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## THE PANDEMIC AND THE FOOD INDUSTRY

What have we  
learned?





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# From The Editor

## A New Meaning to Supply Chain Issues and Food Shortages

The world changed in February 2020 when a virus emerged that would infect the world. The world changed yet again on February 24, 2022, when Putin's Russia initiated a "special military operation" against Ukraine.



I wondered how to write about this; there will be devastating food shortages to be sure, but others will cover that. Maybe Ukrainian President Zelenskyy's inspirational leadership is where I should focus. He is the glue holding his country together, but many have already pointed this out.

One thing has become clear to me: Russia is awful at logistics. Tanks are abandoned for lack of fuel. Russian troops seem to lack basic rations; they were ordered to pack parade uniforms. While it's still brutally cold for refugees, the ground is no longer frozen, so Russian tanks and heavy equipment convoys are quickly stuck in the mud and left behind. Was this the story I was looking for?

March 8 was International Women's Day. With images of Russian attacks on maternity hospitals fresh in my mind, my focus became the courage and bravery of the Ukrainian women who are fighting to save their children, their families, and their country as Russian troops relentlessly bomb their homes.

Putin has not hesitated to lay waste to civilian areas. Cities are bombarded daily, resulting in horrific, haunting images. Residents remain trapped with little food or water and no electricity for heat. On camera, journalists stop to help the elderly cross makeshift bridges, while in the background a woman is seen pushing a wheelbarrow carrying her husband.

Border checkpoints are overwhelmed, millions have crossed into Poland, and millions more are believed to be displaced. After taking their children to safety, some 100,000 women reportedly have returned to join the fight to defend Ukraine.

A small, elderly woman was seen approaching one of the Russian soldiers guarding an intersection near her home. Unafraid, she let him know in no uncertain terms that he was not wanted in her country. Not wanting an altercation with someone who looked like his "Babushka" (grandmother), he pleaded with her to go home. The back and forth went on for a few more minutes until she finally turned to leave. As she did, she threw a handful of seeds at the soldier, telling him to pick them up. "Put those sunflower seeds in your pocket so flowers will grow where you lay down and die here." The sunflower is the Ukrainian national flower and that woman is an example of Ukrainian heroism.

While people flee the conflict, the food supply will need to follow. Shortages will develop as farmers fight when they need to plant. For now, our hearts will remain with all Ukrainians.

**Patricia A. Wester**  
 Executive Industry Editor

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# NEWS & NOTES

## FDA Clears Genome-Edited Cattle for Food

BY KEITH LORIA

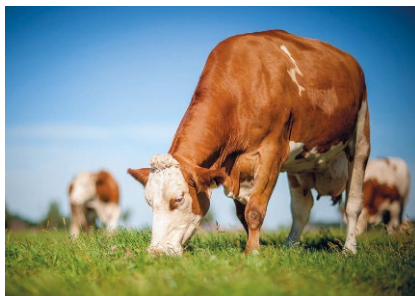
FDA has given the OK for genome-edited cattle to be used as meat after making a “low-risk determination” that the offspring of two genome-edited beef cattle may be used for food.

The cattle were bioengineered to have short hair, known as a “slick coat,” which helps the animals endure hot weather, and FDA determined that this intentional genomic alteration (IGA) did not raise any food safety concerns. This is FDA’s first-ever low-risk determination for enforcement discretion for an IGA in an animal for food use, which means that the agency has deemed that the product does not raise any safety concerns.

The IGA in these cattle, known as PRLR-SLICK cattle, was introduced using the

genome-editing technique CRISPR. This IGA can be passed on to offspring so that the altered traits can occur through conventional breeding in subsequent generations.

In making its determination, FDA reviewed genomic data and other information submitted by the product developer and confirmed that the IGA in the PRLR-SLICK



cattle is comparable to naturally occurring mutations that have arisen in several breeds of cattle as an adaptation to being raised in tropical or subtropical environments. “The data also confirmed that the IGA results in the same slick hair trait [seen] in cattle found in conventional agriculture,” said Steven M. Solomon, DVM, MPH, director of the FDA’s Center for Veterinary Medicine. “Further, the food from the [PRLR-SLICK] cattle is the same as food from conventionally bred cattle that have the same slick hair trait.”

The developer of the PRLR-SLICK cattle plans to use the genetic products from these two animals with select customers in the global market soon and anticipates that meat products will be available for sale within the next two years.

## USDA Approves Increased Line Speeds for Three Pork Producers

BY KEITH LORIA AND PATRICIA A. WESTER

USDA has granted three pork plants the go-ahead to increase processing line speeds this month as part of a pilot program. The three plants are Clemens Food Group in Hatfield, Penn.; Quality Pork Processors in Austin, Minn.; and Wholestone Farms Cooperative in Fremont, Neb.

In this pilot, plants can operate at faster line speeds for up to a year while collecting data on how line speeds impact workers. “The trial will facilitate experimentation with different ergonomics, automation, and crewing to design custom work environments that increase productivity and protect



food safety while decreasing the probability of worker injuries,” a spokesperson for USDA said.

The pilot is designed to provide more data on the age-old questions around line speeds, worker conditions, and product safety that have persisted in the industry for years. Meat inspection relied almost exclusively on organoleptic assessment of carcasses to protect consumers for years. Over time, line equipment speeds have increased well beyond the visual capabilities of the human eye, often leaving industry, workers, and regulators at odds over the best approach to inspect as many carcasses as possible while keeping workers and consumers safe. While increased analytical testing can provide data to reduce some of the product safety concerns, it ignores the worker component.

At one time, line speeds were limited to 140 carcasses per minute, double the speed historically seen. Studies have used line speeds as high as 175 carcasses per minute, but participating plants have often

struggled to meet the food safety components at such high speeds, forcing some participants to drop out of those trials.

In 2019, the FSIS issued the New Swine Inspection System (NSIS), which would allow companies to choose their own slaughter speeds. The rule also mandated new microbial testing for facilities to improve process control. However, a decision by the U.S. District Court for the District of Minnesota in 2021 upheld a lawsuit against USDA, ruling that a controversial final rule that removes line speeds in pork processing plants and transfers certain inspection responsibilities to plant workers compromises worker health and consumer welfare.

At the time, Jen Sorenson, president of the National Pork Producers Council, said the court decision would reduce processing capacity by 2.5% nationally. Those numbers would certainly have made a difference in production during the difficult early days of the pandemic, but the question remains as to whether they are necessary under regular operating conditions.

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## Federal Court Orders Raw Pet Food Manufacturer to Cease Production



Bravo Packing, Inc., an animal food manufacturing company based in Carneys Point, N.J., has agreed to stop selling, manufacturing, and distributing raw pet food and come into compliance with the Federal Food, Drug, and Cosmetic Act.

The action marks the first consent decree of permanent injunction against an animal food manufacturer for violating public safety standards under Part 507 (Current Good Manufacturing Practice (CGMP) requirements) of the Food Safety Modernization Act (FSMA) Preventive Controls for Animal Food Regulation. Part 507 requires that animal food facilities take adequate precautions to prevent animal food from becoming contaminated and that all animal

food manufacturing, processing, packing, and holding is conducted under the conditions necessary to minimize the potential for the growth of undesirable microorganisms to protect against the contamination of animal food.

“The food we give our pets should be safe for them to eat and safe for people to handle,” said Steven Solomon, DVM, MPH, director of FDA’s Center for Veterinary Medicine, in a statement. “The FDA has taken this action to protect public health because, despite multiple inspections, notifications of violations, and recalls, this firm continued to operate under insanitary conditions and produce pet food contaminated with harmful bacteria. We will not tolerate firms that put

people or animals at risk and will take enforcement actions when needed.”

FDA conducted inspections in 2019 and 2021 and issued a warning letter to the facility in 2020. During these inspections, FDA found evidence of significant food safety violations, including grossly insanitary conditions and the failure to follow CGMP regulations for animal food. Multiple samples of finished raw pet food products collected during the inspections tested positive for *Salmonella*. Pet food that is contaminated with *Salmonella* can lead to illness in both the pets consuming the food and the humans who handle the food and care for the pets. Some of these finished samples as well as environmental samples from the two inspections also tested positive for *Listeria monocytogenes*.

The consent decree of permanent injunction prohibits the defendants from receiving, preparing, processing, packing, holding, labeling, and/or distributing pet food unless and until the company completes corrective actions. The decree also allows FDA to order a shutdown, recall, or other corrective action in the event of future violations and requires the defendants to pay the costs of inspections performed pursuant to the decree. Failure to abide by the agreement can also lead to civil or criminal penalties.

## Insect Wings Inspire New Antibacterial Food Packaging

A laboratory-made nanotexture from an Australian-Japanese team of researchers has been shown to kill up to 70% of bacteria and retain its effectiveness when transferred to plastic. The investigators say that this sets the scene for a significant reduction in food waste, particularly in meat and dairy exports, while at the same time extending the shelf life and improving the quality and safety of packaged food.

Elena Ivanova, PhD, a professor at RMIT University in Melbourne, Australia, says her research team successfully applied a natural phenomenon to a synthetic material—plastic. “Eliminating bacterial contamination is a huge step in extending the shelf life of food,” she said in a statement. “We knew the wings of cicadas and dragonflies were highly efficient bacteria killers and could help inspire a solution, but replicating nature is always a challenge. We have now created a nanotexturing that mimics the bacteria-destroying

effect of insect wings and retains its antibacterial power when printed on plastic.”

The research, published in *ACS Applied Nano Materials*, is a collaboration among RMIT, Tokyo Metropolitan University, and Mitsubishi Chemical’s The KAITEKI Institute.

Dragonfly and cicada wings are covered with a vast array of nanopillars, blunted spikes similar in size to bacteria cells. When bacteria settle on a wing, the pattern of nanopillars pulls the cells apart, rupturing their membranes and killing them. “It’s like stretching a latex glove,” Dr. Ivanova said. “As it slowly stretches, the weakest point in the latex will become thinner and eventually tear.”

Dr. Ivanova’s team developed their nanotexture by replicating insects’ nanopillars and developing nanopatterns of their own. The best antibacterial patterns were shared with team in Japan, who developed a way to reproduce the patterns on plastic polymer.



Dr. Ivanova’s team then tested the plastic nanopatterns and found the one that best replicated insect wings but was also easiest to fabricate and scale up.

Dr. Ivanova said that dealing with plastic was more difficult than other materials such as silicon and metals due to its flexibility. “The nanotexturing created in this study holds its own when used in rigid plastic. Our next challenge is adapting it for use on softer plastics,” she added.

# Washington Report



## FDA Issues New Priorities for Food Guidance in 2022

Lead levels in food, genome-edited foods top list

BY KEITH LORIA

**E**arlier this year, FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Office of Food Policy and Response (OFPR) gave an overview of the food guidance topics that the agency's Foods Program will focus on over the course of 2022.

