls in place for the ingredient, if undeclared sesame is identified as a potential hazard.

When developing an allergen management plan or analysis strategy for sesame, one of the most important considerations is the form of the sesame ingredient. Sesame seeds, sesame paste, sesame flour, and sesame oil present very different challenges for allergen control and detection. With sesame seeds, it is important to recognize the particulate nature of potential cross-contact. In developing allergen change-over procedures, visual inspection for sesame seeds remaining on equipment is likely more crucial than analysis of equipment swabs. If ingredients or finished products are analyzed for cross-contact with sesame seeds, additional rigorous homogenization techniques (e.g., grinding under liquid nitrogen) are often required to break the seed coat and achieve sufficient sesame protein extraction for analysis. In the case of sesame paste, the oily, sticky nature of resulting food soils can be a challenge for allergen cleaning protocols. Soil removal strategies for similar ingredients (e.g., peanut butter and tree nut butters) have been successfully developed, however, and may be applicable to the cleaning of sesame paste. Sesame oil that has not been highly refined is likely to contain sesame protein; however, the protein may not be at concentrations high enough to be detectable in equipment swabs during allergen change-over validations. A swab of dirty equipment, after production of the product containing sesame oil and prior to cleaning, can serve as a positive control to verify the detection of sesame protein residues.

Impact on Food Safety Plans

While sesame has long been known to cause food allergies, the requirements to manage sesame as a major food allergen as a result of the FASTER Act will likely require multiple layers of changes on the part of some food manufacturers. Both allergen labeling controls and allergen cross-contact controls will be required for operations that handle sesame seeds or other sesame-derived ingredients. Despite the changes that may be required for food safety plans, the principles used for other food allergen controls are also relevant for sesame. Food manufacturers should be able to use existing best practices, tools, and resources to comply with the new application of food allergen regulations to sesame going forward. ■

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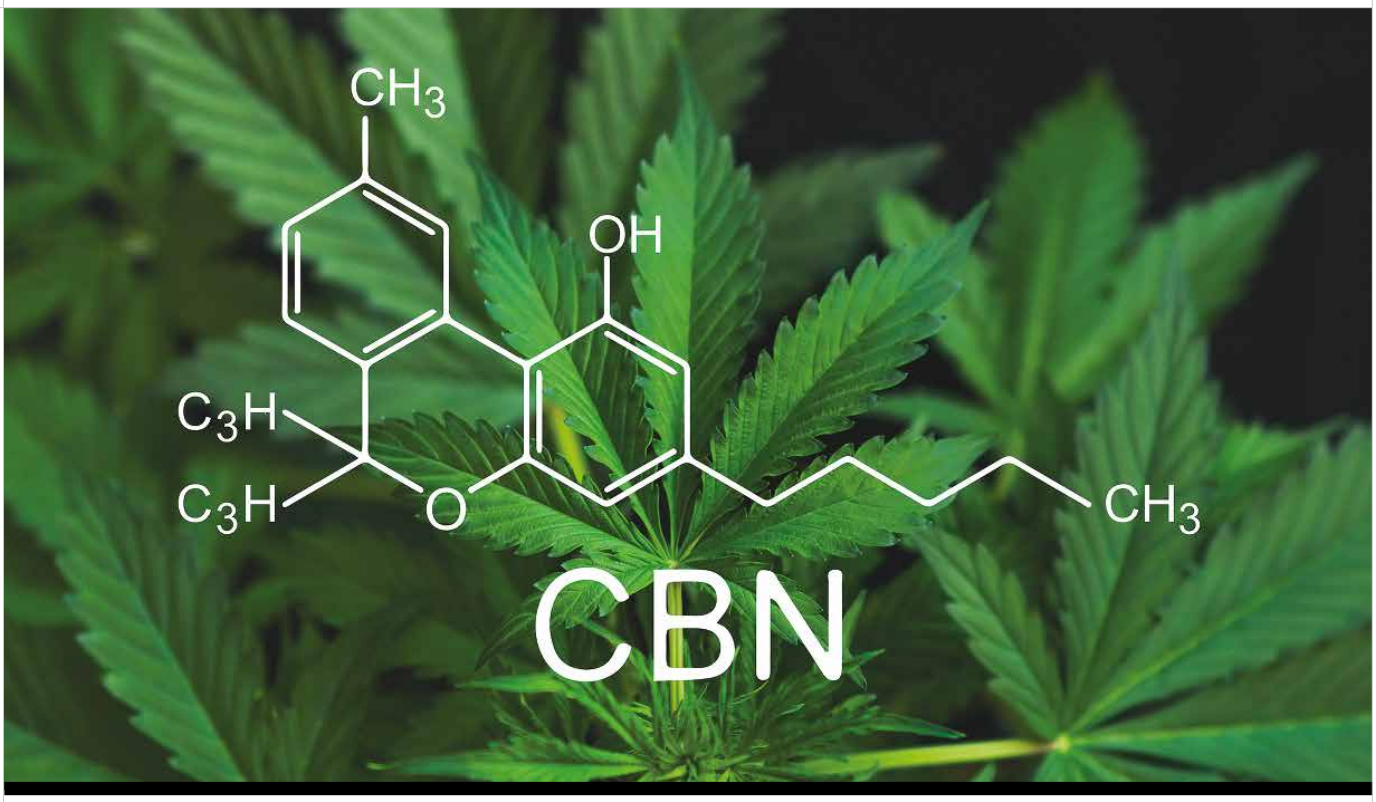
Cannabis Corner



"Rare" Cannabinoids

Researchers are working to unravel the potential benefits of niche cannabinoids; are they the next "big thing"?

BY **JESSE STANIFORTH**

Five years ago, few consumers or food producers had ever heard of cannabidiol (CBD), unless they also happened to be cannabis afficionados or medical cannabis consumers. Yet in the past three years, since hemp-based CBD became legal across all 50 U.S. states and cannabis was legalized federally in Canada, consumers had little time to learn about CBD before it was all around them.

Due both to its clinically proven effects and to aggressive marketing by CBD manufacturers, the cannabinoid has become known as a wellness buzz molecule, available everywhere from pharmacies to vegan smoothie shops to gas stations. Yet, the cannabis plant—which refers both to low-tetrahydrocannabinol (THC) hemp and higher-THC cultivars for medical or recreational use—has far more cannabinoids than the upstart CBD and best-known THC. The plant may produce as many as 110 individual cannabinoids, along with other potentially therapeutic compounds such as terpenes and flavonoids.

Since state-level legalization began in Colorado in 2015, researchers have been rushing to catch up on the 100 years of research that cannabis prohibition prevented them from conducting. As the cannabis industry has watched CBD's rapid ascent toward multi-billion-dollar annual sales, everyone has been trying to determine which cannabinoids could be central to the next wellness bonanza. The two cannabinoids that infused-foods producers and consumers are likeliest to encounter today, outside of THC and CBD, are cannabigerol (CBG) and cannabinol (CBN).

"There are already various products on the market that have CBN [and CBG] present in various doses," says independent cannabinoid researcher Winston Peki, who operates cannabis research-and-review site herbonaut.com. "Most of these products are a combination of CBD and CBN and are marketed as products for sleep [or] stress relief—not that different than CBD products, which are marketed for the same."

Unlike THC and CBD, which have usually been noticeably a part of cannabis as it has been consumed for millennia, CBG and CBN have, until the last few years,

occurred only in trace amounts in the cannabis plant. CBG occurs as a precursor cannabinoid, which the plant produces and immediately turns into THC and CBD, leaving little or no CBG behind. CBN is different in that it occurs in trace amounts in fresh cannabis but can also occur as the product of exposing THC to sunlight or ultraviolet light.

"CBG and CBN usually occur in much smaller concentrations in modern cannabis that is used medicinally or used to manufacture cannabis products," says Scott Churchill, VP of scientific development for Framingham, Mass.-based cannabis testing firm MCR Labs.

The fact that CBG and CBN are so naturally rare makes them significantly more expensive to manufacture than "native" cannabinoids THC and CBD, says Bryan Quoc Le, PhD, an independent food scientist and cannabis researcher in Sequim, Wash. "We're still learning more about them," he says. "We are still uncertain of their safety profiles in humans, and more research is needed to uncover potential side effects from long-term consumption. But as researchers begin to unravel the potential benefits of rare cannabinoids, as well as develop technologies to manufacture them at lower cost, we may be seeing a higher prevalence of them in cannabis-infused foods down the road."

The Research

Dr. Le also stresses that cannabinoids are chronically understudied and, given what we've learned so far about the therapeutic potential of CBD and THC, "rare cannabinoids are a potential gold mine of new pharmaceuticals, but we are still just learning how to produce them at the scale needed to do adequate clinical research on them."

To begin manufacturing products containing CBG and CBN, researchers first must breed plants containing higher concentrations of those molecules, though as Mike Hennesy, VP of Innovation for edibles producer Wana Brands in Boulder, Colo., stresses, companies like his are looking beyond plant-based cannabinoids and into the use of yeast or bacteria to produce chemically identical cannabinoids out of raw ingredients.

Even as researchers study technologies that might help replace the plant itself, Hennesy's company has long been looking past THC and CBD toward other cannabinoids, as well as terpenes, believed to have pharmacological effects.

Hennesy is optimistic: His company plans to develop products with these molecules as well as other rare cannabinoids, such as cannabichromene (CBC) and tetrahydrocannabivarin (THC-V). Wana Brands is preparing to launch a sleep-aid gummy product in Colorado that is infused with CBD, CBN, CBG, a low dose of THC, melatonin, and 30 terpenes. "We believe this market for these [minor cannabinoids] will continue to grow with increasing consumer demand for them, as knowledge and information about them continues to spread," Hennesy says.

> Unlike THC and CBD, which have usually been noticeably a part of cannabis as it has been consumed for millennia, CBG and CBN have, until the last few years, occurred only in trace amounts in the cannabis plant.

For food producers considering bringing minor cannabinoids into their recipes, Hennesy says there's little learning curve, since most phytocannabinoids have similar chemical structures and tend to behave in similar ways. Accordingly, he adds that rare cannabinoids don't require complete recipe overhauls to introduce them to a product. They can have different flavors, however, with some more and others less agreeable.

What We Know

Yet, like Dr. Le, Hennesy acknowledges that CBG and CBN are still little understood. There is a body of anecdotal evidence suggesting that CBN helps with sleep, supported by "only one study [...] conducted in 1975 with just five participants," Hennesy says, "so the jury is out on whether CBN truly deserves to be known as 'the sleepy cannabinoid.' That said, new research does come out nearly every month, increasing our body of knowledge about these new minor cannabinoids."

What we know for sure about CBN, according to Dr. Le, is that, as a generally non-psychoactive compound, CBN has about 10% of the activity of THC and is metabolized more slowly than THC. Due to the difference in structure, CBN and other rare cannabinoids interact with the body's endocannabinoid system differently from THC. Both Peki and Dr. Le say that CBN is believed to have a more sedative effect than CBD.

Kent Vrana, PhD, is the Elliot S. Vesell Professor and Chair of Penn State College of Medicine's department of pharmacology. He says evidence is slim for the effects of CBG, but that the cannabinoid appears, in theory, to have activity that falls somewhere between CBD and THC, both in terms of its potency (how much it takes to have an effect) and the effects themselves.

In February 2021, Dr. Vrana and colleagues published "The Pharmacological Case for Cannabigerol" in the *Journal of Pharmacology and Experimental Therapeutics*. That paper acknowledged previously suggested therapeutic potential for CBG in treating neurologic disorders and inflammatory bowel disease, but it also noted (with uneasiness) the growing commercial interest in CBG as a wellness tool.

Dr. Vrana and his colleagues found that CBG had somewhat of an effect on receptors of the endocannabinoid system. "Looking at CB1, the receptor that gets you high," he says, "THC is partially active, but CBD is not. CBG is someplace in between, both in terms of its strength at that site, and what it does when it's bound to that site. It's likely to cause a very mild high, and it all depends on how much of it you can get in the body." He notes that the same thing occurs with receptor CB2, believed to be anti-inflammatory and the site where CBD has the most effect: there, CBG remains a partial stimulant.

Evidence outside the endocannabinoid system alarmed Dr. Vrana, however. "What we got interested in was based on one of its reported activities in a non-cannabinoid receptor called Alpha-2," he says. "That receptor, 40 years ago, was a target for hypertension. So, my colleagues administered CBG to mice and we saw a dramatic drop in blood pressure. For me,

(Continued on p. 16)

(Continued from p. 15)

that strikes me as a potential side effect that nobody's thinking about."

The paper predicts that, due to CBG's effects on Alpha-2, pure or highly enriched CBG will have unintended consequences that will also be unexpected because they'll come from outside the endocannabinoid system. "[CBG is] not just working on CB1 or CB2," he says. "It's potentially working on a dozen other receptors, all of which have differing activities, and no one's ever taken CBG at high concentrations," including, he notes, in the studies, which were conducted on mice. He says there is no data at all regarding humans and CBG, let alone CBG in a concentrated form.

For Dr. Vrana, that concentration is the very essence of the discussion about CBG, which under normal conditions appears in tiny amounts. "For CBG in particular, it's important for people to hear that no one is experienced with high concentrations of CBG because, historically, it hasn't existed. Under normal conditions, I don't believe [consumers feel the effects of CBG]. Cannabis doesn't express a ton of this. The fact that the plant makes it en route to making THC and CBD does not make it 'all natural.' There's also the misrepresentation of it as 'the mother of all cannabinoids,' which gives you the impression if you eat it, your body will convert that into THC and CBD. That's simply not the case."

Churchill concurs, saying, "There simply aren't a large enough number of studies, specifically clinical studies in humans, for us to draw any firm conclusions about the effects of CBN and CBG. The studies that do exist rarely control for these cannabinoids in particular. That may be changing, but for now, any claims about effects are based on speculation or anecdotal evidence."

Long-Term Research Still Needed

At the same time, Churchill also acknowledges there hasn't been any proof that CBN or CBG are unsafe for consumption either orally or by inhalation. "It's hard to ground their safety in science at this time, but the lack of reports of negative effects, even with cannabis use becoming increasingly common, is encouraging." Because THC, CBD, and CBN all derive from CBG, and they share a similar chemical structure, Churchill thinks it's likely that "CBN and CBG are no more dangerous than their more well-known cousins, THC and CBD."

That's nothing more than an educated guess, though. Churchill is quick to stress that we simply don't have very much information about CBG and CBN, and it will take time and study to figure out exactly what these compounds do—or don't do. He adds that long-term studies on cannabis use are still needed to be able to fully grasp the benefits and the risks that come with frequent cannabis consumption. "Until we know more about how [minor cannabinoids] interact with other cannabis constituents, we cannot predict the strength of physiological effects these cannabinoids may produce," he says.