The expectation is that FDA will publish most of these priority documents by January 2023, although the agency cautions that it is not bound by these 30 topics and is not required to issue every guidance document on the list. It's worth noting that food guidance documents do not have the force of law, but rather represent the agency's current thinking on a topic.

Matt Regusci, director of growth at ASI Food Safety, notes that a lot of industry and regulatory input goes into figuring out what will be on the list; therefore, putting the list out at the beginning of the year allows the industry to know what FDA plans to tackle throughout the year and holds the

government accountable for finalizing it. This also allows the food industry to watch out for new guidelines that may come out and provide input to the FDA.

"The FDA has a multiple-step process from guidance to regulation," Regusci says. "These guidance documents help the industry to provide feedback and real-time examples of what works in theory and what works in reality. Food is not produced in a lab-like environment, so as industry leaders implement the FDA guidelines, they can provide feedback to the FDA."

Steve Gendel, principal of Gendel Food Integrity Consulting and a member of the *Food Quality & Safety* Editorial Advisory Board, who spent 24 years at FDA, notes that releasing a list of topics like this is unprecedented, adding that these are clearly areas that the agency thinks are important and has been working on. "[They] encompass many different areas—all things that are of some priority for the Foods Pro-

gram," he says. Several topics listed involve FDA's approach to enforcement actions.

According to an FDA spokesperson, the list was released to continue providing transparency for stakeholders regarding its Foods Program priorities. Guidance documents represent FDA's current thinking on specific topics, and the information can help stakeholders plan for potential changes that may impact their businesses and organizations.

Ten of the topics deal with the Food Safety Modernization Act (FSMA). "When the FDA started implementing the FSMA regulations, it was a very big deal for the industry," Gendel says. "A number of years ago, they issued a [preventive controls] guidance document that started to fill in all the information the industry needed, but it covers a lot of different things, and the initial guidance had several placeholders for chapters and subjects they said were coming soon."

### A Look at Food Safety

There are eight guidelines slated for 2022 dealing with food safety.

Significant topics regarding food safety include action levels for lead in food intended for babies and young children, action levels for lead in juice, and foods derived from plants produced using genome editing.

"If you look at the things on this list, there are several that relate to heavy metal topics, which has become of interest to the agency, and [is] something that has received a lot of public attention," Gendel says. "This is an effort by the agency to demonstrate its transparency and, to me, what's interesting is that it does cover a wide array of topics. Creating guidance is important for the agency, the public, and everyone."

Sara Bratager, a food traceability and food safety scientist at the Institute of Food Technologists, notes that, given the spotlight on heavy metals in baby foods over the last year, it's not surprising to see that three of the nine listed food safety guidance



topics center on heavy metals—specifically on lead and arsenic in juices and foods meant for babies or small children.

“With four of the remaining topics touching on microbial food safety in various food systems, it appears that both chemical and biological hazards will be a primary focus for the year,” she adds.

Ben Miller, vice president of regulatory and scientific affairs at The Acheson Group, notes the list of forthcoming guidance documents includes some clear themes around allergens, GRAS panels, plant-based and cell-cultured foods, ready-to-eat (RTE) and non-RTE food classification, and heavy metals in infant foods and juices. “These are issues that are driven by industry innovation, such as plant-based and cell-cultured foods, and GRAS panels for GRAS self-determination,” he says. “Other issues have been driven by consumer group and congressional testing, such as heavy metals in infant foods. Clearly issues dealing with infant and child health and risks associated with heavy metals in infant food will be a regulatory and public health priority for the agency.”

Likewise, further evaluating the public health importance of allergens in addition to the Big 8 (plus the upcoming addition of sesame) will have a direct impact on industry and consumer health and safety.

Several guidelines are related to seafood, with one planned on reconditioning of fish and fishery products by segregation, and a second on Detention Without Physical Examination (DWPE) of fish and fishery products due to the appearance of adulteration by bacterial pathogens, unlawful animal drugs, scombrotoxin, or decomposition.

There’s also one on the prevention of *Salmonella enteritidis* in shell eggs during production, storage, and transportation.

Regusci notes that food safety issues in eggs and sprouts are ongoing and have been for years, so this clarity in the industry for minimizing risk and providing best practices is helpful. “It looks like CFSAN is signaling to the industry areas where they feel that industry, consumers, and Congress have shared or competing interests,” he says. “Those with experience in the food industry know that guidance documents are a window into the agency’s thinking on how industry may comply with regulation.”

### Labeling Concerns

One area of focus is on labeling, especially dealing with plant-based food, genome-edited foods, and dietary guidance. “The public should know what they are eating and how it affects their diet,” Regusci says. “With the expansion of both plant-based imitation meat and milk, the meat and dairy industry are lobbying for more clarity. The big question from the

**This is an effort by the agency to demonstrate its transparency and, to me, what’s interesting is that it does cover a wide array of topics. Creating guidance is important for the agency, the public, and everyone.**

—STEVE GENDEL

meat and dairy lobbyists is: ‘Can you call something meat or milk, if it is not meat or milk?’”

Whether the subject of concern is dietary guidance statements or food ingredients, clear and consistent food labeling allows consumers to make informed purchases. “Innovative new foods, like plant-based alternatives to animal-derived products, have brought about some labeling debates among producers and consumers,” Bratager says. “Innovation in our food systems is critical to manage both a growing population and the impacts of climate change.”

As the food industry grows and changes, labeling requirements (or the interpretation of labeling requirements) must adapt to both support and respond to innovation. Additionally, clear guidance that helps food producers maintain accurate and compliant labels can help prevent food waste and financial impact due to misbranding issues.

Other promised topics by FDA deal with the accredited third-party certification program; the implementation of standards for growing, harvesting, packing and holding of produce; and potential hazards for foods and processes. Nine of the topics

deal with food safety and three with labeling. Other topics of note deal with allergens, nutrition, and dietary supplements.

### Enforcement Action

New guidance begins an implementation cycle in which regulated entities and FDA work to deploy the new information to their field operations. “Enforcement capacity is heavily dependent on funding; without knowing how this guidance fits into the budget scheme, it is difficult to speculate on enforcement,” Bratager says. “However, the inclusion of draft guidance for FDA staff, ‘Compliance Policy Guide Sec. 555.320,’ in the list of guidance topics suggests that producers may expect updates to FDA’s enforcement policy for *Listeria monocytogenes* in human foods.

Food producers don’t need to immediately panic about making changes, Miller says, as it usually takes some time for guidance documents to affect industry practice, especially when guidance causes a shift in regulatory interpretation, as in determining when a food may or may not be RTE. “The agency recognizes that new or updated guidance may take some time to implement and often will not shift its enforcement approach unless there are egregious violations that are further clarified by the updated guidance documents,” he adds. “Most typically, guidance may gradually shift industry best practices to a place that then becomes the baseline performance standard for enforcement in the future.”

The exception to this approach will likely occur in instances when the agency is defining new action levels for heavy metals in foods for sensitive populations. In those instances, industry should expect to incorporate these updated action levels into their food safety plans when considering what constitutes a reasonably foreseeable hazard.

“By signaling these priorities, the agency is communicating to industry, politicians, and consumers its priorities for 2022 and beyond, and this helps industry determine areas for future compliance and regulatory investment,” Miller says.

A full list of the topics can be found on FDA’s website. ■

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# Legal Update



## “Healthy” and “Natural” Claims

Using these terms on your product label may not benefit your bottom line

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

**A**s consumer desire for clean, healthy, and natural foods continues to grow, food companies are increasingly interested in including these types of claims on product labels. The theory is that the more “natural” or “healthy” a food product appears, the more likely consumers are to purchase it. The use of any word or term on a food product label, however, could create significant regulatory or class action risk for food companies.

For this reason, food companies should carefully consider any marketing term that is included on a product label or in product advertising. Although FDA has direct regulatory authority over food labels per se, the agency has interpreted this authority to include food advertising

(i.e., ancillary statements made in flyers, in commercial advertisements, or on the internet). In turn, the Federal Trade Commission (FTC) also has direct regulatory authority over food advertising claims and can take its own regulatory enforcement actions against food companies that make claims found to be deceptive or misleading. FTC will find an advertisement deceptive and unlawful if it contains a material representation or omission of fact that is likely to mislead consumers acting reasonably under the circumstances.

The risks associated with using such claims can be significant. This is especially true when both regulators and class action lawyers are constantly scanning store shelves for products using these terms. In this article, we will look closely at the

definitions of both “healthy” and “natural” and provide an update on the overall regulatory enforcement approach being adopted, as well as some recent examples of class action lawsuits.

### “Healthy”

When using the term “healthy” on a product label or in advertising, food companies should conduct a careful review of FDA’s definition and previous treatment of the term to avoid regulatory action and potential lawsuits. FDA has previously taken formal regulatory action, including issuing formal (and public) warning letters, for the improper use of the term “healthy” on product labels and in advertising. Even without regulatory action, companies may face lawsuits when “healthy” is improperly used on foods, potentially leading to huge defense expenses and possibly a costly settlement.

As defined by FDA, the term “healthy” requires that the food meet certain nutritional requirements; however, after issuing a Warning Letter to KIND for the use of “healthy” on products that the agency argued did not meet these requirements, and later reversing its decision, FDA has started to refine its policy and approach to enforcing the labeling requirements.

Generally, all agree that a product using the term “healthy” must be low fat, low in saturated fat, and low cholesterol. Additionally, for certain product categories, the product must also be a good source of one or more vitamins or minerals. Additional requirements can be found in the regulations. All companies should thus carefully review the requirements of 21 C.F.R. 101.65(d)(2) before making a “healthy” claim on a product.

In addition to the requirements provided in 21 C.F.R. 101.65(d)(2), FDA has issued guidance stating that products that are not low in total fat but have a fat profile of predominately mono- and polyunsaturated fats or are a good source of potassium or vitamin D can use the term “healthy” in labeling and advertising.



Although guidance documents are not law, FDA has stated that the agency will use enforcement discretion to avoid taking regulatory action against products labeled “healthy” in accordance with the September 2016 guidance document. The agency also indicated that updates to the Dietary Guidelines supported the additional products that can be labeled “healthy,” and that the latest nutrition science would be considered when finalizing an updated definition for the term.

FDA published an update on its research activities on March 28, 2022, indicating that the agency is continuing to review the definition of “healthy” and is currently investigating the use of an approved icon for “healthy” products. The agency has determined that a standardized symbol for “healthy” foods may help improve dietary patterns within the U.S., and the agency is currently conducting research to develop the image and standards for a voluntary “healthy” icon.

With that said, the use of the term could still be dangerous if all regulatory requirements are strictly followed. Notably, many recent class actions litigating foods claiming to be healthy focus on products with high levels of added sugars and include products that only make an implied claim of healthfulness. In a case litigated in 2020, a consumer sued Welch’s for making claims such as “helps support a healthy heart” on various 100% juice products. In *Hanson v. Welch Foods Inc.*, 470 F. Supp. 3d 1066 (N.D. Cal. 2020), the consumer sought to represent a California-wide class, alleging that the products actually increased the risk of heart disease due to their high sugar content. Welch’s ultimately settled with the consumer, on behalf of a class of consumers, for both monetary relief totaling \$1,500,000 and an agreement to remove all claims that suggest the product is healthy.

Similarly, Clif Bar was recently sued for making various claims that suggested certain products were healthy. Among the claims made were “nourishing kids in motion” and “nutritious on-the-go snacks for our kids.” These claims, according to the plaintiff in *Milan v. Clif Bar & Co.*, 489 F. Supp. 3d 1004 (N.D. Cal. 2020), were misleading because of the high levels of added sugar in the Clif Bar products. The consumer sought to represent all New York and California consumers who purchased

the various products, and these classes were approved by the court. The case has not yet been litigated nor have the parties settled.

What is clear from the litigation, however, is that these types of claims and lawsuits can be extremely expensive. The costs of attorneys can easily exceed hundreds of thousands, if not millions, of dollars, and the settlements can be equally costly.

## Regardless of what FDA’s guidance provides, both the terms “natural” and “healthy” have evolving meaning to consumers.

### “Natural”

Unfortunately, FDA has not yet defined the term “natural.” Although the agency previously requested comments in 2016 from the public on the meaning of the term “natural,” it has not yet issued guidance or a final rule implementing a regulatory definition. FDA has, however, stated that the agency considers “natural” to mean that nothing artificial or synthetic, including all color additives, has been added to the food unless the additive is normally expected to be in that food. USDA similarly has not issued a regulatory definition but has stated that the agency considers “natural” meat and poultry products to be those products that contain no artificial ingredients or color and that are only minimally processed.

Until FDA finalizes a definition of “natural,” companies should use the term “natural” with caution and only when the product contains no artificial or synthetic ingredients. Additionally, products being marketed as “natural” should be minimally processed, meaning that any processing the food undergoes does not fundamentally change the product.

In light of this confusion, over the past several years many lawsuits have sought to challenge “natural” claims, targeting everything from yogurt made with milk from cows fed genetically modified feed to granola bars that had trace amounts of herbicides. Other products routinely targeted included those using the term “natural,”

notwithstanding the presence of various ingredients such as citric acid, xanthan gum, and soy lecithin.

More recent class actions continue to focus on the presence of additives or residues that consumers may perceive to be unnatural. McCormick & Co. recently settled a class action lawsuit for use of the claim “all natural” on various seasonings that contained corn starch, white corn flour, and citric acid. The plaintiff alleged that these ingredients were “highly processed, synthetic, and/or genetically modified,” and were, therefore, not natural. In *Holve v. McCormick & Co.*, 334 F. Supp. 3d 535 (W.D.N.Y. 2018), the consumer sought to represent a national class of affected consumers, and the agreement settled the claims on behalf of a national class. The settlement totaled \$3,000,000 in monetary penalties and included an agreement by McCormick to modify the labeling of various products.

Similarly, Tropicana continues to litigate a class action lawsuit, *Willard v. Tropicana Mfg. Co.*, No. 20-cv-01501 (N.D. Ill. Dec. 30, 2021), in which the consumers claim that the presence of DL-malic acid in juices labeled as “100% natural” causes the claim to be deceptive and misleading. The plaintiffs, who have targeted numerous Tropicana products in the action, seek to represent a national class of consumers.

With these risks in mind, be sure to scrutinize your labels, claims, and ingredients to avoid becoming a target. Also, remember that, regardless of what FDA’s guidance provides, both of these terms (“natural” and “healthy”) have evolving meaning to consumers. So, even if the terms are being used appropriately in the technical sense, class action lawyers could still attempt to argue that, based upon current consumer perceptions or understanding, consumers are being misled.

What is clear is that a regulator or plaintiff lawyer may begin to salivate when they see these terms. Review your labels now to make sure that they are salivating over the quality of your product, and not the quantity in your pocketbook. ■

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# Cannabis Corner



California's universal symbol for cannabis-infused product packaging.

## Label Liability

Label requirements for cannabis-infused edible products are notoriously difficult to navigate

BY JESSE STANIFORTH

**T**he process of labeling cannabis-infused edible products in the United States is complicated, for two related reasons. The first is that cannabis's federal status as an illegal product means that only those states that have legalized it have developed packaging regulations. The second issue is that, where packaging and labeling regulations exist, there are notoriously tricky challenges that can even require companies to have full-time compliance experts in place just to keep track of the vast array of regulatory variation among these states.

While none of the U.S. state labeling regulations are worded in exactly the same way, there are some areas that over-

lap, says Michelle Mabugat, a lawyer with Los Angeles-based firm Greenberg Glusker who has worked in the cannabis sector for 11 years. Requirements for labeling seem to consistently include disclosing THC and other cannabinoid content, as well as manufacturer contact and licensing information, and most states—but not all—require batch numbers or health risk warnings. Many states also require some kind of cannabis symbol.

Because cannabis-infused edible products remain illegal at the federal level, they are not regulated by FDA. State regulators are the authorities overseeing packaging and labeling for legal cannabis products. Nick McCormick, a packaging consultant at

Taylor Prime Labels and Packaging in Fairfax, Va., sits on the packaging and labeling committee of the National Cannabis Industry Association (NCIA). "I've been in printing for 27 years, and I've been navigating the alcohol industry for 12," he says. "Selling wine, beer, vodka, gin, bourbon—that's hard to navigate, with the Alcohol and Tobacco Tax and Trade Bureau. Cannabis is 10 times harder."

McCormick sees the immediate challenge for packages and labels in the form of audits from state regulators. "One of the most complicated parts of running a cannabis business is making sure what you're putting on the shelf is compliant," he says. "You could be audited on any given day."

The regulations reflect lingering uneasiness about the safety of cannabis as a product—stoked by its continued status as a federally illegal drug. Mabugat notes that governments who have legalized the products have listened to stakeholders, including those vehemently opposed to cannabis. As a result, she says, "In order to make the public at large give broad support, the regulators and politicians almost have to overregulate. It's to the point that we might as well be dealing with uranium at the level of regulation cannabis receives in the U.S., to placate those concerns and help unwind all the stigma about perceived dangers of this plant."

By the nature of legalization, cannabis regulation has been carried out by agencies that have never before regulated cannabis, a circumstance Mabugat says has left state regulators behind the actual industry. "At least in California, the regulators have been very intentional about hearing feedback from industry operators," Mabugat says, "hearing what's not practical, and constantly updating the regs to catch up to where the industry really is and has always been. Every year, the regulators try to close that gaping hole. But everyone was up in arms when the initial regulations came out; the sentiment was 'Obviously you guys don't know anything about cannabis.'"



McCormick notes that, in Virginia, cannabis is regulated by the pharmaceutical processing division within the state department of health, which he says doesn't know much about cannabis products. "Some states have gotten smart and formed their own commissions around cannabis regulations, but [in] most states [the regulations] are handled by the state department of health," he adds.

### Compliance Challenges

Darwin Millard, of Evergreen, Colo., is a longtime cannabis extractor who is an executive committee member of standards

## Canada's Labeling Austerity

In 2018, when Canada followed Uruguay to become the second nation to legalize cannabis for adult recreational use, the task force overseeing legalization was aware that the country's size—10 times that of Uruguay—meant Canada would be treated as a global proving ground for legalization.

As a result, federal regulator Health Canada (akin to the US FDA) adopted attitudes of extreme care in legalization. The rules governing packaging and labeling of cannabis products are the most visible manifestation of Health Canada's demanding regulatory framework, which exists at all levels of cannabis production, processing, distribution, and retail. In sum, Health Canada demands that cannabis products containing THC be sold in childproof, non-transparent packaging, dominated by a large health warning and a smaller stop sign-shaped cannabis warning symbol. The package must feature a smooth, non-embossed surface texture in only one uniform color. This color may not be metallic or fluorescent and must contrast both with the yellow of the health warning message and the red of the stop sign cannabis warning symbol.

The brand name can be displayed only once, in a font of the same size as or smaller than that in the health warning. A single brand element is allowed but cannot be larger than the stop-sign warning symbol, meaning the brand logo never occupies more than roughly one eighth of the label.

Further, a Canadian cannabis brand element may not appeal to young people; feature a testimonial or endorsement; depict a real or fictional person, character, or animal; or associate the product or brand with an aspirational way of life.—JS

One of the most complicated parts of running a cannabis business is making sure what you're putting on the shelf is compliant. You could be audited on any given day.

—NICK MCCORMICK

and training organization ASTM International's Technical Committee D37 on Cannabis. "All the content and the barcodes and universal symbols are all different. If you're a multi-state operator brand, you have a compliance department in each state that focuses on labels. Especially if you have a tremendous number of SKUs, developing compliant labels can be a whole department's full-time job, especially if each batch has different batch data that you have to report for cannabinoid content specifically."

Millard says compliance is both a necessity and an enormous time drain. "You have to go through multiple different steps of verification and approval; then you print them and have to verify them again. Sometimes you have to reprint."

Mabugat puts it very bluntly: "I really can't say I've ever seen a single client's [product] label pass muster on the first try. That doesn't mean these aren't professional, compliant operators. It's more of a reflection of the rules and regulations getting more and more complex and changing constantly."

### Legal Exposure

From the perspective of a lawyer such as Mabugat, it's entirely possible for an operator who follows existing state regulations to the letter to get sued by a consumer who feels harmed by an edible cannabis product. Legal states have come a long way from the early wild west days of legalization in Colorado, during which high-potency infused foods were sold without critical dosage information on the label. In fact, the nation's oldest legal markets, such as Colorado and California, have developed some of the most stringent labeling regulations in the

country. Mabugat compares California's packaging demands to Canada's notoriously austere labeling regulations (see "Canada's Labeling Austerity," left). But newer states have fewer regulations.

Regardless of the level of regulation taking place in a state, Mabugat says, operators bear the legal responsibility for their product and may accordingly be open to lawsuits from consumers who feel that the producer's packaging failed to warn them of or protect them from an inherent danger.

"No matter the state regulation, you're exposed to litigation," she says.