Dr. Le agrees that the safety profile for rare cannabinoids remains unknown, and he too calls for further testing. "It's one thing to have rare cannabinoids at low concentrations as a side product of cannabis production. It's another thing entirely to deliver therapeutic levels of these compounds to consumers."

For CBG in particular, it's important for people to hear that no one is experienced with high concentrations of CBG because, historically, it hasn't existed.

—KENT VRANA, PHD

The good news, says Dr. Vrana, is that the concerns he has about CBG causing harm to consumers are limited to CBG being smoked or vaped. "If it's not being smoked," he says, "if it's being taken orally, it's not going to achieve terribly high concentrations and it's going to be a slow onset. That's why with edibles, you have such high concentrations [of cannabinoids]: It's not well-absorbed into circulation from the GI tract. These compounds are metabolized by the liver very assiduously."

Above all, Dr. Vrana argues that we shouldn't presume that CBG, CBN, or other rare cannabinoids, have therapeutic potential simply because CBD and THC do, because nothing yet has proven this to be true.

"Now, all of a sudden," Dr. Vrana says, "we have CBG where we didn't before, and people are making claims that it's going to have some advantages that we simply don't think are going to be proven true. They haven't been tested, and it has the potential for side effects."

The lack of regulation, Dr. Vrana believes, has allowed entrepreneurs to get out in front of the science, and that leaves him very uneasy about the future of rare cannabinoids. "I'm not here to be a Debbie Downer," he says, "but when people make these claims, ask them: What's the evidence for that? Tell me how you know that. I guarantee you they'll have none, or it'll be apocryphal." ■

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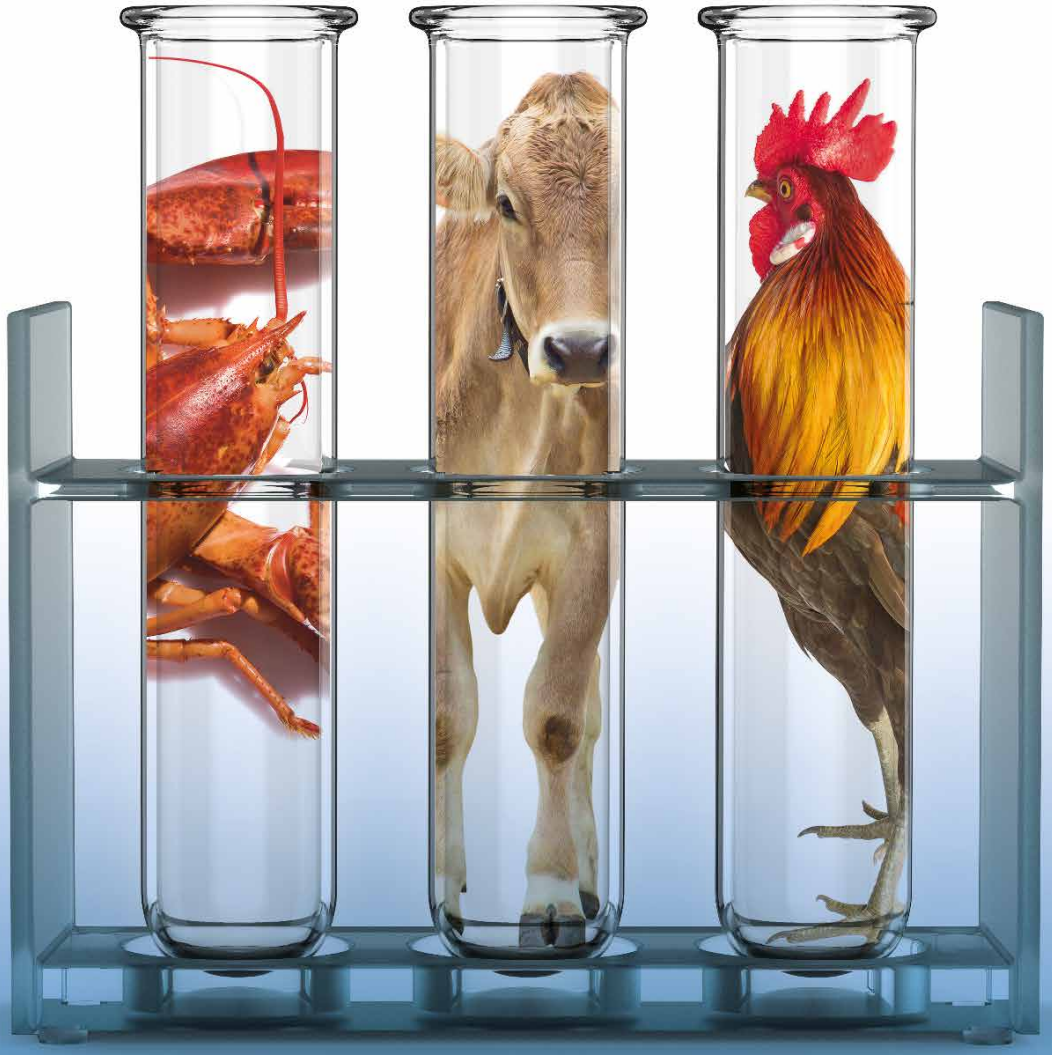
TAKE YOUR PICK!

Cell-Based Meat: The State of the Industry

The science and regulation behind cultivated meat, poultry, and seafood products

BY **MARY BETH NIERENGARTEN**



In November 2020, a major regulatory breakthrough occurred in Singapore: The Singapore Food Agency approved a cultivated meat product for commercial sale. The chicken product, developed by GOOD Meat, a subsidiary of San Francisco-based company Eat Just, was then launched commercially in restaurants and, in April 2021, it become available via home-delivered dishes.

The approval marks the first entry of a cultivated meat (also referred to as cell-based meat, lab-grown meat, or cellular agriculture; see "What's In a Name," p. 21) product into the commercial market, a milestone that comes after years of speculation, hype, and investor funds that anticipate these products will play a central role in the future of the meat industry. "This was an important milestone, not just for us, but for the food industry as a whole and the whole food system," says Peter Licari, chief technology officer at Eat Just.

Ronit Bakimer-Kleiner, vice president of regulatory affairs and product quality and safety at Aleph Farms, an Israel-based company that produced the first cultivated steak in 2018, also called this approval a milestone in bringing cell-based meat products to global markets and underscored the idea that the approval demonstrates that these products have become a reality much more quickly than many people may have anticipated. "It is not a long-term vision anymore, but rather a practical solution to some of our most urgent issues today associated with food production," she says.

For the growing number of companies now working to bring these types of meat and seafood products to market and the millions of dollars that have been invested—a recent report from Lux Research cited 80 startup companies in the sector as of 2021, with more than $800 million invested since 2016—ongoing challenges for developing widely available safe and high quality products remain, including scaling up production and distribution of the products once developed, educating consumers, and meeting regulatory requirements.

Technical Challenges: Developing Safe and High-Quality Products

Despite success in bringing the first cultivated meat product to market, Licari emphasizes that the technology for these products is still in its infancy. Ongoing work will continue to fine-tune important aspects of production such as nutritional composition and health considerations. Another important component of the research is developing products that create a sensory experience that consumers demand and want in their food, he says.

> There is a growing effort in the academic community to conduct and publish peer-reviewed studies on these topics, so things are progressing better the last few years, but we still have a long way to go and many fundamental questions to be addressed.
>
> —DAVID KAPLAN, PHD

Samuel S. Peabody IV, a PhD student in animal science at Texas Tech University in Lubbock, Texas, and a research fellow at New Harvest, a non-profit research institute focused on cellular agriculture, underscores the many challenges of bringing these types of products to fruition. "There are perhaps a thousand or more distinct research questions and engineering challenges to bring forward," he says.

Among the challenges are the methodologies and technologies used to actually create cultivated meat and seafood products, as well as the cost and optimization needed to manufacture them. Peabody says that the methodologies and technologies used depend on the intention and goals of the product desired.

A primary technology that has been successfully developed is using proliferated muscle cells from animals. "The core concept behind the process of cultivating meat lies in the 'tissue regeneration' process that is naturally happening in the body of any animal, when tissues renew and grow to repair or replace older tissues," says Bakimer-Kleiner, explaining that the platform used at Aleph Farms for cultivating their steak products mirrors this process of tissue regeneration. "The process is designed to use a fraction of the resources required for raising an entire animal for meat, and without antibiotics."

Explaining it another way, Eric Shulze, vice president of product and regulation at UPSIDE Foods, a California-based company that produced the first cultured beef meatball in 2016 and first cultured chicken and duck in 2017, says the process of making cultivated meat is similar to the one used for brewing beer. "It is an industrial cell culture process based upon well-hewn

(Continued on p. 20)

[Because this is] a new technology going to a regulator, I think it's imperative that we provide a complete package of all safety deliberations—from the master cell banks all the way through [to] the chicken that is served to the consumer.

—PETER LICARI

(Continued from p. 19)

fermentation technology," he says. "However, instead of growing yeast or bacteria, we grow animal cells."

"We start by taking a small amount of cells from high-quality livestock animals, like a cow or chicken, and then figure out which of those cells have the ability to multiply and form delicious meat food products," he adds. Once the cells are identified, they are grown in bioreactors or large containers in which they are provided essential nutrients to naturally replicate and mature in a clean and controlled environment. Shulze describes this environment as recreating the conditions that exist inside an animal's body. "Once the meat is ready, we harvest it, process it like conventional meat products, and then package, cook, or otherwise prepare it for consumption," he says.

Critical components to the process include identifying cell sources, selecting the media in which to grow the cells, determining how to permit cells growing in the media to create a matrix and structure (scaffold) that mimics the architecture of meat (or seafood), and designing bioreactors to provide a controlled environment in which to grow the cells.

David Kaplan, PhD, professor and chair in the department of biomedical engineering at Tufts University in Boston, is at the forefront of understanding the science of cultivated meat and seafood. He says that a lot of progress has been made on all of these components but that much more is needed to figure out and optimize the processes. "There is a growing effort in the academic community to conduct and publish peer-reviewed studies on these topics, so things are progressing better the last few years, but we still have a long way to go and many fundamental questions to be addressed," he says.

Peabody gives examples of areas that need further research. One is the need for developing alternative media preparations when using proliferated muscle cells that don't require animal products other than donor cells. Another is improving optimization and reducing the cost of media preparations, a task he says is being undertaken by numerous research groups and companies. He adds that much of the research to date has been conducted in mammalian models. "There is a considerable gap, in my opinion, for fish and other non-mammalian species," he says. "However, it should be noted that muscles are older than fish and mammals and dinosaurs, etc., so there might be comparisons that can be made to simplify."

Concomitant with the ongoing work to better understand the science of producing cultivated meat and seafood products is ensuring their safety and then, once approved, scaling up production to meet consumer demand.

Ensuring Safety

Licari takes a broad view of safety, particularly given the new technology involved in bringing these types of products to market. "[Because this is] a new technology going to a regulator, I think it's imperative that we provide a complete package of all safety deliberations—from the master cell banks all the way through [to] the chicken that is served to the consumer," he says.

Environmental management and monitoring are critical components of that package, he says. For example, he cites the importance of ensuring that all components in the growth media are safe, as are the equipment and supplies used. "We need an environment that allows us to maintain sterility through the duration of the run," he adds.

Bakimer-Kleiner also emphasizes the food safety strategy implemented at Aleph Farms that addresses the distinctive aspects of cultivated meat production. Among them is identification of safety measures to avoid contamination using the good manufacturing practices, hazard analysis, and risk-based preventive controls, implementing quality assurance of cellular attributes at each stage of the process, preventing food fraud by developing a set of product trackers that can provide inspectors with a tool to verify products that differentiate cell-cultured meat from conventional meat, and thoroughly screening cell banks that are prepared as raw materials for producing cultivated meat to ensure that only high-quality and safe cells are used.

What's In a Name?

The question of what to label these cultivated products is ongoing, with no standard term yet agreed upon. In Singapore, GOOD Meat is referring to its first commercially launched product as "cultured chicken," but is leaning toward labelling these products as "cultivated meat" in the U.S. UPSIDE Foods refers to their products as "cultured," and Aleph Farms refers to their products as "cultivated." Other common phrases for these products are "cell-based" and "cell-cultured." While all of these terms denote the same type of product, the variation may be confusing to consumers when these products become more widely available.

William Hallman, PhD, professor and chair in the department of human ecology at the School of Environmental and Biological Sciences at Rutgers University in New Brunswick, N.J., cites a number of reasons to create a standard or uniform label for these products, among them ensuring that consumers know exactly what they're buying and eating. "I'm an experimental psychologist, and one of the things we talk about is a concept known as 'gist'—do people get the underlying meaning?" he says. "I'm interested in finding a name that helps convey intuitively what these products are."

Not only is consumer understanding desired, but when it comes to the FDA and USDA, it is legally required. Dr. Hallman underscores the fact that both agencies require products to be labeled by their common or usual name so that consumers are not misled about what food they are buying.

"If we can get the industry and regulators and consumer groups and activist groups to choose a single name and stick with it, it will become the common name for these products," he says. "When these products finally hit the market in the U.S., there will be a wave of publicity. Consumers will begin to search the Internet to learn more about them, so it's important that the term chosen leads them to the right information."

Licari agrees that a standard term used globally is important. "Being the first for regulatory approval and launch, we're charting new territory, but certainly I think having a term that we can all rely on, and understand exactly what that is, is important," he says.

In September 2021, the USDA Food Safety and Inspection Service published an advance notice of proposed rulemaking on how to label meat or poultry products composed of or containing cultured animal cells. The 60-day period for comment ends November 2, 2021. Visit www.fsis.usda.gov for more information.—*MBN*

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Both Licari and Bakimer-Kleiner emphasize that, unlike conventional meat, antibiotics are not needed to produce cultivated meat products. In addition, because no animal slaughter is involved, the risk of pathogens, such as *Salmonella* or *E. coli*, is mitigated in cultivated meat.

Scaling Up Production and Meeting Consumer Demands

The product from GOOD Meat is being marketed as an alternative to conventional chicken that doesn't involve intense animal farming or slaughter of animals, says Licari. He emphasizes that a primary motivator behind the creation of these products is that they are seen not only as a more humane and sustainable way to offer a meat-based protein to consumers, but also as a way to broaden the reach of meat protein to consumers in a world where meat consumption—and population growth—is on the rise. "As the world's population grows and our hunger for meat continues to grow, alternative technology like this is necessary," he says.