### California's Prop 65

Mabugat operates in California, where Proposition 65 mandates warnings for products containing chemicals that might cause reproductive harm. The rules of Proposition 65 are changing to include cannabis, and she calls this a major challenge. "From a design standpoint, it's a hurdle itself to fit all the required information on the label," Mabugat says, adding that "it's a lot of work for us lawyers just to review, so I can't even imagine what it's like for operators. If operators—cannabis or non-cannabis—aren't compliant with Prop 65, it's fertile ground for private plaintiffs to allege exposure occurred."

### Consolidation

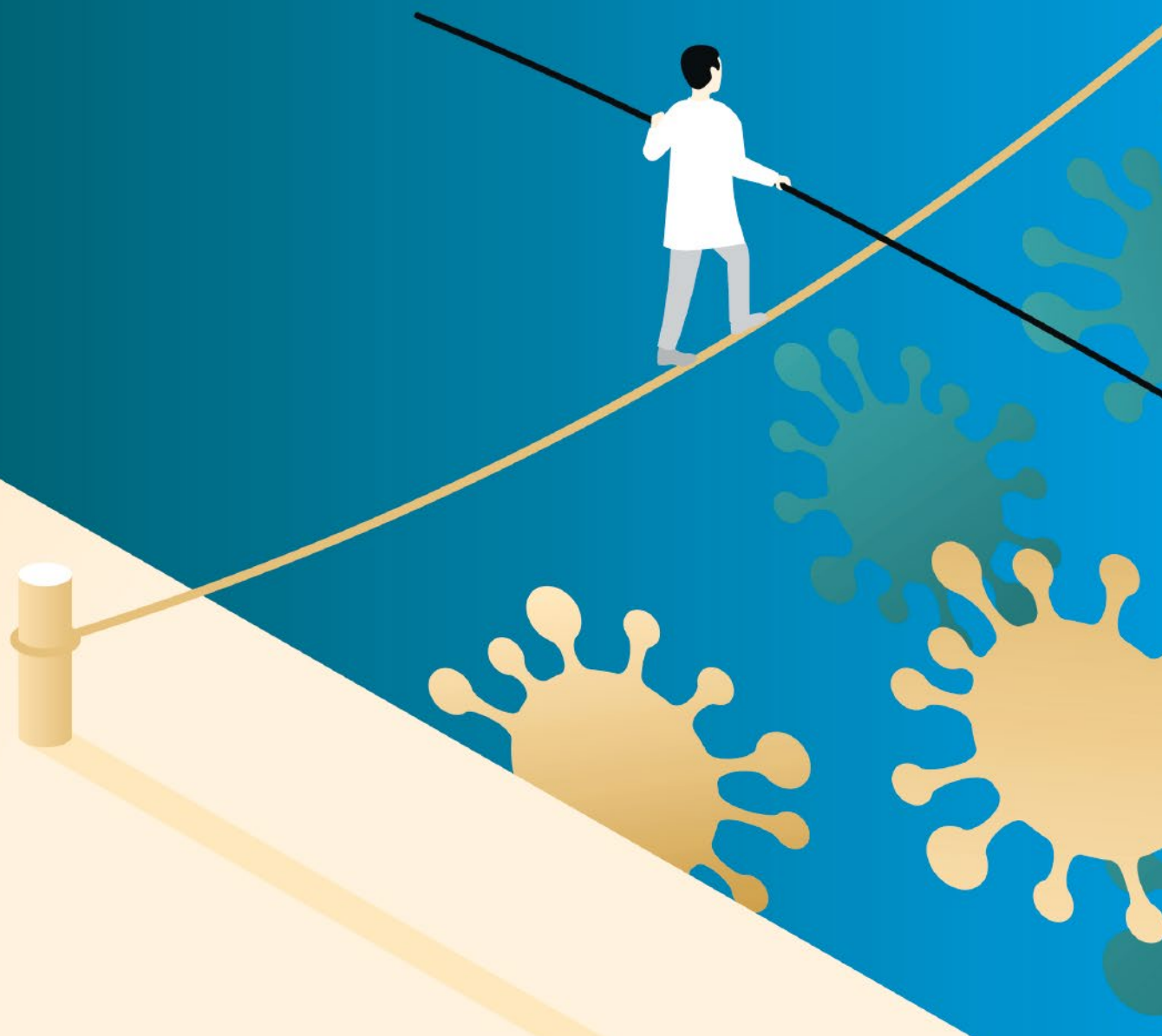
National uniformity in labeling and packaging standards is not coming soon. In the meantime, ASTM International's Technical Committee D37 on Cannabis is currently voting on a proposed new "Specification for Label Content and Style, Format, Location, and Prominence of Elements for Consumer Products Containing Cannabinoids." Darwin Millard sits on that committee, and notes that, at the moment,

(Continued on p. 40)

# The Pandemic's Impact on the Food Industry

What have we learned, and how prepared are we for future large-scale disruptions?

BY MARY BETH NIERENGARTEN





**A**s the Omicron variant fades, many anticipate at least a respite from a virus that has shattered systems and societies, even while another variant, BA.2, gains ground. Both the respite from one variant of COVID-19 and the increasing spread of another underscore the uncertainties remaining about the full impact of this virus.

How has the food industry adapted? What have the past two years shown about the vulnerabilities and strengths of the food industry, and what lessons have been learned that can carry the industry forward through inevitable future major disruptions?

“COVID-19 was a real wake-up call to highlight vulnerabilities in our food supply chain,” says Jeffrey LeJeune, PhD, food safety officer at the Food and Agriculture Organization (FAO) of the United Nations. The organization has provided many guidance and policy briefs on COVID-19 and the food supply, and continues to monitor, update, and advise the industry.

As an internationally recognized expert in food safety and diseases transmitted between animals and people, Dr. LeJeune emphasizes that the challenges to the food industry brought on by the pandemic are not related to the biology of the virus itself, in the critical sense that the virus causing COVID-19 is not transmitted by foods or food packaging.

What did stress the food industry during the first wave of the virus was the need to rapidly adapt systems from farm to table to safeguard against a new infectious virus with deadly potential. Among the changes was the need to quickly develop and implement strategies around supply chain issues to accommodate changing consumer demands. Food packaged and labeled for restaurants, for example, had to be repackaged and labeled for sale at grocery stores. Worker safety issues and facility safety protocols moved to the forefront as meat and other food processing facilities had to quickly impose measures to protect workers and facilities from the rapidly and highly contagious virus. Worker shortages, brought on by worker absenteeism due to illness or by the millions of people who have left the workforce, continue to strain the industry.

**Worker safety issues and facility safety protocols moved to the forefront as meat and other food processing facilities had to quickly impose measures to protect workers and facilities from the rapidly and highly contagious virus.**

Major disruptions to the supply chain continue to cause major fallout. Aljoša Trmcic, PhD, dairy extension associate at Cornell University in New York, NY, and part of the Food Industry COVID-19 Emergency Task Force that assisted local, national, and international food industries with issues related to the pandemic, says that supply chain disruptions hit every sector of the food industry and resulted in difficulty getting sufficient amounts of raw materials and supplies (such as packaging and cleaning chemicals), maintaining a sufficient workforce to make and distribute products, and—particularly challenging—protecting workers from the virus.

Now, going into the beginning of the third year of the pandemic, the food industry continues to grapple with its effects. Response by the food industry to these effects has helped the industry adapt and move forward with potentially increased resilience to meet future major disruptions. What issues still face the food industry? How can the sector be ready for any large-scale obstacles that come down the pipeline?

### Supply Chain Disruptions

Shawn K. Stevens, a food industry attorney in Milwaukee and a member of the *Food Quality & Safety* Editorial Advisory Board, underscores the supply chain issues still facing most companies—from difficulty obtaining certain ingredients to the challenge of retaining sufficient employees to manage the work. “Everyone is feeling pressure,” he says.

*(Continued on p. 18)*

(Continued from p. 17)

Recent evidence from Minnesota attests to these ongoing issues. General Mills, as reported recently in the *Minneapolis Star Tribune*, is seeing major disruptions in ingredients getting into their plants and is having difficulty, for example, keeping up with consumer demand for various products (e.g., ready-to-bake items, hot snacks, and pizza). The hospitality industry in Minnesota cites higher costs and supply chain challenges; a major issue is that the industry has 32,000 fewer workers compared with pre-pandemic levels.

### Resources: COVID-19 Guidance for the Food Industry

- FAO: Food Safety in the Time of COVID-19. April 2020. Available at [fao.org](http://fao.org).
- FAO. COVID-19: Guidance for Preventing Transmission of COVID-19 within Food Businesses. Updated Guidance. August 2021. Available at [fao.org](http://fao.org).
- Trmčič A, Demmings E, Kniel K, et al. Food Safety and Employment Health Implications of COVID-19: A Review. *J Food Protect.* 2021;84:1973-1989.
- Food Industry Counsel, LLC. Managing Coronavirus in the Food Industry. Available at [foodindustrycounsel.com/blog](http://foodindustrycounsel.com/blog).
- Institute for Food Safety at Cornell University. Food Industry FAQs. Available at [instituteforfoodsafety.cornell.edu](http://instituteforfoodsafety.cornell.edu).

Table 1. Potential Long-Term Impacts of the Pandemic on the Food Industry

Long-Term Changes	Potential Impacts
Food production and processing practices	<ul style="list-style-type: none"> <li>• More frequent cleaning of touched surfaces to reduce transmission of foodborne diseases (advantage).</li> <li>• Reallocation of resources to more frequent cleaning of touched surfaces may reduce the thoroughness of cleaning of other critical areas and may result in greater food safety risk (disadvantage).</li> </ul>
Behaviors and attitudes toward food safety and food safety practices	<ul style="list-style-type: none"> <li>• Increased use of face masks.</li> <li>• Increased availability of sick leave.</li> <li>• Increased willingness regarding vaccinations.</li> </ul>
Regulatory approaches and policies	<ul style="list-style-type: none"> <li>• Continued use of remote audits and inspections.</li> <li>• Accelerated efforts to implement risk-based food safety approaches versus a zero-risk approach.</li> </ul>

Adapted from Trmčič et al. *J Food Protect.* 2021;84:1973-1989

Along with the challenges involved in finding sufficient ingredients, supplies, and workers, another ongoing negative effect of the pandemic on industry, Stevens says, is the increased lack of safety when it comes to certain commodities. Cashew pieces or splits, for instance, are in short supply, so consumers are obtaining them through unregulated cottage industry vendors.

On the positive side, Stevens cites a heightened awareness in the industry, from manufacturing facilities to restaurants, of the need for good personnel hygiene within facilities to protect workers against the COVID virus.

Dr. Trmčič too sees a shift from focusing on food safety and quality to protecting employees inside and outside of the work environment. Noting that good manufacturing practices (GMPs) have always played an important role in the food industry to protect consumers and, indirectly, business, Dr. Trmčič says that parts of GMPs put in place as COVID-19 control strategies now directly protect employee and business health, in addition to protecting consumers from foodborne illness. “As much as GMPs were always followed, this shift meant that even more energy was put into it,” he says, citing, for example, employers encouraging employees to stay home if not feeling well, even offering paid sick leave. “Today, we have data to show that some foodborne infections were reduced during the pandemic, which can in part be attributed to enhanced control strategies implemented by the food industry,” he adds.

Stevens notes, however, that the drop in recalls during the past two years (from 800 in 2017 and 2018 to 400 in 2020) are one factor likely affecting the reduction in foodborne infections. Although the stricter worker safety protections in place due to COVID-19 could be a factor in the reduction of foodborne infections over the past two years, he also says this could be due, in part, to the lack of federal oversight given the distractions of COVID-19. “The FDA has been in hibernation mode for the past two years, and have not been visiting food facilities,” he adds.

Stevens thinks that food manufacturing and processing facilities are in for a “rude awakening” as FDA begins aggressively inspecting facilities again. He suspects companies will receive a lot of 483s and warning letters because of what he sees as a bit of sloppiness within the industry, given the extra demands they have had to meet in order to maintain their day-to-day foundational food safety programs during the pandemic. Worker protections are typically under OSHA jurisdiction, not FDA, so it remains to be seen how oversight and enforcement activities in this area will be handled.

### Food Safety Culture

Over the past decade, many have argued for the adoption of a culture of food safety within food industries, to promote a mindset of attitudes and behavior shared among management and employees toward ensuring food safety. For Dr. Trmčič, COVID-19 occasioned the opportunity for manufacturing facilities and other food industry sectors to move closer to adopting such a culture.

As described in a 2021 review of food safety and employment health implications of COVID-19, Dr. Trmčič uses the phrase “COVID-19 control culture” to capture the response by the food industry, which has adapted rapidly to the need to protect workers and operations.

“This culture captures the mentality of every single employee that is focused on the common goal of preventing the introduction





**The main positive impact [of the pandemic], I think, is that the food industry was forced to build this COVID-19 control culture, and now they can use this to shift to a food safety culture.**

—ALJOŠA TRMČIČ, PhD

and spread of COVID-19 in the food operation and maintaining the health of all employees and functionality of the entire food operation,” he says, adding that each operation within the food industry managed to build a COVID-19 control culture through its successful fight with the pandemic.

Going forward, Dr. Trmčič encourages the food industry to sustain the same mentality it had tackling COVID-19, converting it to a food safety culture where all employees are focused on the common goal of preventing foodborne illnesses. “The main positive impact [of the pandemic], I think, is that the food industry was forced to build this COVID-19 control culture, and now they can use this to shift to a food safety culture,” he says.

Table 1 (p. 18) lists several potential long-term changes in industry caused by the pandemic, as well as their impacts on food safety and quality and the issues industry can consider as they prepare their operations for future large-scale disruptions.

### Ready Roadmap

If nothing else, the pandemic demonstrated the critical need for the food industry to be ready and able to adapt to the inevitable occurrence of future large-scale disruptions. Wheat shortages from the war in Ukraine are already looming, and more frequent severe climate events will continue to stress the food supply chain.

The key to being ready, says Dr. Trmčič, is to have a roadmap for the first days, weeks, and months of the disruption. As part of the Food Industry COVID-19 Emergency Task Force, he and his colleagues are encouraging food operations to create a type of toolbox of everything they did during the pandemic to manage the different parts of the supply chain and then use this to adapt to a future disruption.

For example, he says, a cheese producer that primarily provides products to restaurants could be ready to switch to smaller consumer packaging and start offering product to retailers.

To build a roadmap, Dr. Trmčič suggests that companies document the effects of the pandemic on their business over the past two years, detail the unexpected events that occurred along with their responses—what worked, what didn’t work—and describe how the parts that did not work could be fixed. Calling this plan A, he says that at the end of this process a company should be ready for a disruption.

He also recommends developing alternative plans for other types of interruptions, such as a chemical company not sending cleaning supplies, a drastic reduction in the workforce, the loss

of a major customer, the unavailability of a key ingredient, and so on. He encourages industry to diversify and broaden their business connections with, for example, more than one supplier for each key ingredient, and to find more than one way for a product to be used, packaged, distributed, and marketed. “I would include in the plan some type of cost–benefit analysis so you know for each plan how much you can invest based on how much you expect to gain,” he adds.

Ellen Shumaker, PhD, director of outreach for Safe Plates program at North Carolina State University, underscores the idea that those in the food industry who used what they learned during the pandemic to put guidelines in place will be better positioned going forward to deal with another disruption, but will be limited in their preparedness depending on the vagaries of the next potential pathogen. “Those who are taking that proactive step are going to be much better positioned in the event of another pandemic, but there is a limit to how prepared the industry can be ultimately,” she says, citing unknowns about the type of pathogen, how easily it spreads, and whether it is foodborne.

### Staying Nimble

Underlying all of these efforts is the need for the food industry to adapt. “Every time we’re faced with a massive disruption, we learn a lot,” says Stevens. “We learn to become nimble, flexible, and creative in the new ways of doing business that will stay with us a very long time.”

Dr. LeJeune also uses the word “nimble” to characterize what the food industry needs to ensure that they can adapt to disruptions going forward. “The lessons learned remind us that we need to be more nimble and work proactively to prevent, detect, and have rapid holistic (One Health) responses to provide solutions to problems as they emerge,” he says.

He lauds the food industry for adapting to new scientific information as it became available and keeping the supply chains open. “This experience, I believe, has strengthened food systems and made us better prepared for the next pandemic.”

Dr. Trmčič, food workers in particular should be given credit for their role during the pandemic. “In my eyes, food workers are the champions of this pandemic, immediately after all the doctors and nurses who worked days and nights to help COVID-19 patients,” he says. ■

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# Safety & Sanitation



## Reducing *Salmonella* in Pre-Harvest Poultry

Live-side interventions are important for improving food safety

BY **BILL POTTER, PHD**

**U**SDA's Food Safety Inspection Service (FSIS) recently launched a new comprehensive focus on reducing *Salmonella* illnesses caused by poultry products. "Reducing *Salmonella* infections attributable to poultry is one of the department's top priorities" says Sandra Eskin, USDA deputy under secretary, who is leading the initiative. "Time has shown that our current policies are not moving us closer to our public health goal. It's time to rethink our approach."

USDA will be seeking stakeholder feedback on specific *Salmonella* control and measurement strategies that will support achieving or lowering the targeted reduction in consumer illnesses.

The announcement further emphasizes the fact that the effort will leverage USDA's strong research capabilities and strengthen FSIS's partnership with the Research, Education and Economics (REE) mission area to address data gaps and develop new laboratory methods to guide future *Salmonella* policy.

A key component in the new FSIS approach is to consider the use of pre-harvest controls to reduce *Salmonella* contamination in live birds coming into the plant. For years, the Centers for Disease Control and Prevention has attributed a large portion of foodborne illnesses to *Salmonella* associated with chickens, turkeys, and eggs. FSIS is looking to reduce these illnesses by working with poultry companies on advancing initiatives such as pilot projects, pre-harvest controls, and new quantitative measures of *Salmonella* loads.

While poultry producers, processors, and consumers all play an important role in preventing foodborne illnesses, *Salmonella* in poultry originates pre-harvest and can proliferate at farms that do not have a comprehensive *Salmonella* control strategy. This is where poultry producers and live operations managers play a crucial role. One way to describe effective

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*Salmonella* controls pre-harvest is to take a “360-degree” approach.

### A Holistic Approach to Pre-Harvest *Salmonella* Reduction

A holistic approach to preventing *Salmonella* pre-harvest can be divided into five major components:

1. Vaccines to build *Salmonella* immunity and offer protection throughout the life cycle, including the progeny.
2. Intestinal integrity programs to support bird immunity and reduce opportunities for *Salmonella* to colonize.
3. Nutritional and functional feed supplements to help mitigate *Salmonella* colonization while improving bird performance.
4. Integrated pest management (IPM) programs to reduce external *Salmonella* vectors through the use of approved insecticides and rodenticides.
5. Farm and poultry house best management practices to reduce *Salmonella* proliferation through effective management of water, bedding material, biosecurity, and cleaning practices.

#### 1. *Salmonella* Vaccine Programs

A vaccination program is the first step in building bird immunity and helping to prevent *Salmonella* colonization. When *Salmonella* is an issue at the plant, it all starts with colonization of the pathogen within birds at the farm. Vaccines are strategically used early in the process to address the “root cause” of the problem. Comprehensive *Salmonella* vaccination programs in breeders and meat birds, consistently applied over time, have been successfully used in broilers and turkeys.

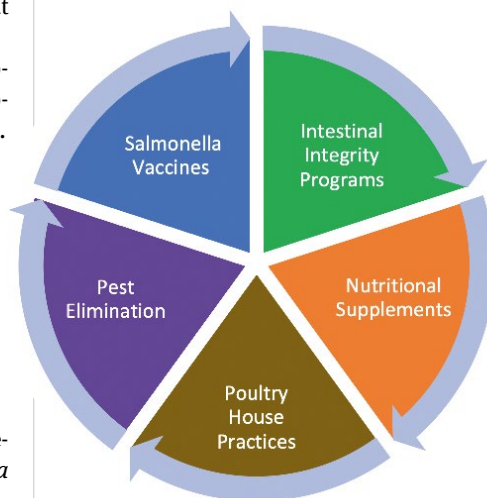
There are two groups of vaccines—inactivated and live—and each plays a role in poultry health and pathogen reduction. Also, when *Salmonella* vaccines decrease pathogen loads in live birds coming into the slaughterhouse, the in-plant interventions have a lower burden of decreasing quantitative loads and have an improved likelihood of effectiveness.

#### 2. Intestinal Strength and Integrity Programs

Bird health and food safety go hand in hand, and it’s important for producers to consider products that promote intestinal

integrity by reducing coccidiosis, necrotic enteritis, and other causes of damage to intestinal strength. The intestinal wall acts as a physical barrier to prevent the colonization of harmful bacteria or otherwise harmful pathogens that could lead to food safety concerns down the line.

An effective intestinal integrity program includes careful planning with



Pre-harvest *Salmonella* reduction 360° approach.

ionophores and non-antibiotic intestinal integrity products as well as management strategies. When issues arise, producers can evaluate and adjust their disease prevention program to maintain intestinal integrity.