Scaling up the production of these products to meet this growing demand is another challenge. For Peabody, it goes hand in hand with food safety. "For stakeholders who are successful in scale-up, there ought to be a careful consideration of preventive controls," he says, citing four types of preventive controls (process, sanitation, supply chain, and allergen) that play a role in a food safety plan and are essential to ensuring an efficient and safe scale-up of a product that also meets regulatory approval.

"Every person involved in the scale-up process should have an intuitive grasp of what these [preventive controls] are and how they work," he adds.

The bottom line is that, given the level of investment made into the research that must go into bringing these products to a wide audience, meat grown from cells is no longer science fiction, but reality. ■

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Dry Cleaning in the Food Industry

Part 2: Solutions to Challenges

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

Editors' note: *This is part 2 of a two-part series on dry cleaning. Part 1, which published in the August/September 2021 issue of* Food Quality & Safety, *looked at the rationale for dry cleaning and the challenges that can accompany the process. Part 2, published here, focuses on solutions to these challenges.*

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

Control Water at the Site of Personnel Entry

As discussed in the first article in this series, the water used to ensure personnel hygiene at the entry point to the production area can itself lead to the growth and spread of contamination. For dry food production, this risk could be minimized through a slight change to the personnel entry procedure; have personnel wear clean production area footwear and protective clothing after thorough hand washing and drying, followed by the use of a hand sanitizer immediately after entry to the food production area (see Figure 1, p. 23).

Control Water Through Dry Cleaning

Fortunately, when it comes to controlling microbial growth and spread through the use of dry cleaning, there are plenty of methods available. This dry cleaning can be as simple as using a brush and dustpan or as complex as dry ice blasting. Dry cleaning methods include:

- Pigging;
- Granular purging, scrubs, and blasting;
- Dry ice;
- Compressed air;
- Vacuuming;
- Wiping;
- Scraping;
- Scourer pads;
- Brushing, scrubbing, and sweeping;
- Detail cleaning;
- Dry steam; and, if all else fails,
- Disassembly and removal for wet cleaning and drying.

While the use of these dry cleaning methods will limit microbial growth, all have the potential to spread contamination if used inappropriately. Figure 2 (see p. 23) ranks most of the different cleaning methods in order of risk with regard to the spread of contamination.

Most dry cleaning methods are ranked at the lower end of this scale. Notable exceptions to this are the blasting of surfaces with inert granules, sugar, salt, or dry ice fragments and the use of compressed air.

Pigging. This method uses a specialist projectile (the "pig") that is pushed or pulled through pipework to remove dry debris inside. The pig has a diameter slightly larger than the pipe, and this compact fit enables it to maintain full contact with the pipe and push most of the debris to waste or for recovery. Pigging is a gross contamination removal technique, and further cleaning of the pipes may be required.

Granular purging, scrubs, and blasting. This involves the use of inert granules, or food items such as salt and

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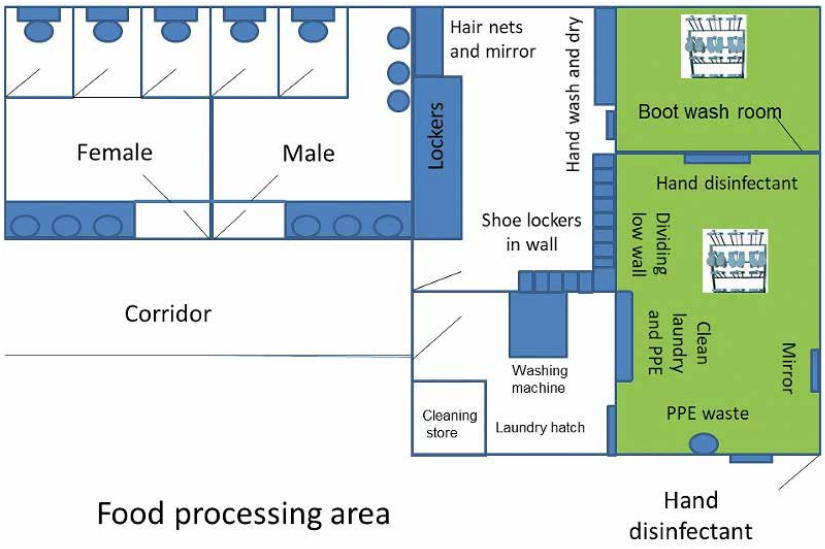

COURTESY OF VIKAN.

Figure 1: Suggested personnel entry facility layout for a dry food plant.

sugar, to provide an abrasive force for the removal of contamination from the inside surfaces of pipework or open surfaces. For pipework cleaning, care must be taken to select a purge material that will not affect the quality or safety of the product and/or that can be fully recovered or removed as part of the cleaning process.

Dry ice. This method uses carbon dioxide to form dry ice crystals that are then projected at high velocity onto an open surface, where they provide an inert abrasive force for the removal of contamination.

Compressed air. Here, high-pressure air can be used to dislodge contamination from the nooks and crannies of equipment with complex, detailed structures.

For the techniques above that use high speed and/or pressure to aid open surfaces cleaning, be aware that all they do is move the contamination from a surface to the surrounding environment. Thorough cleaning of the surrounding environment will still be required to control the build-up of contamination.

Additionally, be aware that the use of these techniques will lead to the uncontrolled dispersion of particles that may be contaminated with microbes and/or allergens; these particles can remain in the air for considerable periods of time and travel great distances to settle elsewhere in the production area, including on food contact surfaces. Consequently, their use must be considered very carefully.

Vacuuming. This is a fast, effective, and low risk cleaning activity commonly used in dry food production. Even so, there are several things to consider regarding safety and the spread of contamination.

First, in Europe, vacuum cleaners used in dry, dusty environments must be certified to ATEX 95 "equipment" directive 94/9/EC, which covers equipment and protective systems intended for use in potentially explosive atmospheres. In the U.S., equipment used for this purpose must have the specific mark of one of the testing laboratories recognized nationally to test and certify this type of equipment.

Vacuum cleaners should also be fitted with appropriate bag and exhaust filters (e.g., HEPA) to prevent re-contamination of the environment by the air being expelled from the vacuum exhaust.

Another challenge associated with vacuum cleaners is that the attachments, such as brushes and nozzles, are rarely available in different colors, making it difficult to segregate them for different uses, e.g., the cleaning of allergenic versus non-allergenic dry ingredients. Many resort to the use of colored tape, which can bubble and peel, creating contamination traps and increasing foreign body risk.

Vacuum systems are available for high-level cleaning. These will minimize the risk of debris falling onto surfaces below and reduce particle generation.

Wiping. This is another low risk dry cleaning activity. Cloths can be made of fabric, paper, or microfiber, and can be reuseable or disposable. Low linting fabric and microfiber cloths are recommended, as they minimize foreign bodies, but, if reuseable, they must undergo a suitably validated laundry process to remove contamination between uses. Microfiber that is used dry or damp—not wet—can be extremely effective at removing traces of allergen and oily residues, respectively, even without the use of chemicals.

Similarly, microfiber dry and damp "mopping" systems can be used on floors, walls, and other large, flat surfaces, and microfiber dusters can help remove and capture dry surface contamination.

Scrapers. These can be used for the removal of stubborn deposits that have been

(Continued on p. 24)

Figure 2: Risk ranking of cleaning methods with regard to spread of contamination.

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(Continued from p. 23)

dried or baked onto a surface, or heavy grease or confectionary deposits. Scraper blades come in stainless steel, polypropylene, or nylon materials. The choice will depend on the surface type to be cleaned (e.g., liable to scratching or a hot surface), just as the blade shape, size, and thickness will depend on what you are cleaning, such as floors or equipment. Some scrapers can be fitted to a variety of handles to achieve the required reach (see Figure 3, at right).

Scourer pads. These can also be very effective at removing stubborn deposits; however, they tend to break up during use and, consequently, create a foreign body hazard. They are also difficult to clean and disinfect, due to their net-like structure, which allows food debris and microbes to penetrate and be difficult to remove. Additionally, most, if not all, are non-food contact compliant.

Brushes. These can be used for a variety of dry cleaning activities, including scrubbing, brushing, and sweeping. Stiff-bristled brushes are good for scrubbing and removal of dried-on, stubborn soils. Soft-bristled brushes are good for removal of loose, dry soils, in combination with a dustpan, scoop, or shovel. Single-bladed squeegees are also very effective at removing loose, dry soils and have the advantage that they don't clog and are much quicker and easier to clean after use.

Brushes can also be used for the removal of high-level debris, but be aware of possible cross-contamination of any surfaces below. Also, be aware that vigorous scrubbing, sweeping, and brushing can lead to greater spread of contamination. The cleaning and sanitation crew should be trained in the efficient, effective use of the cleaning tools and understand that the way they are used can impact contamination spread.

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Figure 3: Use scrapers to remove dried or baked on soils, and heavy grease, or confectionary deposits.

Detail cleaning. This method uses small-scale brushes and scrapers to clean nooks and crannies in complex equipment.

Dry steam. Dry steam is saturated steam that has been very slightly superheated. This state results when water is heated to boiling point and is then vaporized with additional heat. It has a very high dryness fraction, with almost no moisture (<0.5%). The use of dry steam for cleaning has proved useful in aiding the removal of low moisture foods such as fats and chocolate, in combination with scrapers and wipes.

Disassembly and removal for wet cleaning and drying. If any of the above dry cleaning techniques prove untenable, equipment that is moveable can always be removed from the dry production area to a segregated room, where it can be thoroughly wet cleaned and dried before being returned to production.

Control Contamination Through the Use of Dry Sanitization

Several dry sanitization options are available, including the use of alcohol-based wipes and sprays, heat (including dry steam), radiation (including ultraviolet (UV) light), and fumigation using hydrogen peroxide vapor and ozone gas.

Alcohol-based wipes and sprays. The constituents of alcohol-based wipes

Table 1. Advantages and disadvantages of some dry sanitization methods.

Dry sanitization method	Characteristics	Advantages	Disadvantages
Alcohol-based wipes and sprays	Good for food contact surfaces that need to be dry after application, and hand hygiene products.	Broad spectrum activity. Can be used on water sensitive equipment. Quick drying, no residue. Non-staining, non-corrosive.	Not effective against spores. Quickly inactivated by organic material. Flammable. Expensive.
Heat	Shorter exposure time requires a higher temperature. Wet heat more effective than dry heat.	Broad spectrum efficacy. Non-corrosive. Penetrates surface. Leaves no residues.	Not suitable for all materials. Health and safety.
UV	Dose is a combination of intensity and time. Dust, thin films of grease, and opaque or turbid solutions can attenuate UV.	Non-thermal. Non-chemical. Wide spectrum. Non-corrosive.	Set up and maintenance costs. Shadowing. No residual effect. Occupational exposure hazard.
VHP	Powerful oxidizing agent as a vapor for small equipment or area (whole room) sanitization.	Broad spectrum efficacy. Leaves no residue. Decomposes to oxygen and water. Able to penetrate areas inaccessible to chemical fogs. Non-corrosive.	Cost of specialist equipment. Health and safety. Unstable. Humidity sensitive. Not suitable for use with nylon.
Ozone	Powerful oxidizing agent as a gas for small equipment and area (whole room) sanitization.	Broad spectrum efficacy. Leaves no residue. Decomposes to oxygen and water. Able to penetrate areas inaccessible to chemical fogs.	Cost of specialist equipment. Health and safety. Unstable. Humidity sensitive.

and sprays produced for use in dry-processing environments should be effective against the target microorganisms, should not introduce water into the environment, and should dry rapidly following application to the surface. For best results, they should also have a residual antimicrobial effect and must be approved for use with food. Common constituents of these wipes and sprays are ethanol or isopropyl alcohol (~60%) and a quaternary ammonium compound (~200 ppm).

Heat. Whether applied to the cleaned surface through the use of hot air, radiated heat, or dry steam, heat is a useful tool in dry sanitization. Dry heat sanitizers can be used for smaller pieces of equipment. This technique is nontoxic, is easy to install, has relatively low operating costs, penetrates materials, and is noncorrosive for metal and sharp instruments. The disadvantages of this method are the slow rate of heat penetration and microbial kill compared with wet-heat options and the fact that the high temperatures used are not suitable for many materials. The most common time–temperature relationships for sanitization with dry-heat sanitizers are 170°C (340°F) for 60 minutes, 160°C (320°F) for 120 minutes, and 150°C (300°F) for 150 minutes.

UV. Treatment with UV light provides a non-thermal, non-chemical technology that will inactivate microorganisms. UV light units are commonly used to disinfect food processing water in factories, treat the air entering the processing area, and sterilize packaging materials before filling. The dose required is a combination of intensity and time and, to be effective, the light rays must strike the microorganism.

UV light is a part of the electromagnetic spectrum within the wavelength range of 100 to 400 nanometers (nm). It can be divided into three main bands: UV-C (200 to 280 nm), UV-B (280 to 315 nm), and UV-A (315 to 400 nm). UV-C is commercially used for decontamination applications because it has the greatest germicidal activity. UV-C light (254 nm) primarily inactivates microorganisms by damaging their DNA, which prevents further replication. Microorganisms differ in their sensitivities toward UV treatment due to differences in cell structure, DNA base content, and repair mechanisms. Many microorganisms have enzyme systems that can repair damage caused by UV exposure. Therefore, it's important to ensure that a sufficient fluence of UV-C is delivered to inactivate the targeted microorganism.

Fumigation

Vaporized hydrogen peroxide (VHP). Hydrogen peroxide solutions have been used as chemical sterilants for many years. However, VHP offers a broad spectrum, dry oxidizing sanitization technique that can be used to sanitize both small pieces of equipment (in a chamber), and large and small areas (using atmospheric systems). The chamber systems use a deep vacuum to pull liquid hydrogen peroxide (30% to 35% concentration) from a disposable cartridge through a heated vaporizer and then, following vaporization, into the sterilization chamber. The atmospheric systems typically use a decontamination cycle consisting of four phases:

1. Dehumidification, which reduces the relative humidity of the room being disinfected to less than 40%;
2. Conditioning, when the VHP is produced by vaporization of 35% liquid hydrogen peroxide;
3. Decontamination, maintaining a steady concentration by introducing and removing VHP; and,
4. Aeration, where the residual vapor is catalytically decomposed into water vapor and oxygen.

Fumigation using VHP offers rapid cycle time (e.g., 30-45 minutes), low temperature operation, environmentally safe by-products (H_2O, O_2), good material compatibility, and ease of operation, installation, and monitoring. It has been found to be a highly effective method of eradicating vegetative cells, spores, and viruses. VHP does have some limitations, one of which is that it will cause nylon to become brittle.