#### 3. Nutritional and Functional Feed Supplements

The advancement of functional feed ingredients in recent years has added a valuable tool to use in decreasing pathogens at the farm. These feed ingredients use a variety of different modes of action to reduce *Salmonella*. For example, such products may serve as prebiotics, probiotics, competitive exclusion products, acidifiers, gut oxygen modulators, and pathogen agglutination compounds, among numerous other roles. One of the most important functions some of these nutritional health products provide is improving the intestinal wall physiology, including bringing about increased villi length and tighter gap junctions. These attributes not only lead to reduced pathogen colonization, but can also improve nutrient absorption, leading to improved bird growth performance.

#### 4. Insecticide and Rodent Control Programs

The control of insects and rodents is often seen as a way to manage the well-being and performance potential of a poultry flock, but this should also be considered a crucial strategy for reducing *Salmonella* proliferation at the farm. Common pests, such as darkling beetles, mites, flies, and rodents, can carry *Salmonella* and other pathogens into poultry barns. An effective IPM program should address infestation and create a cleaner environment for the birds, reducing the potential for *Salmonella* to enter post-slaughter operations.

#### 5. Poultry Farm Best Management Practices

Other pre-harvest strategies are also important to reduce *Salmonella* proliferation, such as optimal feed and water management, hygiene and disinfection of the poultry house per a written plan, litter management, and biosecurity measures. A comprehensive program tailored to control and manage disease will not only help the flock achieve its full potential, but also help minimize food safety risks originating from on-the-farm activities.

#### Working Together to Reduce *Salmonella* in Poultry Production

Reducing the risk of *Salmonella* in poultry products is an enormous responsibility, one that can’t be placed on the processing plant alone. Pathogen reduction activities can be successful at multiple steps along the entire continuum from farm to plant. Improved technologies in *Salmonella* quantification and detection at the pre-harvest phase have made measuring the impact of pre-harvest interventions more possible than ever before.

While processing facility interventions are very important, live-side interventions are just as important for improving the overall food safety of poultry products, because reductions at the farm can be realized throughout the supply chain. By reducing *Salmonella* infections in live-bird operations, poultry producers can decrease the likelihood that *Salmonella* will be a problem at the processing plant and beyond. ■

Dr. Potter is a technical advisor for Elanco Food Safety.

## HOW TO WASH YOUR HANDS



# Hand and Personal Hygiene for Food Safety

## Tips for food plant workers

BY CRAIG NELSON

According to the World Health Organization, there are 600 million cases of foodborne diseases that lead to 420,000 deaths worldwide each year. Proper hand hygiene is an important and effective way to prevent cross-contamination in a food processing facility. Contaminated hands can transfer germs to surfaces, utensils, office supplies, telephones, door handles, and other items commonly touched, making hand hygiene the first line of defense to prevent cross-contamination.

Here, we look at several techniques for good employee hygiene in the food plant setting.

### Personal and Hand Hygiene

Practicing proper hand washing techniques is a good way to reduce bacteria on hands. The Centers for Disease Control and Prevention (CDC) guidelines for proper hand washing technique are as follows: Thoroughly wet hands with clean, running water, apply an adequate amount of soap, rub palms and backs of hands,

rub thumbs and interlace fingers, rub fingertips into palms of opposite hands, and rub wrists.

The actual hand washing portion should last 20 seconds to ensure effective cleaning. Rinse well with running water and dry hands thoroughly with a disposable paper towel. For maximum results, sanitize hands after they've been properly washed to further reduce the presence of pathogens on the hands. The goal of hand hygiene is to reduce the number of pathogens on the hands to the smallest number possible, making hand sanitizing a crucial part of the process.

When choosing soap, choose a quality hand soap that won't dry out employee hands and, preferably, choose a sanitizing hand soap designed specifically for food processors. Choose an E2-rated, fragrance and dye-free hand soap formulated with emollients to keep skin soft and healthy. Sanitizing with a quality alcohol-based hand sanitizer after handwashing will further reduce germs on the hands. An atomized spray saturates fingernails, cuti-

cles, cracks and crevices of the fingers and hands, where pathogens commonly hide.

### Footwear Sanitation

In addition to practicing proper hand hygiene, implementing more personal hygiene best practices, such as a footwear sanitation program can help reduce pathogens in a food processing environment. A footwear cleaning and sanitation program is important for food processing facilities because employees can bring pathogens into critical control areas through contaminated footwear. Without a dedicated footwear cleaning and sanitation program, food production facilities are at risk of workers bringing contaminants into their facilities and possibly contaminating product. Footwear should be cleaned prior to sanitization to remove any dirt or debris on the bottoms or sides.

A successful footwear hygiene program should be customized to fit a facility's specific needs, making it crucial for food processors to choose the equipment best suited for their facility. Footwear should be properly cleaned using a boot scrubber or some other method that effectively removes debris. Once footwear is cleaned, food production workers can move on to a footwear sanitizing station for maximum pathogen reduction. Adding a walkthrough footwear sanitizing unit helps reduce cross-contamination. Unlike traditional footbaths, a footwear sanitizing unit provides more consistent results because it provides each worker with a fresh dose of sanitizer; there is no need for constant monitoring. Traffic flow can be designed to eliminate the possibility of workers avoiding the units, and the unsightly visual of a messy foot bath is replaced with a clean, effective piece of equipment.

### Training Employees for Proper Sanitation

When training employees on hand hygiene, it's important to implement a training program that presents the how, when, and why of proper hand hygiene. Using an expert to conduct the training and demonstrate correct hand washing techniques is crucial. In addition, demonstrations and

*(Continued on p. 40)*

# Quality



## Cell-Cultured Meat

How it's made and potential areas of growth on the way to commercialization

BY ALEX RAJANGAM, PHD, DERIN ALEMLI, AND MATT TOM

Nearly 33% of meat eaters worldwide today identify as “guilty meat eaters” with concerns about conventional animal agriculture and meat processing. And, just like other sectors such as automotives and energy, the meat processing industry needs to change.

Plant-based meat options, a \$5 billion market in the U.S., are growing annually by double-digit percentages, according to research from the Plant Based Foods Association; however, a 2019 report from NielsenIQ concluded that 98% of grocery shoppers who buy plant-based options still purchase conventional meat, suggest-

ing that plant-based meat alternatives are still missing the complete organoleptics of meat.

To make an impact on the \$1.6 trillion global meat industry, cell-cultured meat offers several advantages over conventional animal meat by employing a controlled bioprocess that significantly mitigates risks to food safety and human health, from animal farming’s environmental concerns and pollution to unethical and unhygienic treatment of animals during farming and meat processing.

While cell-cultured meat is still in the early stages of development, it’s important to implement industry best practices

now. Therefore, it’s prudent to begin assessing risk for and demonstrating the safety of the design and execution of the commercialization of cell-cultured meat. Here, we describe how cell-cultured meat is made, why it’s a safe and healthy alternative to meat that comes from animal farming, and what the potential areas of growth are for research professionals from related disciplines in this space.

### The Method

Cell-cultured meat is like the meat you’ve eaten all your life—it just uses more modernized production methods. For millennia, humans have relied on “animals as bioreactors” for all animal-derived food products. But, for nearly 100 years, humans have been producing not just food products, but all kinds of products, from pharmaceuticals to cosmetics, in precision-controlled, human-made bioreactors. In these shiny, sterile, stainless

*(Continued on p. 24)*



(Continued from p. 23)

steel vessels, biological processes can be optimized in a way that emphasizes the best parts of the system directed toward a single purpose: meat production. When it comes down to it, fundamentally, the same process is required whether in an animal or in a bioreactor: Grow a lot of cells that eventually make meat. Unfortunately, the animal is quite inefficient at doing this because that wasn't its intention. With cell-cultured meat, on the other hand, that is the sole purpose, and the process focuses only on the components required to produce meat.

In animal agriculture, animals are fed nutrient-dense calories, often along with hormones and antibiotics, so that they can grow large as quickly as possible. When they have reached the appropriate age

**FDA and USDA are jointly overseeing the [cell-cultured meat] process, but, as with any cutting-edge industry, the body of knowledge is still being gathered.**

(mass), they are slaughtered and processed into meat. In “cellular agriculture,” cells—for example, from a pig, which is what we use—are selected and placed in a carefully controlled bioreactor where they are fed a nutrient-rich growth medium, so that the cells can multiply as quickly as possible. The medium is composed of a variety of different growth factors, the formula of which is proprietary for any company, which are, in a way, the “calories” that you would feed a pig. The cells then multiply, expanding their mass via mitosis. When they begin, the cells are uncharacterized stem cells. Near the end of the process, they can be fed a new kind of medium that will make them differentiate—that is, become muscle, fat, or connective tissue.

When the cells have reached the appropriate mass, they are collected, and this biomass is processed into meat. This last step is non-trivial: The cells coming out of the reactors are often a sludgy clump, not good to look at and not a product itself. Our



process is our own, but from here, we combine our cells with high quality soy protein to create a pork sausage that tastes just like a high-end conventional sausage. This last step most closely resembles a typical food manufacturing facility; there are tumblers, mixers, packers, sealers, and so on. The difference, of course, is that this sausage used fewer resources and energy—and no animals.

**Health and Safety**

While there are plenty of reasons to advocate for cell-cultured meat’s impact on the environment, the benefits for safety and health cannot be understated. In animal agriculture, many, many animals are raised in close proximity to other animals, and sickness and disease, pathogenic bacteria, animal waste, and other hazards are a constant threat. These risks can be compounded in slaughterhouses and meat-packing plants, where human workers are added into the mix. In cellular agriculture, aseptic techniques and filtered media are carefully added to sterile bioreactors. When it is time to harvest the cells, the bioreactor outlet is connected aseptically to a collection vessel and then transferred for additional food-grade processing.

Currently, FDA and USDA are jointly overseeing the process, but, as with any cutting-edge industry, the body of knowledge is still being gathered, and currently, no company has yet received approval in the U.S. to supply cell-cultured meat.

**How to Prepare to Manufacture Cell-Cultured Meats**

As any industry professional will tell you, it’s better to design safety and risk mitigation into the process rather than to rely on testing after the fact. Because cell-cultured meat is still in the early stages of development, the opportunity to investigate and get ahead of issues is now.

Since the technical rabbit hole goes pretty deep, the following will just be thought-provoking highlights. The main phases to produce cell-cultured meat contain ample opportunities for the curious R&D and quality professional.

**Obtaining the source tissue.** For many of the companies in this space, source cells must be obtained from an animal, in the form of a biopsy if live or from the carcass if slaughtered. As the industry matures, there is likely to be a better supply source, but for now these are the best options. In both cases, a clear hazard is the health status of the animal. Was it sick or did it have some infectious disease? Was it a younger or older animal? What particular part of the animal was the target? And, depending on the where, when, and how of the collection, which might be riskier in the carcass case, could the cells be contaminated with pathogens, endo- and exotoxins, other viruses, or antibiotics? Is it necessary to develop a process to ensure that only healthy tissue is collected?