Ozone. Ozone is a water-soluble, naturally occurring gas that is a powerful oxidizing agent. It is also very unstable, with a half-life of 22 minutes at room temperature, and, on exposure to air and water, it rapidly converts back to oxygen and water; it therefore needs to be generated at the point of use. Ozone has been used for years as a drinking water disinfectant and can be used as a fumigant to sanitize small pieces of equipment (in a chamber) and for whole-room sanitization. It is created using oxygen, steam-quality water, and electricity. When the O_2 is energized, it splits into two monatomic (O_1) molecules. These then collide with O_2 molecules to form O_3 (ozone). This additional oxygen atom creates the powerful ozone oxidant with demonstrable efficacy with a variety of microorganisms. As a rule, a 2-log reduction in two hours with 2 ppm gaseous ozone has been suggested. Ozone also has the advantage of being compatible with a wide range of commonly used materials, including stainless steel, titanium, anodized aluminum, ceramic, glass, silica, PVC, Teflon, silicone, polypropylene, polyethylene, and acrylic (see Table 1, page 24).

No matter which solutions you choose, it is essential that the equipment and chemicals you use are appropriately approved for use in food preparation areas and can be used in contact with food and/or food-contact surfaces. The cleaning and sanitization processes should also be validated and verified. ■

For Further Reading

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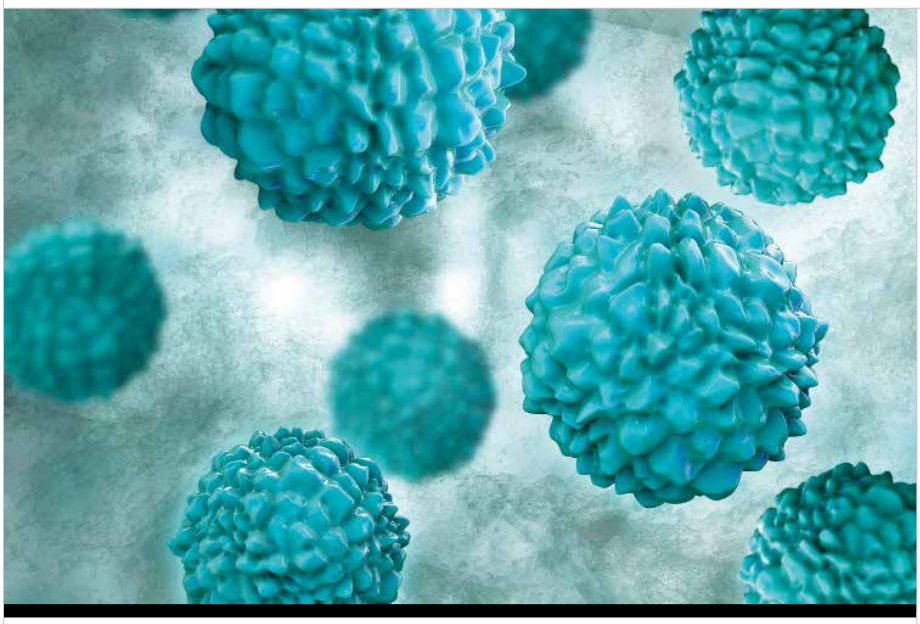

COVID-19 and Food: A Japanese Perspective

An increase in norovirus cases in Japan has the country's media reporting on COVID-19 infection via food; how the viruses differ

BY **KIYOKO R. KUBOMURA, PHD**

Since the beginning of the COVID-19 pandemic, people around the world have eaten billions of meals and, despite significant rates of infection throughout food processing, handling, distribution, and retailing facilities, there appears to be no conclusive evidence that the disease has been transmitted from the source of infection via the food supply chain.

There has been considerable discussion in Japan about the connection between food and the potential risk of SARS-CoV-2 transmission through food and the potential implications for food safety. The context for this has been the Japanese media reporting on news that Chinese regulatory authorities have detected the virus on frozen food products and speculation that an employee infection cluster in a Japanese food factory was caused by food contact. Recent announcements from China seem to indicate that this mode of transmission may have contributed to the global pandemic. Because China is one of Japan's closest neighbors and exports foods to the country, these allegations cannot be ignored.

Furthermore, a recent increase in norovirus cases in Japan attributed to foods has added to concerns about viral transmission via food. The norovirus season is generally observed from early autumn to mid-winter, but outbreaks have occurred in spring and summer. While norovirus and SARS-CoV-2 are both viruses, they are very different in structure and in how they are affected in different environments. For example, alcohol does not adversely affect norovirus, but is effective for disinfection and as a countermeasure against COVID-19. It is imperative to understand the relationship between COVID-19 and food and to clarify how that coronavirus differs from norovirus.

Viruses usually remain viable and stable at cooler temperatures, even at a domestic refrigerator temperature of approximately 4°C. They are not inactivated, remaining viable for months. They do not lose their infectivity even at -70°C.

One report indicates that COVID-19 is able to maintain viability and will remain infective for between four and 21 days at 4°C. Therefore, it is not improbable to see reports that the virus was detected on frozen products. There are reports that COVID-19 has been isolated on chicken meat from Brazil and on shrimp from Ecuador.

Viral Infection from Food

There are two proposed routes for viral infection from food. In the first route, it is theorized that COVID-19 adheres to the surface of food, food containers, and packaging and is released through handling, allowing the virus to enter the body via the mucous membranes of the mouth, nose, and eyes. The second route involves COVID-19 that is present on or in food products that are consumed and the theory says this causes infection through the epithelial cells of the digestive tract and thereby proliferates. Neither of these routes have yet been verified.

Experiments with coronavirus attached to various materials in the laboratory have shown that the virus retains its infectivity on the surface of objects for quite some time. COVID-19 has been compared with the severe acute respiratory syndrome (SARS) virus that prevailed in 2002 and the Middle East respiratory syndrome (MERS) first reported in 2012, and it is thought that it will have a similar lifespan (see Table 1, below).

Table 1. Persistence of Coronaviruses on Different Types of Inanimate Surfaces.

Type of Surface	Virus	Remaining Period
Iron	• MERS • Mouse viral hepatitis	• 48 hours • 4-28 days
Aluminum	• Human coronavirus	• 2-8 hours
Wood	• SARS	• 4 days
Paper	• SARS	• 4-5 days
Glass	• SARS	• 4 days
Plastic	• SARS • MERS	• 6-9 days • 48 hours

Reprinted from *J Hosp Infect*, vol. 104, Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents, pages 246-254. Copyright 2020, with permission from Elsevier.

Table 2. The Difference Between COVID-19 and Norovirus.

	Transmission Route	Days to Potential Infection from Surfaces (e.g., on the surface of furniture, etc.)	Heat Activity to Inactivate	Sterilization/ Disinfection	Preventive Hygiene Measures
COVID-19	Inhalation transmission via mucous membranes of the mouth, nose, or eyes.	A few days.	Time at 70°C	60% alcohol (or greater) surfactants (soap, detergent, sodium hypochlorite solution)	• Wash hands and wear a mask in public. • Keep a 2 m distance from other people. • Avoid crowded areas. • Avoid indoor areas with poor ventilation. • Avoid areas/situations likely to increase transmission. • Sanitize contact surfaces regularly.
Norovirus	Infects and multiplies in the small intestine after oral entry through the mouth.	Multiple days to weeks.	85°C to 90°C for more than 90 seconds.	Sodium hypochlorite solution.	• Wash hands carefully. • Heat food before eating. • Don't cook or handle food if unwell. • Sanitize contact surfaces regularly.

However, in reality, food does not appear to be a significant or likely path to infection with SARS-CoV-2. Experts at the World Health Organization have emphasized that China has sampled very large volumes of food packaging but found very few positive samples. In addition, there have been questions regarding the test methods employed by the Chinese researchers.

The theories about the consumption route to infection come with certain concerns. COVID-19 has an outer membrane called an envelope. It's believed that the envelope makes it easier for the virus to attach to specific cells in the mucous membrane and multiply. However, the envelope is fragile when exposed to an acidic environment; therefore, the virus would lose its infectivity when exposed to stomach acids.

Norovirus has no envelope, and its protein is exposed. Normally, this protein has some resistance to acids. Therefore, even if food containing norovirus enters the mouth and is digested, it retains the ability to pass through the stomach acids and reach the small intestine, resulting in food poisoning. Stomach acid has a pH of about 2.

Envelope viruses are stable at pH 5-9 and have little resistance to an acidic environment, so even if the new coronavirus is eaten, the envelope will be broken and viral activity will be lost when it comes into contact with stomach gastric acid. So, contracting an infection through this route is not believed to be possible. It is reported that norovirus can tolerate a pH of 3, however, so if you eat foods high in norovirus, there is the potential that some of them will pass through your stomach acids and enter your small intestine. The end result is that norovirus can cause food poisoning, but that the new coronavirus does not.

Gastrointestinal issues such as diarrhea may affect people infected with the new coronavirus. It's believed that this may occur after the new coronavirus has entered the lungs and spread through blood vessels, eventually reaching the digestive tract. This route has not been confirmed, however, and the WHO and the Japanese Ministry of Health, Labour and Welfare have not declared that infection by food does not occur.

It's obviously quite confusing for the average person trying to understand the realities of viral infectivity. No one can say that the chances of both the first and second routes are zero, but the odds of food or food packaging being the cause of a COVID-19 infection are extremely low. Therefore, infection from food is regarded as highly unlikely and is considered even more unlikely if one looks at Japanese food factories. They typically have highly developed food hygiene processes and generally have a commitment to a food safety culture that minimizes the potential for foodborne infection.

The Difference Between COVID-19 and Norovirus

Recently, the norovirus infection rate has increased noticeably in Japan. Norovirus is different from the new coronavirus both in terms of viability in stomach acid and heat resistance. Generally, norovirus is inactivated by exposure to temperatures between 85°C and 90°C for more than 90 seconds. The new coronavirus is inactivated at 70°C. Furthermore, there are earlier significant differences in how the two viruses react to different chemicals used for disinfecting (see Table 2, above).

Because the new coronavirus has an envelope, alcohol and surfactants, such as soap or detergent, that break the envelope work well. Of course, a sodium hypochlorite solution (made by diluting bleach at home) is also effective. On the other hand, because norovirus has no envelope, it's actually quite strong against alcohol and surfactants in detergents or soaps. In other words, these do not work. Sodium hypochlorite solution must be used to disinfect norovirus.

Understanding the infection route of norovirus makes it easier to understand the countermeasures. Norovirus propagates in the human body but cannot multiply in food or on its surfaces. There are also contact infections through doors and toilets, and droplet infections. Therefore, as countermeasures against norovirus, food should be heated to inactivate the virus before eating, and an infected person should not handle food or cook. Wash hands thoroughly before doing anything with food, and disinfect with the appropriate chemicals.

Today, the real concerns with food poisoning come from pathogenic bacteria such as *Campylobacter*, *Salmonella*, and *Listeria monocytogenes*, not viruses. ■

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Quality

The Lactic Acid Shortage

The acid has many uses in the food processing industry, but the pandemic has placed it in high demand | BY **ELIS OWENS, PHD**

According to a 2020 report from Reportlinker.com, the global lactic acid market is projected to reach nearly $2,218 million by 2027, up from some $1,070 million pre-pandemic. Experts estimate the market will grow at a compound annual growth rate of 9.6% between 2020 and 2027.

While many industries experienced heavy losses or disruption over the past year due to the pandemic, others—such as the lactic acid market—faced skyrocketing demand for their products. Versatile, eco-friendly, and generally safe, lactic acid is one of those products for which demand has outstripped production.

For food processors, the shortage is concerning. Lactic acid and its derivatives are highly effective in controlling pathogenic bacteria in both fresh and ready-to-eat meat products, such as deli meat and jerky, and thus play an essential role in food safety. Here's a rundown of the state of the industry and how food processors can navigate the shortage.

Why the Shortage?

With applications in a wide range of industries, from pharmaceutical to meat and poultry production, lactic acid has been in high demand for many years. It is also a common ingredient in skincare products, cosmetics, and some "natural" disinfectant products and has endless applications in the food and beverage industry, including a role in producing cheese and yogurt, extending the shelf-life of various foods, and assisting with the fermentation process. In the brewing industry, lactic acid is used as an acidulent to increase process efficiency and support proper flavor development. These industries favor lactic acid over other ingredients, as it's a natural product and is an expected component of the flavor profile of these products.

These uses are just the start of the many applications for lactic acid; it's also a vital ingredient in bioplastics and packaging, both of which have increased in production in recent years and, in themselves, have countless other uses. Now, the COVID-19 pandemic, in conjunction with the push for more sustainable plastics, has exacerbated the need for lactic acid.

The Role of Packaging Sustainability and COVID-19

Heightened attention to plastic pollution has driven companies around the globe to reduce their reliance on plastics in recent years. Armed with a new awareness of the Great Pacific Garbage Patch and the growing piles of plastics in oceans and landfills, consumers have started to call for more sustainable practices and packaging, leading in part to increased use and development of bioplastics. Polylactic acid (PLA)—derived from lactic acid—is a critical building block of bioplastics, and researchers anticipate that PLA will reach a market value of $2,091.29 million by 2023, compared with $698.27 million in 2017, according to 360 Market Updates. The growing market value is due to this focus on degradability, as well as new government policies.

The COVID-19 pandemic has also heavily influenced the demand for PLA. As the virus began to spread globally, so did the need for PPE—and, therefore, plastics. Consumers and governments began to see plastic less as the enemy and more as a necessary evil as suppliers scrambled to get PPE into hospitals and stores. However, that perception has again shifted with the growing sea of single-use PPE, takeout containers, and plastic bags making it to landfills. As the pandemic slows in the U.S. and other countries, PPE suppliers are still using petroleum-based plastics in their production of these supplies. But they're setting their sights on degradable options, as are other producers of single-use plastics.

That's because PLA-based plastics offer an advantage when it comes to environmental and sustainability initiatives. PLA-derived materials can break down in commercial or industrial composting facilities, unlike petroleum-derived materials, which can persist for hundreds of years.

At the same time packaging and plastic producers are experiencing higher pressures to use more sustainable materials, lactic acid and PLA producers face barriers to meeting the demand for their products. While the spread of COVID-19 has slowed in places like the

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Aseptic Food Processing

Seven critical components for optimal performance

BY **PABLO CORONEL, PHD**

Aseptic food processing involves sterilizing a product that is then filled and packaged under sterile conditions into a sterilized container before being exposed to the environment. Aseptic processing results in shelf-stable products that have a long shelf life. This is a complicated process in which many critical factors must be managed, monitored, and documented.