Of course, the tissue sample is likely a collection of many types of cells, some

of which are preferred and some of which are not. The desirable cells are ones that can proliferate and differentiate. For this reason, they are likely to be embryonic stem cells, induced pluripotent stem cells, mesenchymal stem cells, or adult stem cells. Note the common thread: They are all stem cells.

**Preparing the cells.** After the tissue has been collected, it must now undergo “preparatory” processing. As mentioned previously, because there was a collection of many different types of cells in the tissue, the first step is discarding all the non-stem cells. The result must then be sorted out “like with like” so that these stem cells can develop into the desired differentiated cell type. That is to say, some stem cells will eventually become bone cells, while others will become fat cells, and so on.



**It's better to design safety and risk mitigation into the process rather than to rely on testing after the fact. Because cell-cultured meat is still in the early stages of development, the opportunity to investigate and get ahead of issues is now.**

This is known as culturing, and the culture medium (the mixture of sugars, salts, vitamins, amino acids, lipids, hormones, growth factors, antibiotics, antimycotics, tissue dissociation reagents, and other substances) plays a large role in facilitating the optimal growth of the particular cell type.

Another point to note is that, implicit to all of this working, cells exist that are able to both proliferate quickly and as much as possible, which generally isn't something cells do. But by growing cell culture, we are dissociating the growth regulators and hormones in vivo and then introducing that control in vitro. For example, obtaining cells that do this may require specific screening and isolation techniques involving chemicals or similar that must be tracked and removed.

Protocols to ensure that the safety can be verified at final output is paramount to the success of the industry.

**Mass producing cells.** Scale, scale, scale is the name of the game in this phase, and that means a lot of proliferation followed by a lot of differentiation and then “cell finishing” (coming up to target biomass). Mass production is carried out in bioreactors where the selected cells are immersed in the culture medium and conditions are optimized for maximum proliferation in the shortest time. This means that the media inputs may be dynamically tuned based on real-time feedback of the system; the addition of one growth factor inducing a positive response of cell density, for example, could be preferred. It will be important to keep track of what exactly goes in, along with what concentrations as well, like growth factors, amino acids, hormones, vitamins and minerals. When the proliferation phase is complete, a different medium optimized to commence differentiation may be required, so the list of parameters to monitor and ensure safe concentrations grows during this exchange.

Finally, there is a question of whether these cells need something on which to anchor in order to grow (i.e., adherent dependent culture) or can do so free floating (i.e., suspension culture). Adherent culture necessitates the use of microcarriers and/or scaffolds for the cells, and

material selection and shape is important here (e.g., polystyrene, gelatin, collagens, polymers, polysaccharides).

**Processing as food.** In the current state of regulatory affairs, the time at which the cells are harvested from the bioreactors is when they transition from being regarded as a biotech product to becoming a food product. However, depending on how they were mass produced, some further optimization may be required before they can be used as a food ingredient. Assuming the adherent case from before, the cells must be removed from their microcarriers or scaffolds, especially if they are non-edible. This is usually accomplished chemically, enzymatically, or mechanically to ensure that the product is safe and healthy for human consumption. From here, more traditional food processing can be employed to make the meats everyone can enjoy, such as deli meats, sausages, meatballs, and steaks.

Cell-cultured meat has the potential to be transformative to our world, changing our relationship with animals and the planet for the better while improving human health and safety in the process. It may seem like the future, but this innovation is happening right now. ■

The authors are with New Age Meats, which specializes in developing cell-cultured pork and is based in Berkeley, Calif. **Dr. Rajangam** is the chief technology officer, **Alemli** is the chief operating officer, and **Tom** is the head of product. Reach them at [press@newagemeats.com](mailto:press@newagemeats.com).



# Cyber Resilience for the Food and Agriculture Sector

How to protect your organization | BY JOHN T. HOFFMAN

**T**he current state of cyber security across the United States food and agriculture sector is worrisome for many reasons. Even with the long history of computer hacking, intellectual property theft, and even outright extortion over the past two decades, few private sector firms within our national food supply chains have taken the steps needed to harden their systems and build in resilience against such attacks. Although cyber risks within food processing operations can very easily become food safety risks, most firms do not invest in cyber hardening the same way they invest in food safety.

This may be because there are almost no regulations on cyber hygiene for food and agriculture firms today. Few firms share cyber defense technology or actions with their supply chain partners, as they do for food safety issues. Some companies who were quick to claim tight cyber security over the past few years have recently experienced humbling and costly cyber attacks. Why is this the case? The answers are both simple and complex.

Simply put, most cyber defenses in place across the food and agriculture sector are not configured to mitigate the most prevalent attacks today. The truth is that

our vulnerability to cyber attacks in the food and agriculture sector results from two problems: The first is the extensive use of legacy technologies in food processing; the second is the integrated nature and interdependencies within our critical infrastructures and throughout our supply chain relationships themselves. Countless successful attacks have already leveraged these very vulnerabilities.

Unless your firm is utterly isolated from the Internet and allows no external connections of any kind to any of your networks, you are at risk. When cyber criminals mount attacks today, they cast a wide net to detect and penetrate every network that may have an Internet connection. If you are connected, you are at risk.

The primary attack modality today is not the same as it was 10 or even five years ago. Today's cybercriminals are far more sophisticated and much better equipped. They target money and valuable intellectual property (IP), and they do not want to be detected ... until they're ready. They need time to explore your network connections undetected to learn your networks, find your IP, and then insert their malware. They may gain entry via phishing by targeting your employee's email accounts, or they may find a security hole in a net-

worked device in your operational technology (OT). They might find a security hole in a network operated by one of your suppliers or customers, which may offer a connection to you.

When a cybercriminal does find a connection pathway or entry point, they explore your networks and seek data pathways they can exploit in your suppliers' or customers' networks. They can be in your systems for months, undetected. Then, when they are ready, they lock your systems, and often those of your suppliers and customers, and demand enormous ransom payments in exchange for releasing your data and your systems.

## The Cascade Effect

You might think that these cybercrooks need substantial resources and extensive IT infrastructure to do what they do. They do not. The real key for their success is the available computer power and the bandwidth now deployed across the globe. The computing power available in high-end gaming computers is astonishing. That power means that a well-trained cybercrook can operate 24/7 to execute millions of probes against thousands of network infrastructures or millions of email accounts, trying to find a network to exploit.

The current advantage is with the cyber attacker. They only need to be right once when attacking your networks, while you must be right every time, 24/7, to protect against them. You may even face cascading impacts from attacks on firms in other infrastructures, such as energy, transportation, or water. These providers are often connected to your firm's IT infrastructure in some manner to facilitate transactions and services.

This cascade aspect is, itself, a triple-edged sword. First, when external but critical infrastructures are penetrated and disrupted, the result can directly impact your business operations, creating delays and shortage. Next, such impacts can increase your costs and, consequently, your customers'. Lastly, and most dangerously, these attacks can enable penetration and exploitation of your own IT and OT infrastructures.

It is an ugly situation today for every firm with an IT and/or OT infrastructure. All are at risk at some level. Even your employee base is being targeted with socially



engineered emails trying to get them to “click” on a malware link. Indeed, your entire supply chain is under attack, whether they realize it or not.

### Taking Action

So, what can we do to defend our critical food and agriculture supply chains?

There are a lot of actions we can undertake, but often, we do not implement all of them. First, company leadership is often not invested in this critical aspect of their firm. They see IT and even OT system components as implements of management efficiency and convenience. They view OT system technology as labor and cost reducing, not fully appreciating the inherent risks or the broad vulnerabilities these systems represent. Where corporate management is engaged, it is usually with the business IT systems because these systems are closer to their day-to-day activities. Yet, the OT system is where their most valuable IP is located and where a disruption can have the greatest financial

impact on the firm. Management often views the OT environment as working just fine, so why disturb it with modernization?

If leadership does not see the need for OT cybersecurity investments now, they certainly will after a costly cyberattack. We need to encourage leadership engagement in OT cyber system hardening before an attack. When that engagement does occur, understanding brings action in most firms.

So, what are those actions?

First is continuous education on cyber hygiene for every employee, from the boardroom to the processing floor. Training must include risk, cyber threats as they evolve, and company policies and countermeasures that will, by necessity, also evolve over time. Next, every network needs to be isolated or segmented within the larger IT and OT computing environment across the firm. Only those with an absolute business or operational imperative should be directly connected to the Internet.

Your email system should be a stand-alone network with powerful firewalls,

strongly defended system gateways, and inbound traffic filters to keep most malware out of the network. This, combined with employee education and monitoring, will reduce your vulnerability to socially engineered phishing emails from cybercrooks.

You also need active intrusion monitoring throughout your network to detect penetrations. In many of the recent ransomware events, the cybercrooks were present in the targeted firm’s networks for months. Today, most firms rely upon passive intrusion detection, not active intrusion monitoring. Passive monitoring can only tell you what happened after the attack. With active intrusion detection, your IT and OT teams can rapidly detect, isolate, and then repel such penetration attempts. It may be useful to engage a third-party cyber defense specialty firm to carry out this active monitoring function.

Lastly, you must invest in modernizing your technology, particularly at the OT level. This is where legacy devices are often present. Such devices employ outdated and vulnerable device drivers, management software, and network operating systems, such as Windows 98. A lowly temperature sensor, valve, gate actuator, or even a magnetic sensor could be the Achilles’ heel of your OT infrastructure because one or more of them rely upon old, vulnerable software.

These are the most immediate steps that you will need to undertake to harden your systems and build your firm’s cyber resilience in the face of current and evolving cyber threats, but there are many more. There are sources of assistance that you can tap into for help as you work to reduce your cyber risks. Local law enforcement organizations and your local FBI field offices can also provide help and leads to other resources. The Department of Homeland Security may have a local protective security advisor who can also offer assistance. Private cyber security firms can be engaged to advise your team or provide cyber defense services. There is a lot of valuable help available, but you need to reach out and access it. A modest investment can be critical in building your cyber resilience. ■

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## Food Industry Cyber Attacks

Over Memorial Day weekend in 2021, JBS USA, one of the largest meat processors in the U.S., was hit by an organized cybersecurity attack, which resulted in shift cancellations at several of the company’s plants across the country. The company had received a ransom request from a criminal organization “likely based in Russia.”

Several days later, the company announced a resolution to the breach, stating that its factories were fully operational. Following consultations with internal IT professionals and third-party cybersecurity experts, JBS paid a ransom equivalent to U.S. \$11 million.