The COVID-19 pandemic has shown us that this type of processing is a smart investment that will continue to pay off. As restrictions during the pandemic caused bottlenecks and scarcity in the fresh food supply chain, consumers flocked toward shelf-stable items, revealing demand. Aseptic processing and packaging will continue to close supply chain gaps as manufacturers are freed from providing refrigerated or frozen storage.

While the demand for shelf-stable items is here to stay, aseptic processing is a complex undertaking with many variables not seen in traditional food processing—from product and process design, to instrumentation and records, to training and monitoring. To maximize your investment—and to protect the end consumer—it's important to fully understand the processes and commit to maintaining and monitoring aseptic production performance. In other words, it's not a "build it and forget it" endeavor.

Based on my more than two decades working globally in aseptic processing and packaging facilities with design and production teams, I've seen in real time the successes—and challenges—of aseptic processing operations. Here are my top seven strategies for long-term aseptic processing performance, including designing, monitoring for quality assurance, training, and improving continuously.

1. Coordinate Processing Operations

Every part of the system, from purchasing, utilities, ingredient dosing, batching, and mixing, to the thermal process, control, and data recorder, must be designed with the purpose of operating as designed—concurrently—at all times. Aseptic processing and packaging require high attention to detail, and small mistakes in any of these areas can lead to costly problems.

I've seen large quantities of product destroyed because a simple gasket wasn't replaced on time, which led to contamination. It's worth the time, effort, and expense to execute a flawless design from the very beginning, in which the key stakeholders of the company—including quality assurance and safety and experienced and qualified engineers—produce a good design, taking into account every aspect of the process line, including utilities, sanitation, and environmental equipment.

2. Success Comes from a Good Plan

Aseptic processing design requires planning for several scenarios based on the flexibility needed by the producer as well as the variability in ingredients and supply chain. Aseptic "hidden costs"—such as downtime for maintenance and sanitation, preventive maintenance, calibration, and inspections—should be considered from the start. Design that simplifies these operations allows faster turnaround time and higher productivity.

It's important to involve a process authority from the beginning to ensure that all legal requirements are considered and that future modifications to the line will be minimal. Aseptic processing relies heavily on the scheduled process given by a process authority, as part of a complete food safety plan, to produce safe and high-quality products. During the design stage, it's a good idea to develop a design/food safety plan where several control points will be identified and design allowances made for instrumentation, recordkeeping, and calibration.

3. Validation Is Not a One-Time Activity

Validation is typically associated with commissioning and hazard analysis and critical control points (HACCP), but in real life, it's a continuous activity that is closely tied with operations and quality. During commissioning, validation activities are carried out to ensure that the production line and packaging equipment will perform as designed. Automated control systems, clean in place, and sanitation, as well as process line, need to be validated periodically to ensure they are still working as planned. Other activities, such as maintenance and change management, should also be considered part of continuous validation.

4. People Make the Difference

This is one of the biggest culprits in waning vigilance over time for aseptic processing. Every employee involved in the validation

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Testing

Harmonized Enrichment

Accelerate food pathogen detection by enriching multiple bacterial species at the same time

BY **REBECCA DIEVART** AND **YANNICK BICHOT**

According to the World Health Organization, 600 million cases of foodborne illness occur every year worldwide, causing 420,000 deaths. About 60% of these cases are caused by pathogenic bacteria. As such, the detection of bacterial contamination in foods represents an important health safety concern and a great challenge to global food security.

To prevent foodborne illness, food safety regulations require that manufacturers ensure their food meets highly specific microbiological standards, but pathogenic bacteria, such as *Salmonella* spp., *Listeria monocytogenes*, Shiga toxin-producing *Escherichia coli* (STEC), and *Cronobacter* spp., are usually present only in a very small amount within a food sample. Therefore, manufacturers need to enrich their samples prior to testing in order to detect pathogens.

The Need for Bacterial Enrichment Prior to Food Analysis

A reliable method for detecting pathogenic bacteria must support their growth and enable their identification based on physiological, metabolic, or molecular characteristics. It also must be sensitive enough to detect one pathogenic bacterium in a 25-gram food portion for the food to be considered safe. However, no method, whether microbiological, immunological, or molecular, is sensitive enough to directly and reliably detect such a low concentration of bacteria, especially in the complex environment of a food sample. For this reason, regardless of the detection method used, all samples must undergo preliminary enrichment to grow the target bacteria to detectable levels.

Enrichment poses different challenges than pathogen detection. For example, during enrichment, pathogen growth might be interfered with by important and various competitive background microflora. The growth of these competitive species must be limited using selective conditions; however, the target bacteria might also be sensitive to these conditions, especially if they've been exposed to environmental stressors, such as heat, drying, freezing, or exposure to acids or to sanitary compounds during food processing treatments. These stressors can cause damage to bacterial cell membranes, delaying exponential growth. Consequently, the detection method must enable a rapid resuscitation of the stressed bacteria and promote their growth by inhibiting other competitive microorganisms.

How Harmonized Enrichment Works

Pathogen detection methods traditionally employ an enrichment step that targets one pathogenic genus or species; however, pathogen detection would be more efficient if one could enrich multiple bacterial species at once. About 20 years ago, the concept of simultaneous pathogen detection emerged with the development of the universal pre-enrichment broth (UPB). This medium was initially designed for the co-detection of *Salmonella* spp. and *Listeria* spp., two pathogens commonly found in dairy products, meat, and poultry. Then, the protocol was extended to STEC, another organism commonly found in these food products.

This co-enrichment strategy offers tremendous cost savings, as it reduces the number of sample preparations, the need for supplies and reagents, the space needed in incubators, and hands-on time. UPB is highly buffered and low in carbohydrates to prevent a rapid drop in pH and to support strong recovery of the stressed target pathogens but may lead to the overgrowth of background microflora, especially in challenging foods.

Intrinsic differences between Gram-negative and Gram-positive bacteria make their simultaneous enrichment impossible, but by using a single selective medium or a second specific enrichment broth, scientists can still enrich multiple organisms with similar characteristics. For example, harmonized enrichment involves detecting all of the genera that share the same properties, such as Gram-negative bacteria that exhibit similar growth rates, in one enrichment step. Harmonized enrichment encapsulates a wider number of species, thereby increasing efficiency. Reducing the number of analysis steps using harmonized enrichment decreases costs, both by reducing the need for media and by streamlining laboratory workflows.

(Continued on p.40)

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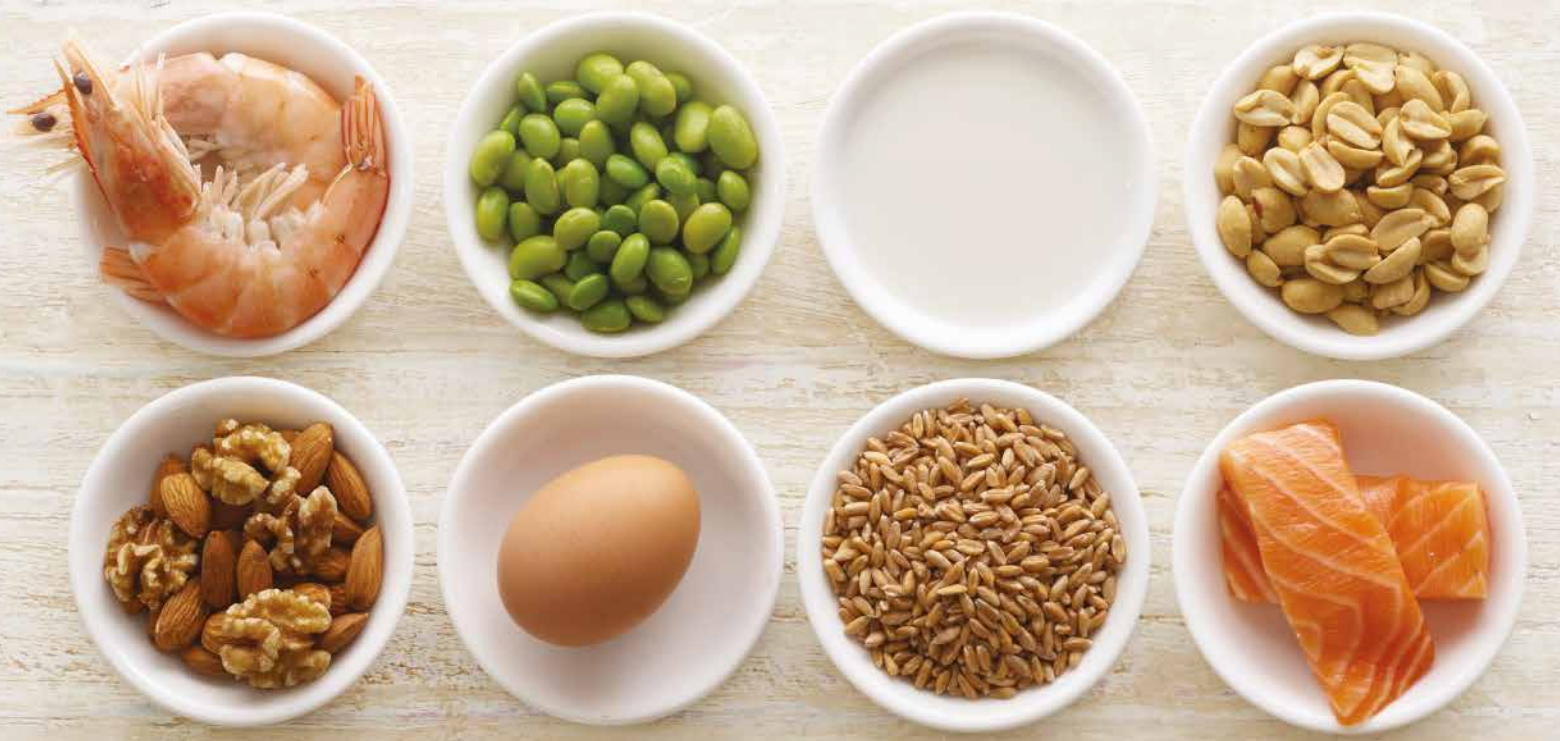

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Use LIMS to Drive Compliance in Food Safety Testing

An effective laboratory information management system is essential to ensuring compliance with new food safety standards | BY **JEFF COLLINS**

Globally, food safety has some room for improvement. According to the World Health Organization, almost one in 10 people falls ill each year after eating contaminated food, and 420,000 die as a result. These illnesses can stem from issues around physical and chemical contaminants, additive and pesticide testing, and allergen labeling. To prevent these issues, manufacturers must ensure and prove food quality, i.e., the set of physical, chemical, biological, and sensory characteristics that make a product safe and acceptable to consumers.

To ensure process consistency and control in testing, manufacturers need food safety standards to guide their procedures. Food safety standards include measures put in place to prevent physical, chemical, and biological contaminants. The International Organization for Standardization (ISO) is an independent, non-governmental body that brings together experts from around the world to develop and share international standards.

Laboratories that conduct food safety testing often look to adhere to ISO 17025, a standard that outlines general requirements for the competence of testing and calibration laboratories. ISO 17025 helps to safeguard consumer health by ensuring that results produced by food testing laboratories are of sufficient sensitivity, reliability, and accuracy.

To better manage food safety, FDA has mandated that the testing of imported food and addressing food safety problems must be conducted by laboratories that are sufficiently compliant with ISO 17025. The new rules, which will come into effect by February 2022, will require laboratories to maintain a high level of process management and control. To achieve and maintain compliance with ISO 17025, laboratories need a system to help them manage and demonstrate adherence to requirements; many would benefit from having a laboratory information management system (LIMS) in place.

The Evolution of ISO 17025: from Prescriptive to Process Based

ISO 17025, released in 1999, became widely recognized as the international reference for testing and calibration laboratories. In 2017, an update was implemented that shifted the standard away from prescriptive requirements and toward a more process-based approach that gives laboratories more flexibility in how they operate. The updated version has a different structure and places a greater emphasis on risk assessment. There is also an increased focus on information technology, e.g., the provision of electronic test results and records.

If there were to be one single theme of ISO 17025:2017, it would be recordkeeping. The standard provides a structure to plan and measure adherence to preventive control procedures and determine their effectiveness. This "plan and measure" approach is a key ISO philosophy and can only be implemented when supported by a system that supports and enables process management and improvement. In practice, this is referred to as a "plan-do-check-act" cycle that involves planning, supporting process execution, and managing organization and performance.

ISO standards share themes and goals with other regulatory standards and systems. The implementation of ALCOA+ principles, for example, helps laboratories maintain reliable records. These principles are designed to support data integrity and look to ensure that data is attributable, legible, contemporaneous, original, and accurate, as well as complete, consistent, and enduring. By driving data integrity throughout all processes, laboratories increase confidence in the data they deliver. Hazard analysis and critical control points (HACCP) is another internationally recognized system that requires food and beverage producers to systematically look for critical points that may affect or pose a risk to product safety. By identifying these points, manufacturers can implement routine testing to monitor any critical levels and ensure corrective actions are put in place where required.

The Food Safety Modernization Act (FSMA) also provides a framework that aligns with ISO 17025:2017. Hazard analysis and preventive control are two key parts of this framework that are particularly aligned with ISO 17025:2017.

New Regulations Require a Different Approach to Quality Assurance

To be compliant with ISO 17025:2017, food testing laboratories need to implement regular testing of tools and processes to confirm suitable operation. If any issues are found, corrective processes are required, and continual monitoring would confirm the success of such adjustments. This cycle forms the basis of risk assessment and continual improvement for the organization. The updated standard has requirements that help laboratories to constantly optimize their resourcing, processes, and management systems. Overall, laboratories are encouraged to take a broader, more logical perspective in tracking the flow of how an item is tested in the laboratory.

In terms of direct implications for laboratories, clauses 6 and 7 of ISO 17025:2017 are the most relevant, while others are more related to planning and management. For example, clause 6 outlines the records that must be kept related to personnel (e.g., training, competency), equipment (e.g., maintenance, calibration), and system and support services (e.g., external testing services). In clause 7, there is a focus on the selection, verification, and validation of methods, as well as requirements for handling calibration items and evaluating measurement uncertainty. Laboratories are expected to have procedures in place for monitoring all these processes. Data measurements should be recorded in a way that enables trends to be detected, and determines where practical, statistical techniques should be applied to review the results and check for any signs of processes heading out of control. Overall, meeting the requirements of ISO 17025:2017 requires performance to be measured and monitored in a way that can be easily checked, reported, and acted upon.

How LIMS Software Can Help Align Processes to Ensure Compliance

Keeping up with the monitoring required by ISO 17025:2017 is a big task. Thousands of data points are generated each day across an endless stream of activity, such as instrument calibration, incoming samples, equipment updates, and staff training. Harnessing digital automation via an effective LIMS is, therefore, essential to ensuring compliance with the new standards. LIMS software can automatically store data in a secure, centralized location for easy access and sharing, which ultimately supports efficiency and reduces the potential for error in manual processes and data entry.

Critically, ISO 17025:2017 standards can be built into the LIMS, making compliance the "default" action. For example, when equipment is set up within an advanced LIMS, calibration and service intervals can be defined. The system will then use this information to notify stakeholders and take instruments out of service when maintenance is required. Other types of corrective actions can also be initiated; for instance, an out-of-spec result, such as bacterial growth on a medium, may trigger an automated warning on the system and prevent the user from progressing without implementing a corrective action.

It is difficult to imagine how a busy laboratory might accurately keep track of metadata associated with the analysis of a sample without the use of digital tools that automatically keep track of all the information required for ISO 17025:2017. A modern LIMS, for example, records all data, including the time, date, person who ran the analysis, equipment used, shipment details, condition on receipt, and any preparation for testing. Any deviations from planned methods can also be recorded, a critical step for ensuring compliance.

Maintaining control of records is another important aspect of clause 7. ISO 17025:2017 audits often start by checking certificates of conformance, which are controlled documents that go through an approved life cycle within the LIMS software. Only staff with certain roles should be able to access data, and logs should advise of improper attempts at data access. Modern LIMS are available to support this level of control, using password controls, audit trails, and electronic signatures.

The Benefits of Using an Effective LIMS

There are other benefits to using digital solutions that extend beyond supporting compliance. In general, committing to ISO 17025:2017 by implementing a LIMS is an important statement of intent that tells a customer you are committed to excellence and best practices. Additionally, using a LIMS makes for easier customer management, which will likely lead to a more streamlined and positive customer experience downstream. Modern contract testing portals support quote reviews and approvals and allow samples to be logged and labels to be printed for shipping. Having a unique and professional interface for your business is a welcome change from old systems, making it easier to review everything from invoices to results. All maintenance records can be recorded on the LIMS, removing the need for multiple log books and reducing the risk of manual errors.

Fortunately, implementing modern LIMS software is now a very cost-effective solution that does not require large IT departments or support. For further improvements to data integrity and efficiency, LIMS can be integrated with other software systems, e.g., a laboratory execution system (LES). An LES is fundamentally geared to streamline analytical tests, whereby a process is mapped and enforced through the LES, and outcomes are recorded. However, an LES can also be used to ensure correct steps are taken for non-analytical tests, such as a corrective action in response to a customer complaint. The ISO 17025:2017 standard requirements can be built into the LES to further support compliance.

The update to ISO 17025 has placed a strong emphasis on taking a process-oriented approach to quality assurance. As a result, food testing laboratories need a system such as a LIMS to monitor analytical data, daily activities, training, and corrective actions on a large scale. Further benefits of modern data solutions can also be found in the increased productivity and customer management that come with easier record keeping. ISO 17025:2017 standards need to be embedded in the workflow of food safety laboratories, whereby compliance is the easy, default option. Implementing effective LIMS software is critical to optimizing workflows and streamlining data management, which ultimately eases the process of achieving and maintaining compliance. ■

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Automation Generation

How automation is changing the food and beverage industry

BY **ANDREA TOLU**

The food industry has been relatively slow to adopt what industry insiders call "Industry 4.0," the fourth revolution in manufacturing. Central to this "revolution," according to *Forbes* magazine, are autonomous systems driven by data and machine learning, or the "digitization of manufacturing." While some level of automation in the food industry is the norm, it's typically limited to specific processing steps such as washing, sorting, and packing.

In other factories, however, automation takes on another meaning and uses more advanced technologies, such as the Internet of Things (IoT), to connect equipment and devices, smart sensors to collect real-time data, and 3D vision and artificial intelligence (AI) to execute complicated tasks.

One reason for this delay in automation adoption in the food industry is an element of fragmentation within food processing. "While in other sectors you can connect various devices together and collect data, in the food industry there is a lot of standalone equipment," says Craig Salvalaggio, COO at Applied Manufacturing Technologies, an automation engineering company based in Anaheim, Calif., and member of the board of directors for the Association for Advancing Automation. "It's like having little islands connected by conveyors."

Another reason for the food industry's slow adoption of Industry 4.0 comes from the complexity of certain operations: "In the meat sector, for instance, some companies believe they're able to realize higher yield by having more skilled labor and personnel," says Lee Coffey, market development manager for the CPG segment at Milwaukee, Wisc.-based Rockwell Automation.

The Impact of COVID-19

Part of this gap was recovered during the COVID-19 pandemic, when the adoption of Industry 4.0 solutions was accelerated by new challenges, such as the rise of online grocery shopping: "E-commerce created new opportunities throughout the industry," says Coffey. "Anywhere from beverage manufacturers to meat processors, companies can reach new customers and markets, but they're also producing more SKUs than ever. There are more changeovers and more ingredients being used, and that's adding complexity and downward pressure on productivity and profits." Workforce shortages is another factor that has become problematic during the pandemic "With workers not showing up and COVID-19 restrictions, companies have been struggling with scheduling production and meeting demands, especially in those labor-intensive areas where you have to handle the product and get it into a tray and then into a box," he adds.

Key Automation Technologies

With these new challenges, some key technologies are proving to be particularly sound solutions. Manufacturing execution systems (MES) are one such solution; they keep track of all food processing data, from raw materials to finished products, and have existed in the food industry for a long time. Recently, however, the approach to these systems is different, says Gerardo Villafuerte, digitalization manager for North America at Liquid Consulting, a Sanford, Fla.-based firm that provides engineering and automation solutions to food manufacturers. "You used to have reports with all kinds of variables and data; now, companies are looking for data that matters to them. It's no longer about just the technology but also about how it can be applied to have safer processes around products."

Having the right data is crucial in the case of a product recall: "If a contamination is detected," says Villafuerte, "you can use your MES and [enterprise resource planning] ERP systems to find out exactly where that lot was produced, where it was shipped, what instruments and ingredients were used to produce it, and how long the ingredients were stored before being processed."

At the same time, the Industrial Internet of Things (IIoT) can help food companies improve overall equipment effectiveness (OEE), one of the most important metrics in manufacturing plants. "IIoT is a big enabler right now," says Coffey. "A lot of our customers are deploying it to connect people, processes, and assets throughout the plant and aggregate real-time data to make better decisions on the fly, versus going through data collected manually at the end of the shift. Data can be anything from the temperature of the product to vibration analysis of how a machine is running. It's an evolution where companies are going from a reactive approach to predictive models that allow them to see when a failure is coming and check the machine in advance."

A third area where Industry 4.0 can make a difference is the automation of tasks that require a high level of manual dexterity. "Robot end-of-arm tools for grasping can now pick fragile and irregular objects without damaging or marking them," says Salvalaggio. "For example, we worked with a manufacturer to automate the process of putting pickles in jars. Using a combination of AI, grasping, and vision technology, we designed an application to identify the size and the structure of the pickles and select an optimal pick sequence. We demonstrated that we could get about 70% of the pickles into the jar reliably, with human intervention helping with the remaining 30%."

Plan for Success

While automation can provide great benefits, it requires proper planning. Villafuerte says it's important to have a flexible master plan with clear objectives and a timeline so you can organize your investments step by step. "Automation is a journey: You want to first crawl, then walk, and then run," says Salvalaggio. "Before buying any equipment, companies should understand their current process, data, and metrics, and where they want to go from there, whether it's increasing capacity, demand, or flexibility. You can learn a lot from visiting factories in other industries, such as automotive or aerospace."

Before buying any [automation] equipment, companies should understand their current process, data, and metrics, and where they want to go from there—whether it's increasing capacity, demand, or flexibility. You can learn a lot from visiting factories in other industries, such as automotive or aerospace.

—CRAIG SALVALAGGIO

The plan should always be for the long term, even if you cannot implement everything at once. "It's likely that you're not going to have the funding for everything right away," says Coffey. "The best thing is to prioritize the most critical projects and then identify low-risk, high-yield targets where you can get a couple of quick wins."

Not having a plan in place might save some time at first but will likely cause issues down the line. "One of the main problems," says Villafuerte, "is when companies see automation as a one-off project, where in fact, it's a constant evolution that changes as the market evolves."

"Where we see people getting into trouble," says Salvalaggio, "is when they buy random machines from different vendors, only to find out they can't support them in the long term because they use different processors and communication networks, or they behave differently from one another."

The ability of different pieces of equipment to communicate with each other is another critical aspect of automation projects. For this reason, it may be necessary to replace old devices, even if they are still working perfectly. That is particularly true for programmable logic controllers (PLCs): "There are some PLCs from the '90s that many customers are still using today," says Villafuerte. "They're very reliable and durable, but when they are too old it becomes risky to work with them because they're impossible to communicate with, and also because there won't be any spare parts on the market if they break down."

Finally, companies should not forget the human and cultural component: "Automation requires a deep dive into organizational culture and change management, so you need to ensure that your employees feel engaged and empowered in the process," says Coffey. "If you deploy a new technology without the buy-in from the people that are going to actually use it, adoption will be poor, and you'll miss your ROI targets."

With automation being such an important change, it is likely that organizations will have to train their workforce or hire new talent. Salvalaggio recommends a model that involves three levels of training: "maintenance training to ensure that people know how to do preventative maintenance and use the equipment; technical training for troubleshooting and debugging; and engineering, where you define what equipment goes into the plant, its specifications, safety requirements, etc."

"The most important skill for an automation engineer or technician is creative thinking," says Villafuerte. "Anyone can write a program, but if you want to think about the whole system, you need to be open minded and creative about how that is going to work."

Future Trends

With a new wave of automation that's just started, what lies ahead for the food industry is the further adoption of technologies that are already being used in other industries. "There will likely be an increase in robotics," says Coffey. "Not only robots but 'cobots,' collaborative robots that can work alongside the workforce."

Salvalaggio echoes this view: "There will be more robotics, in particular Delta robots, which can handle objects with high speed and throughput rates. Also, we're going to see a combination 3D sensing technology, along with AI algorithms that are specifically designed for handling distorted or unstructured products." ■

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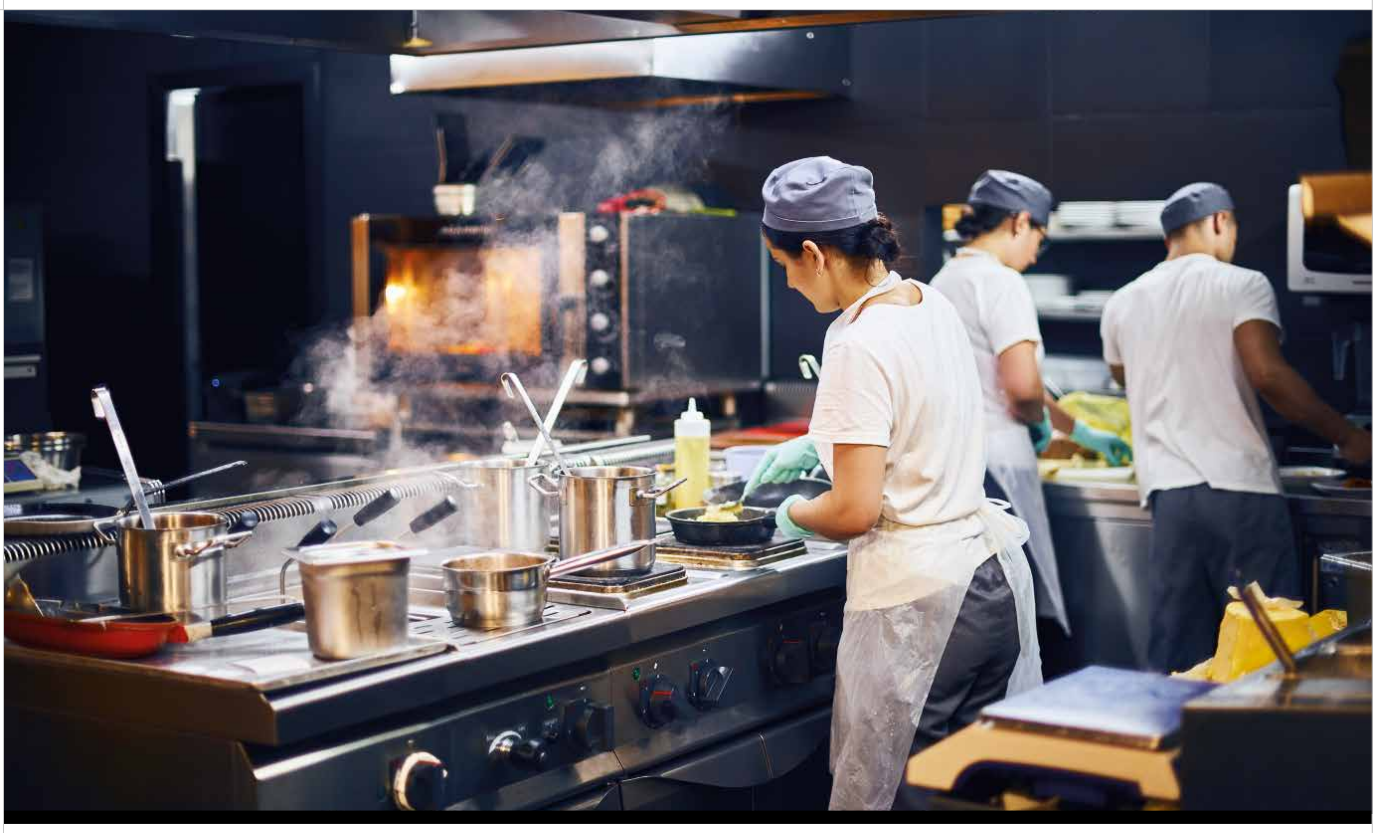
Food Service & Retail



Ghost Kitchens

Do these "virtual" kitchens make the grade for food safety?

BY **LORI VALIGRA**

The COVID-19 pandemic that has kept people at home and curtailed restaurant visits accentuated a trend for so-called "ghost kitchens." Ghost kitchens, also known as virtual kitchens or dark kitchens, do not have a storefront or dining area, but instead rely on customer pick-up or delivery services. Their popularity boomed during the pandemic, as consumers opted for delivered meals and some restaurateurs expanded or started up inexpensively in small spaces with low overhead.

The term "ghost kitchen" was first used in a 2015 investigative report referring to several operations operating below regulatory standards, some illegally, in New York City, according to Francine Shaw, CEO of Savvy Food Safety Inc., a Hagerstown, Md.-based food safety consultancy. The phrase has evolved to mean a delivery- or pickup-only restaurant. These facilities take a variety of forms, with the simplest having one location with one or more restaurants under the same roof, sometimes sharing equipment and space. In many cases, independent kitchens are the result of major restaurant brands, such as The Halal Guys, taking their delivery and catering services offsite, according to King & Spalding, a New York-based law firm.

Commissary ghost kitchens, the most common arrangement, feature multiple ghost kitchens sharing kitchen space that could be owned and operated by third parties. A newer trend is to have a ghost kitchen operate within a brick-and-mortar restaurant. The ghost kitchen uses the same staff and equipment as the restaurant but offers food from a national brand for delivery only. One example is Combo Kitchen, a Miami-based franchise that partners with large chains so that they can expand inexpensively in a small kitchen on the premises of a different established restaurant.

The Industry Takes Off

In 2020, the United States had approximately 1,500 ghost kitchens. Their numbers continue to grow as restaurants adapt to less expensive ways to operate and to respond to changing consumer demand, says Shaw. "They are much less

labor-intensive," she says. While a typical brick-and-mortar restaurant might process 15 to 20 delivery orders per hour, a ghost kitchen may process 60 or more with a single employee. They're also a less expensive way to open a "restaurant" because they don't require the added dining space and decor.

Food deliveries increased dramatically during the pandemic, changing the nature of the restaurant industry, with delivery orders increasing almost 70% in March 2020 over the the same month in the previous year, while restaurant traffic declined 22%, according to NPD Group.

Brett Buterick, counsel with the franchise and hospitality group at A.Y. Strauss in Roseland, N.J., agrees. The law firm is one of several that has found a new business around the proliferation of ghost kitchens, advising franchise restaurant brands about federal and state regulations. "The pandemic left a big impact on the restaurant industry and accelerated the growing trend of ghost kitchens," he says. That has benefited many restaurants because they can expand with little cost, and a franchisee can get into the restaurant business at a low cost.

Regulation

Ghost kitchens and brick-and-mortar restaurants are regulated in the same way, Shaw says. FDA regulates some ghost kitchens that could be defined as "food facilities," which manufacture, process, pack, or hold food for consumption. But the agency does not regulate facilities that prepare and sell food to consumers for immediate consumption, such as most restaurants and ghost kitchens. Those are subject to the same state and local food quality and safety regulations and oversight as eat-in or quick-service restaurants, including allergy management and hazard planning.

Because of their secretive nature away from the public eye, public health and other officials question whether the largely virtual operations are meeting sanitation standards. There's also little information available to consumers to assess whether the food they are ordering is safe to eat, as ghost kitchens typically do not post ratings from health officials on their doors or websites, leaving reviews up to crowd-sourced platforms like Yelp.

While a typical brick-and-mortar restaurant might process 15 to 20 delivery orders per hour, a ghost kitchen may process 60 or more with a single employee. They're also a less expensive way to open a "restaurant" because they don't require the added dining space and decor.

The growth of ghost kitchens has New York City and other cities looking into their practices. That includes the New York City Council's Committee on Small Business, which has floated three bills related to regulating ghost kitchens, says Reginald Johnson, chief of staff for Bronx councilmember Mark Gjonaj, who heads the committee. One would require the city's letter grades to be posted where customers interact with the ghost kitchen, whether online or at a pickup location, Johnson adds. The council also wants clarification from city administrators about how the kitchens are inspected, so health issues can be traced. "If they have several different restaurants operating in the same space, is there one grade for the entire operation or does each individual kitchen get a separate grade?" Johnson says.

Hossein Kasmai, CEO of Combo Kitchen, says that his business model helps solve this issue. The company operates 50 locations in 20 states, partnering with brand-name restaurant chains to license their food and menu in a ghost kitchen operation that runs within various brick-and-mortar restaurants. The physical restaurant can leverage its staff and equipment with the new business from the ghost kitchen, while the virtual kitchen has a low-overhead operation within an existing restaurant, he says. That also unites the inspection and food safety activities because both operations use the same staff, premises, and equipment.

He adds that Combo Kitchen also inspects each location to protect the quality and reputation of the brand-name restaurant chains. "We use recognized brands with an established reputation so we can ensure the quality," Kasmai says. "And there are regular inspections."

Many of the independent or shared ghost kitchens are smaller than typical restaurant kitchens, however, and thus require special planning for workflow to avoid contamination, such as keeping raw and cooked food separate, says Paula Herald, PhD, technical consultant for Steritech Group Inc., a food safety assessment company based in Charlotte, N.C. She says that some states allow shared kitchens among several ghost kitchens in the same building, while others don't, and it's important for those setting up a kitchen to verify regulations with local inspectors. "Some states require a shared kitchen to have a totally independent water heater, their own walk-in cooler, and their own three-compartment sink to prevent an outbreak of foodborne illness," she adds.

Dr. Herald says it's important to guard against cross contamination, especially when it comes to food allergens. She advises ghost kitchens to work with local health inspectors to learn what they can and cannot share, avoid short cuts, and incorporate food safety practices into the work environment. She also recommends that those starting ghost kitchens have contracts with delivery services that assure the cleanliness of vehicles, employ low-touch food transfers, and keep records of when the food leaves a restaurant and when it's delivered.

While Shaw says she doesn't expect restaurants as we traditionally know them to go away any time soon, but one thing is for certain: Ghost kitchens offer convenience to the consumer, and they're likely here to stay. ■

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Safe Handling and Storage of A2L Refrigerants

How to manage these chemicals to ensure food safety and protect workers and consumers throughout the cold supply chain | BY **BOB CHRISTENSEN**

Handling coolants like those used in air conditioners, food refrigeration, and other systems can be a complex challenge. Workers specifically involved in the cold food supply chain industry must understand how to safely handle and store these dangerous chemicals, including those designated as A2L refrigerants.

New international agreements related to acceptable refrigerants have emerged due to recent regulatory changes to minimize ozone depletion and global warming. As companies phase out older refrigerants, they face new challenges and hazards from the replacement chemicals. For those working in the refrigeration and heating, ventilation, and air conditioning industries, building awareness of these hazards and developing best practices for their use and storage must be a priority.

What Does an A2L Designation Mean?

Every refrigerant is rated and labeled based on the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) 34 designation and classification system. The rating uses a letter to indicate toxicity and a number to rate the flammability of each gas:

- **Toxicity**: A—Lower toxicity; B—Higher toxicity.
- **Flammability**: 1— no flame propagation; 2L—lower burning velocity equal to or less than 10 centimeters per second; 2— lower flammability; 3—higher flammability.

The main difference between A1 refrigerants and A2L refrigerants is the ability to propagate a flame. A2L refrigerants will burn, but with a lower velocity than A3 refrigerants, which can burn explosively when ignited. Practically speaking, even though A2L gases are difficult to ignite, precautions are necessary when handling, storing, and transporting these chemicals.

A2L Regulations in the United States

Flammable refrigerants are relatively new to the cold food supply chain in the United States, but they have been used safely in other parts of the world for years. Currently, there is no federal framework for regulating the use of refrigerants. While the U.S. Environmental Protection Agency (EPA) attempted to implement Significant New Alternatives Policy (SNAP) rules 20 and 21, these regulations were vacated by the U.S. Court of Appeals for the District of Columbia Circuit because it determined that the EPA did not have congressional authority.

This absence of federal regulations has driven some states to implement their own policies. As a result, regulatory requirements vary from state to state. Several organizations, such as the Air-Conditioning, Heating and Refrigeration Institute, ASHRAE, and the United States Department of Energy (DOE), are collaborating to explore potential hazards and recommend standards and codes. Federal policies and regulations are anticipated, with most people only questioning when they might be implemented; it's not a question of "if," only "when."

Despite the lack of official federal regulations, multiple standards have been developed. The most widely adopted is ASHRAE's Standard 15, published in 2019. The ASHRAE 15 requirements establish safeguards for life, health, and property through the recommendations for handling A2L refrigerants. They also address building code requirements for commercial and industrial applications using A2L refrigerants.

Working Considerations

Even though there are no federal laws mandating specific processes for working with A2L refrigerants, it's imperative to follow all best practices and recommendations to maintain a safe working environment. Companies must:

1. Ensure that all relief and purge vent piping is routed outdoors and away from all air intakes per local, state, national, and international codes.
2. Ensure that the area is well ventilated; if auxiliary ventilation is recommended, such as blowers or fans that disperse refrigerant vapors, ensure that it is rated for A2L refrigerants.
3. Employ oxygen testing equipment and leak detection monitors to identify potentially hazardous leaks and ensure that adequate oxygen is present.
4. Review the safety data sheet (SDS) when working with refrigerants; follow any recommendations and don the appropriate personal protective equipment (PPE), such as gloves and eyewear.

COURTESY OF NEVADANANO.

5. Use equipment and tools certified for use with A2L flammable refrigerants.

6. Ensure that a dry powder class B fire extinguisher is accessible.

7. Check the area for obvious sources of sparks or flames before beginning work on equipment that uses A2L refrigerants.

8. Refrain from operating appliances that use open flames or igniters or have hot surfaces while servicing these appliances.

9. Take care to prevent damage to the appliance, and especially the refrigerant lines, if moving equipment containing A2L refrigerant.

10. Immediately ventilate the room, evacuate the area, notify those in the vicinity, and wait until the device reads a safe level before returning if the gas leak detector reports the presence of a leak.

11. Purge refrigerant lines with oxygen-free dry nitrogen before and after a repair.

12. Ensure the equipment is properly grounded if the system is in operation while replacing the refrigerant.

13. Follow all manufacturer's recommendations when replacing the refrigerant.

14. Follow these steps during transportation of A2L refrigerant:

- Ensure that a dry powder class B fire extinguisher is available on the vehicle.
- Review all local, state, and federal regulations applicable in the jurisdiction of transport.
- Do not store refrigerant cylinders near heat or a source of ignition.
- Label all refrigerant cylinders following the guidelines in US 49 CFR part 172.417.
- Secure flammable refrigerant cylinders to prevent theft, tampering, or movement during transport.

ASHRAE 15 also outlines requirements for leak detection monitors. Clause 8.11.2.1 states:

Each refrigerating machinery room shall contain a detector, located in an area where refrigerant from a leak will concentrate, that actuates an alarm and mechanical ventilation in accordance with Section 8.11.4 at a value not greater than the corresponding TLV-TWA (or toxicity measure consistent therewith). The alarm shall annunciate visual and audible alarms inside the refrigerating machinery room and outside each entrance to the refrigerating machinery room.

When identifying an optimal refrigerant leak detection sensor, there are several factors to consider, including:

- **Speed**. To address leaks quickly and ensure a safe workplace, you need a detector that can quickly alert you of a leak so that your response can be just as quick.
- **Ease of use**. A good detector should be easy to use and to understand to prevent you from fumbling with it while hazardous conditions are present.
- **Accuracy**. Accuracy is essential, although it can be difficult to obtain when there is low oxygen, high humidity, and/or multiple gases in an environment. Identify a multi-gas sensor that works under all potential environmental conditions that may exist in your workplace.
- **Total cost of ownership**. Initial cost is important, but don't forget to consider additional calibration or replacement costs when determining the total cost of ownership.

Reviewing these factors when looking for a gas leak detector helps ensure leaks are detected quickly and the workplace remains safe when an A2L refrigerant is being used. ■

Christensen is senior director of business development at NevadaNano.

The Lactic Acid Shortage *(Continued from p. 28)*

United States and Europe, lactic acid and PLA producers in countries with more limited access to the vaccine or higher rates of infection may still be facing labor shortages or other pandemic-related issues. The stronger demand, coupled with slowed production, make for a perfect storm in prolonging the lactic acid shortage.

Given the wide range of uses for, environmental benefits of, and production challenges associated with lactic acid, it's not likely that the shortage will end anytime soon, which means several industries will feel the impact. Food processors, for example, can anticipate an increase in lactic acid prices, making its use uneconomical and possibly forcing changes in their processes. Beef processors in particular can expect to feel some of the burden, as they often use lactic acid as an antimicrobial intervention or pathogen reduction treatment on beef carcasses. To get ahead of the challenge, food and protein processors will want to seek out viable alternatives to lactic acid where they can.

Finding Alternatives

Although lactic acid has proven efficacy against various pathogens, high concentrations can alter a product's surface, texture, color, or flavor. For example, although beef processors typically treat beef using lactic acid concentrations ranging between 2% and 5% to treat beef, USDA has now approved up to 10% uses in some processes. Although lactic acid is an organic compound, it's so acidic that it can eat away at rails, concrete, and substructures. It can also make its way into wastewater, which can erode pipes and potentially increase wastewater treatment costs.

Fortunately, there are alternatives to lactic acid-based chemistries on the market. Food processors can use intervention chemistries that include ingredients such as peracetic acid or blends of lactic and citric acids. These blends offer the opportunity to achieve equal—if not greater—reduction of pathogens at lower concentrations when compared with straight lactic acid, reducing the reliance on lactic acid and the potential negative effects of its use.

Food processors that use alternate chemistries can successfully neutralize pathogens and help insulate themselves against the impact of the lactic acid shortage. As demand continues to increase globally, it will remain important for food processors to stay ahead of the changes. Taking advantage of ways to decrease reliance on lactic acid will ultimately save time and money, all while protecting the food chain. ■

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Aseptic Food Processing (Continued from p. 29)

of aseptic processes—operations, quality control, plant management, maintenance, and engineering—should receive training on high-quality and safe foods. Training programs should adhere to both current good manufacturing practices (cGMPs) and the Better Process Control School. Employers should also offer ongoing professional development and refresher courses. It's important that management commit beforehand to the training tenets of aseptic processing. Training is a great way to combat complacency over time.

5. Quality Assurance

Testing goes hand in hand with coordinating processes. The failure to maintain accurate records and test products periodically can cause the quality to diminish, risking contamination and serious illness, including contamination with *Clostridium botulinum*. The aseptic process is designed and validated to inactivate all microorganisms that could cause spoilage or pose a public health threat, and the scheduled response must be followed carefully. Aseptically processed foods require stringent recordkeeping. As the saying goes, if you didn't document it, it didn't happen.

In addition to recording each of the control points at reasonable intervals, records should also show the actions taken in case of deviation from the schedule. Records must also be kept of quality checks and testing results. These documents must be stored for at least three years, either electronically or through a paper trail.

When routine microbial testing is used, a sampling schedule should be agreed upon beforehand. The samples themselves should be incubated in a hot room upon collection for seven to 15 days to check for package bloating. Microbial tests must also be adequate depending on the product, and should include a decision as to whether mesophilic anaerobic spore testing is needed. All considerations should be part of the food safety plan.

6. Continuous Improvement

Aseptic processing is an intricate and elaborate behavior, where every detail can make the difference between profit and loss. Aside from a careful preventive maintenance program, change control, and daily record review, it makes sense to anticipate deviations and to operate with scrutiny to help decrease the incidence of overlooking a problem. Batch, lot records, critical control point records, and closing data should all be reviewed by quality assurance to ensure critical control point parameters are acceptable. If any parameters are outside of the schedule, a deviation process should begin. Immediately quarantine the products and perform a root cause analysis to determine the next steps for the product. Products may be able to be reprocessed or may have to be destroyed to prevent the possibility of adulterated product going to the public.

7. Hidden Costs

Above, I talked about the benefits of aseptic processing and its viability for both the supply chain and the food supply, but it's important to acknowledge the costs involved in doing it correctly, safely, and in compliance with FDA regulations. Initial capital investment could be as much as two to three times that of fresh production. Additionally, evolving packaging requirements will initiate costs for R&D, so those costs should be figured in as well.

If you're considering adding aseptic processing to your production line, or simply interested in remaining vigilant about an existing line, consider engaging a consultant who can guide your team through the countless challenges. With careful design, recordkeeping, and training, you'll successfully navigate the complexities and pioneer successful long-term aseptic processing. ■

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Harmonized Enrichment (Continued from p. 30)

Table 1. Comparison of time to results between UPB use and simultaneous selective enrichment of two bacterial species.

Target	Method	# of Enrichment Broths Required	Time to Negative Result (hours)	Time to Positive Result (hours)
Cronobacter spp.	ISO 22964:2017	2	66	90
Salmonella spp.	ISO 6579-1:2017	3	66	90
Cronobacter spp. and *Salmonella* spp.	PIF Supplement Protocol	1	21	44

Simultaneous selective enrichment shares the benefits of using UPB in terms of cost savings, but it also reduces enrichment time when compared with standard protocols (see Table 1, above). Additionally, by reducing the number of analyses needed, simultaneous selective enrichment contributes to the ergonomic wellness of laboratory workers.

Optimizing Harmonized Enrichment

Several parameters might influence the effectiveness of bacterial enrichment. The number and variety of standard protocols clearly illustrates the complexity and the significance of this step. For example, chapter five of the Bacteriological Analytical Manual (BAM) prepared by FDA includes more than 20 procedures to detect *Salmonella* spp. in foodstuffs. This dearth of standardization is especially common in the context of simultaneous enrichment.

Two factors that affect the success of co-enrichment are the bacterial species and food matrix type being tested. First, scientists should adapt the buffering properties and the selectivity of their medium to the chemical characteristics of the food sample, such as fat content and pH, as well as the type and ratio of microbial flora. It would be difficult to design a co-enrichment protocol that suits the large variety of food types. For this reason, simultaneous enrichment should target a specific food category. Similarly, co-enrichment works best when performed on

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NEW PRODUCTS

High Absorbency Meat Pad

Elliott Absorbent Products has developed an ultra-thin, super absorbent range of sealed edge pads for fresh meat and fish. The pads also have a low carbon footprint. The UniDry range use 50% less material than traditional. This enables customers to achieve environmental compliance as well as make major reductions in their packaging and cut emissions from transport and storage. The pads use a proprietary core that gives blood and water absorbency of between 7.5 and 26 liters per square meter and are available in both pads and reels, white as standard with other colors upon request. **Elliott Absorbent Products, elliottabsorbents.co.uk**.

Load Cell Technology for Checkweighing Systems

Mettler-Toledo Product Inspection's C-Series checkweighing systems have added a new load cell. The FlashCell load cells weigh food products at speeds of up to 800 ppm. With three different load cell types in the cell portfolio, food manufacturers can select the appropriate load cell for their products, weighing a complete product range up to 10 kg. The technology delivers weighing results with a standard deviation up to four times lower than the previous load cell generation. This helps to reduce overfilling and costly product giveaway. It also works with shorter measuring times at high speeds. The weighing conveyor can therefore be reduced in length, with slower conveyor speeds helping to increase product handling stability and allowing shorter outfeed conveyors and product collection areas. The complete length of the checkweigher itself can be reduced by up to 24%. **Mettler-Toledo, mt.com/pi-precision-weighing.**

Equipment Sanitizer

Enviro Tech Chemical Services has introduced a dry peracetic acid floor and equipment sanitizer. PeraGuard is designed to improve environmental biosecurity and sanitation on surfaces where conditions favor microorganism growth. The product is EPA registered for use in food and beverage facilities. In addition, the sanitizer can be used on farms to control ammonia and odors. PeraGuard is activated by water or moisture and is a highly concentrated, odorless, and dustless application that is effective against *E. coli, Listeria, Salmonella, Staphylococcus,* and other pathogens. **Enviro Tech Chemical Services, environtech.com/peraguard.**

Servomotors Line

The SIMOTICS S-1FS2 line of servomotors is designed for the clean condition requirements of the food and beverage industries. These new servomotors are offered in a variety of power ratings, from 0.45–2kW (0.60–2.68 hp) with torque from 3.1–14 Nm (2.28–10.32 ft-lbs.).

One cable connection is provided for easy installation and cleaning. The standard absolute encoder is 22-bit multi-turn. These new motors are suitable for clean-in-place (CIP) processes and for use with all commercially available cleaning agents used with washdown motors. They are also designed for the 3-A (U.S.) and EHEDG (Euro) requirements of the food and beverage industries. Options include a holding brake, stainless steel shaft (with or without feather key), cable tail for direct drive connection, and a motion connect coupling. The motors are compatible with the SINAMICS S210 drive system. **Siemens, usa.siemens.com/simotics-s1fs2.**

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Raw Milk Analysis

The Indiscope raw milk analysis technology is designed to help milk collection points perform fast and accurate testing to determine fair market value and help ensure a safe raw milk supply chain for consumers. It is designed for low maintenance and ease of use and includes a pre-calibrated instrument with pre-defined methods and built-in software for integration with other systems. With the tool, milk collection stations can test milk's composition for fat and protein levels and detect adulterants such as water, maltodextrin, and urea. Results are delivered in less than 30 seconds. The workflow meets ISO, IDF, and AOAC guidance for testing repeatability and data can be saved via built-in USB ports or exported to a PC. **PerkinElmer, perkinelmer.com/category/dairy-testing-solutions.**

Solvent Retention Capacity Analyzer for the Baking and Milling Industries

The SRC-CHOPIN 2 Analyzer for the baking and milling industries allows a user to perform the solvent retention capacity (SRC) method automatically versus manually. Compared with the original SRC-Chopin introduced in 2014, the SRC-Chopin 2 offers upgrades in software and electrical and mechanical designs and allows bakers and millers to make assessments regarding their flour quality and final product requirements. The manual SRC method is laborious and time-consuming, requiring lab technicians to be trained to perform multiple steps during the analysis. With the SRC-CHOPIN 2, training required to run the analyzer is minimal, and after set-up, the analysis is performed by the instrument, reducing operator engagement and impact of the results. The SRC-CHOPIN 2 is the standardized automated method AACC 56-15.01 and ICC Draft Standard 186. **KPM Analytics, kpmanalytics.com/products/src-chopin-2.**

Foaming Acid for Processing Facilities

The ProClean is a high-foaming, concentrated blend of acids and surfactants that penetrates and removes films, oxide, milkstone, and other soil from dairy and food processing equipment. This NSF-registered product is ideal as an acid cleaner (A3) on all surfaces in and around food and beverage processing areas and is not intended for direct food contact. It can be applied by manual, foam, or immersion methods. When used in a foam generator it produces thick, stable, wet foam necessary for cleaning while reducing dry-out or run-off. It cleans ferrous and stainless surfaces, particularly vertical and overhead surfaces. The foaming acid rinses with potable water and without streaking. When used according to manufacturer's instructions, it is safe to use on stainless steel alloys with controlled etch on aluminum, copper, and ferrous alloys. **Madison Chemical, madchem.com.**

Harmonized Enrichment

(Continued from p. 40)

pathogenic bacteria with similar nutritional and temperature needs, as well as comparable susceptibility to inhibitory compounds.

Validated Protocols with Simultaneous Pathogen Detection

Over the last decade, scientists have developed innovative protocols that enable the simultaneous enrichment of several pathogen targets in a single bag. This development allows more flexibility in food microbiological routine labs and improves the overall ease of use of the pathogen detection workflow. In the context of food safety regulations, these innovative protocols must demonstrate an equivalent level of performance to related reference methods. Recently, we developed a new harmonized protocol that enables the simultaneous growth of *Enterobacteriaceae*, specifically *Cronobacter* spp. and *Salmonella* spp., thanks to the addition of a proprietary reagent to the buffered peptone water. The ISO 16140-2 validation demonstrated that enrichment using this protocol, followed by PCR or chromogenic agar detection for *Cronobacter* spp. and *Salmonella* spp., provides the same level of sensitivity, specificity, and selectivity as each individual reference method.

Harmonized enrichment of food samples allows the simultaneous pathogen detection of several targets. It reduces the cost of analysis and increases flexibility in the laboratory. To achieve an acceptable level of performance, however, this harmonized enrichment can be achieved only on microorganisms that share similar physiologic characteristics. Also, in the context of food safety regulations, these harmonized enrichments are useful when they allow the co-detection of several microorganisms of interest relevant for a single food matrix. The standardization of co-enrichment methods will hopefully lead to quicker and more accurate detection of pathogens in food and reduce the incidence of foodborne illness around the world. ■

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Visit chinafoodsafety.com.

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Chicago, Ill.

Visit myprocessexpo.com.

2-5
Dairy Practices Council Annual Conference
Pittsburgh, Penn.

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

10-11
African Continental Association for Food Protection
Food Safety Conference for Africa
Virtual Event

Visit acafp2021.org.za.

10-12
Asia-Pacific Symposium on Food Safety 2021
Jeju Island, Korea

Visit foodhygiene.or.kr/2021.

18-23
Dubai International Food Safety Conference/IAFP Middle East Symposium
Virtual Event

Visit foodsafetydubai.com.

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5-9
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9-12
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SCIENTIFIC FINDINGS

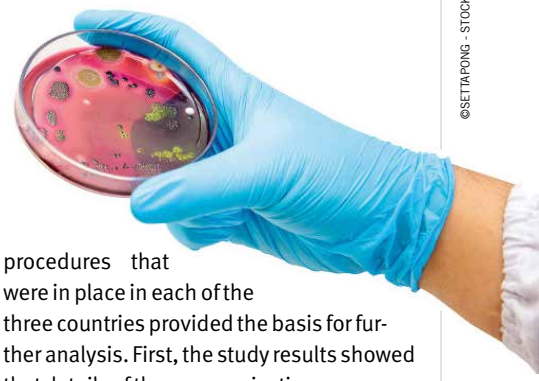
For access to the complete journal articles mentioned below, go to "Food Science Research" in the October/November 2021 issue at foodqualityandsafety.com, or type the headline of the requested article in the website's search box.

Creating Nonallergenic Wheat Products Using Processing Methods: Fact or Fiction?

A wheat allergy is a potentially life-threatening disease that affects millions of people around the world. Food processing has been shown to influence the allergenicity of wheat and other major foods. However, a comprehensive review evaluating whether food processing can be used to develop hypo-/nonallergenic wheat products is unavailable. There were three objectives for this study: to critically evaluate the evidence on the effect of fermentation, thermal processing, and enzyme or acid hydrolysis on wheat allergenicity to identify the potential for and challenges of using these methods to produce hypo-/nonallergenic wheat products; to identify the molecular effects of food processing needed to create such products; and to map the concept questions for future research and development to produce hypo-/nonallergenic wheat products. The authors performed literature research using PubMed and Google Scholar databases with various combinations of keywords to generate the data to accomplish these objectives. They concluded that food processing significantly modulates wheat allergenicity and that, while some methods can reduce or even abolish the allergenicity, others can create mega allergens. They also found that fermentation and enzymatic hydrolysis hold the most potential to create novel hypo-/nonallergenic wheat products, and they identify five specific research concepts to advance the research to enable the creation of hypo-/nonallergenic wheat products for application in the food, medical, and cosmetic industries. ***Comprehensive Reviews in Food Science and Food Safety*. Published online ahead of print August 29, 2021. DOI: 10.1111/1541-4337.12830.**

Interactions Between Risk Assessors and Risk Managers During Three Major European Food Incidents

Risk analysis consists of risk assessment (RA), risk management (RM), and risk communication (RC). In most countries, the RA and RM of food safety are separated to achieve a high scientific integrity and typically occur in sequential order; however, during a food safety incident, even RA and RM are performed simultaneously due to the pressure of time and the expected severity of the impact. The aim of this study was to analyze and evaluate the observed interactions between RA and RM processes during three major food incidents in Europe and to provide suggestions for possible improvement. The enterohemorrhagic *Escherichia coli* (EHEC) crisis in 2011 in Germany, the horsemeat scandal in 2013 in Ireland, and the fipronil incident in 2017 in the Netherlands were used as case studies. Based on the differences observed among the three cases, the authors identified the strengths and weaknesses of each system. The timelines of these incidents and the crisis management procedures that were in place in each of the three countries provided the basis for further analysis. First, the study results showed that details of the communication processes between RA and RM bodies were frequently lacking in crisis management protocols. Second, RA, RM, and RC processes differed for each incident, due to differences in the estimated risk for public health, but also due to differences in the organization within each country. The authors recommend that crisis management protocols contain a section on communication among RA, RM, and RC, stating the best ways of communication, the recommended frequency of communication, and ways to deal with uncertainties. ***Journal of Food Science*. 2021;86:3611-3627.**



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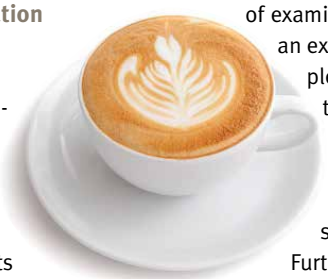
Coffee Bean Classification Based on Fatty Acids Analysis

The research studies constituents of fatty acids (FA) in coffee beans to identify their categories. Since FA are the fundamental constituents of coffee aroma and flavor, classifying the beans' original species in the roasted state is challenging. The examined samples in this study cover 74 coffee beans from different origins and are separated into Arabica and Robusta species based on their FA composition. This research develops a discriminant strategy to identify categories of examined coffee beans and analyzes an experimental dataset using multiple data structure strategies during the identification process, which are different from traditional approaches that aim to improve coffee bean species classification and recognition rate. Furthermore, the developed coffee bean identification strategies implement various normalization and error analyses during the data reasoning process. This research concludes that FA C18:1, C18:2, and C18:3 have essential characteristics for coffee beans. ***Journal of Food Processing and Preservation*. 2021;45:e15703. DOI: 10.1111/jfpp.15703.**



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