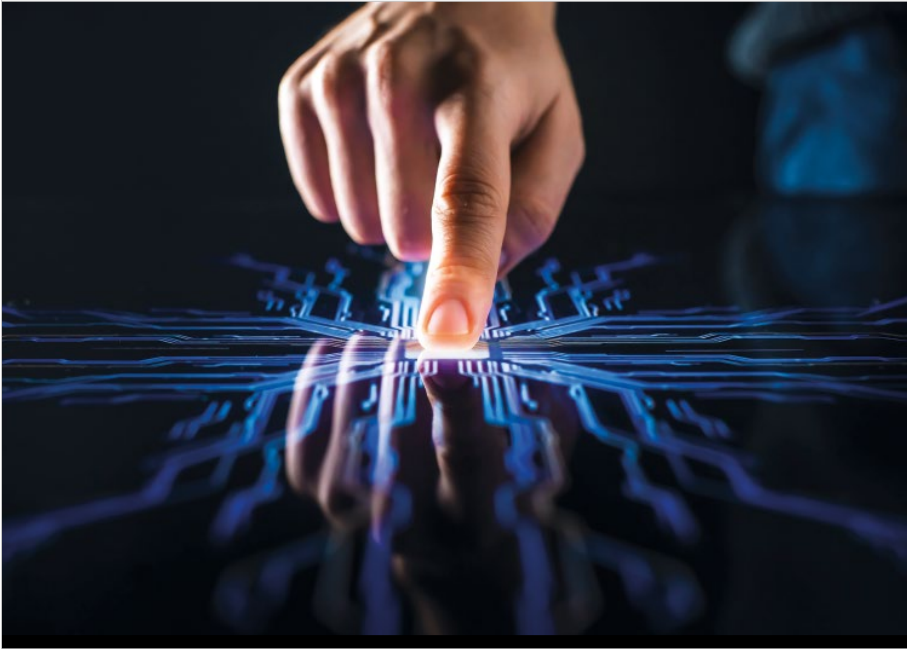
Other examples of food industry cyberattacks include the following:

- In 2015, a malware attack exposed the credit card information of customers at more than 1,000 Wendy’s restaurant locations. The hackers accessed the data in the fall of 2015, but the company did not report the breach until February 2016. Three years later, the company announced a \$50 million settlement with the banks of affected customers. Since this attack on Wendy’s, other fast food chains have been targeted in similar attacks.

- In 2017, Mondelez was part of a global ransomware breach that impacted hundreds of other companies. The attack infected many users when they downloaded a routine update. The attack resulted in freezing Mondelez computer systems and employee laptops and blocked access to email and files on the corporate network, affecting deliveries and causing a backlog of products. It took weeks for the company to recover, and the total cost of the attack was estimated at more than \$100 million. Citing government sponsors for the attack, the company’s insurer applied a “war exemption” to deny claims related to the cyberattack, a factor still worth considering today.

- AriZona Beverages USA was the target of a 2019 ransomware attack that wiped hundreds of computers and shut down sales for days. The malware infection was believed to have been caused by an email attachment. The full cost of the breach has not been disclosed.

- In March 2021, Molson Coors Beverage Company reported that its operations had been affected by a “cybersecurity incident.” The cyberattack affected beer production and shipment processes and caused at least \$2 million in attack-related costs.—*Purnendu C. Vasavada, PhD*



## Digital Transformation

Turn quality control into quality assurance by digitizing your process controls

BY RYAN BEESLEY, CAP

**T**he COVID-19 pandemic has highlighted a need for food manufacturers to automate and streamline their processes, primarily due to workforce and material shortages. Many food manufacturers look to robotic applications and equipment modernization to ensure that production keeps pace with demand.

Manufacturers are beginning to focus their attention on possible improvements found in the digital transformation of their process controls, specifically with regard to process measurements such as temperature, flow, level, and humidity.

A process is typically monitored and manipulated using feedback from instrumentation located within the process stream. For instance, level is used to control the volume of liquids in tanks, temperature is used to control the heat applied to a product, relative humidity is used to control the moisture content of a product before it's fried, and so on. Instruments like these have historically been used to control a closed loop process, offering only

limited data to operations on how the process is performing. The feedback from the instrumentation is used more for information on how that loop is being controlled and not necessarily on the quality of the product. To fully understand how a process affects product quality, tests are performed on the product *ex situ* as a quality control (QC) method.

QC typically performs a set of tests on a product after it has completed the production process to ensure that it meets manufacturing specifications. In food processing, a representative sample of a product is retrieved at certain stages of production (generally after packaging) and tested for quality. The inherent issue with measuring end-of-line product is the delay from when a problem arises to when it is detected in QC. For some processes, this can range from dozens of minutes to hours. If a problem is determined to exist and the source is identified, say, 20 minutes upstream in a process, this results in more than 20 minutes of product potentially going to waste. If you consider the time it takes to correct

the issue and verify the effectiveness of the correction again at the QC checkpoint, losses can be doubled or even exponentially increased. With supply chain delays and issues facing manufacturers, this can result in tremendous losses beyond waste product.

The typical way to combat this problem is by adding more QC checkpoints in the process and retrieving more samples; however, this leads to added labor requirements and increased processes to monitor the quality of a product. Through modern technology and the digitization of process controls, manufacturers can migrate from a QC model to a quality assurance method. The conversion or addition of digital instrumentation gives more accurate, real-time data that operations can act on to control their process. Modernizing process controls can provide the ability to keep a process closer to baseline while optimizing it. This moves the QC *in situ* with the process to assure that product quality is maintained at multiple locations along the process and corrections can be made earlier and with more precision.

With the digital transformation of processes, production-aided controls such as model predictive control can reduce labor force requirements and increase production output by analyzing real-time data and manipulating control variables to achieve optimal performance.

### Where to Start

A smart place to begin with a digital transformation is in temperature control and process monitoring. Temperature affects many attributes of product quality and is used to ensure that a product, particularly in the food and beverage industry, adheres to food safety and regulatory requirements. Temperature is used as a means of determining many things in the production process. In frozen potato products, temperature measurement is used at almost every stage of the process: from raw potato storage, to monitoring the temperature of batter to determine the potential of bacterial growth, to the most obvious of measurements—the temperature of the cooking oil.

Many food processing facilities use chart recorders to maintain a historical record of process data points for record-

keeping and compliance. This method is particularly important in the dairy industry, where food safety and compliance standards are stricter than for most other direct-to-consumer food products. Dairy processing facilities have entire rooms dedicated to chart recorders and data acquisition. These rooms are filled with dozens of chart recorders that take periodic measurements using a pen to draw a trendline onto a circular chart. Depending on the frequency of data sampling, these chart recorders keep a record from one to seven days in duration. This means that the paper discs must be changed frequently, and data retention consists of a physical means of storing the data.

As instrumentation and processes move to a digitized solution, so does the need to digitize data retention. Manufacturers working to reduce the time-to-market of their products require data to become more easily distributable, and with that challenge, data must become digitized. With traditional paper-based data recording, the data record must be physically put into a database to become part of a digital record. To increase the efficiency and accuracy of converting this information into a digital format, many processes are brought into a programmable logic controller (PLC) using 4-20mA analog signals. This data can then be distributed to many consumers for use in controlling production and reporting quality. Another means of converting this data into a digital record is using a digital data logger. Typically, this is localized to the equipment but can be shared via some communication protocol such as Modbus or ethernet.

As Industry 4.0 advances, many manufacturers are looking to move data management and storage off site. More recently, instrumentation and data recorder manufacturers are also adapting to cloud-based data record management. The manufacturers of the data recorders are now producing digitized data recorders. These data recorders are direct replacements for the traditional circular chart recorders and can record multiple data points. The data is then served via ethernet to an off-site, cloud-based data storage repository for retention and easy retrieval for use within a plant or enterprise. This data is available to management, operations, quality

control, and preventive controls qualified individuals (PCQI) to ensure production quality and food safety compliance.

### Physical Information

Another area where digitization of process monitoring control can be implemented is in the communication of physical information—e.g., pressure, temperature, level, humidity—to a controls system. One early means of transmitting remote mea-

Because temperature plays such a crucial role in the food production process, having trust in your instrumentation is paramount to confirming that measurements are accurate and reliable.

surement data was by some mechanical or pneumatic means to a localized control room. This was then converted to an electronic signal, most commonly 4-20mA current. With the introduction of 4-20mA signals, real-time measurements were more easily communicated to the control system. Although this advancement was ground-breaking for measurement and control, the need for more information from devices became more apparent. In the 1980s, the introduction of a hybrid (analog/digital) highway addressable remote transducer (HART) protocol made possible the retrieval of more information from devices. Using specialized HART communicator devices, instrumentation technicians could then communicate with field instruments remotely to diagnose and configure.

In the 1990s and into the current era, ethernet industrial protocol (ethernet/IP) began to emerge as the new standard for the digitization of process control instrumentation. This provided control systems with tremendous amounts of data beyond the process being measured; however, it didn't come without challenges. Ethernet/IP requires multiple twisted pair conductors and a power source to an instrument and is limited to a maximum distance of

100 meters. Converting from an analog device that uses a single twisted pair cable to an ethernet-based device addresses these challenges and is less appealing. More recently, though, a new communication protocol is emerging that will accelerate the transformation to a digitalized process: ethernet advanced physical layer (Ethernet-APL).

Ethernet-APL is an IEEE 820.3cg technology utilizing single-pair ethernet based on 10BASE-T1L. This provides for two major advances over Ethernet/IP: First, a single twisted-pair cable provides communications and power to a field device, with no need for a separate power and multiple pair communications cable. Second, it extends the typical ethernet communications beyond the 100-meter mark to 1,000 meters. This is accomplished using a trunk and spur technology where trunk devices are spaced up to 300 meters from a controls system (PLC) and spur devices (instruments) are up to 1,000 meters away from trunk devices. Many instrumentation manufacturers are adopting this new protocol and will be offering instrumentation in the coming years that will make it easier for users to convert their instrumentation and become digitized.

### The Need for Trust

The ability for instrumentation, such as temperature elements, to provide more data opens a new layer of manufacturing control, quality assurance, and food safety. Because temperature plays such a crucial role in the food production process, having trust in your instrumentation is paramount to confirming that measurements are accurate and reliable. A digitized instrument can provide process measurements along with instrument health, measurement drift or deviations, maintenance data, and more.

Having smart devices in the process ensures that the product stays within compliance, and they can alert operations to a potential baseline drift. A process monitored in situ allows corrections to be made more expediently and results in increased production, reduced waste, and improved product quality and food safety. ■

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# Testing



## FSMA's Final Rule on the Use of Accredited Laboratories

How the rule will impact the food industry

BY PATRICIA A. WESTER

**T**he Laboratory Accreditation for Analyses of Foods (LAAF) Final Rule is one of the last remaining major rules to be published as a requirement of the Food Safety Modernization Act (FSMA). FSMA directed FDA to establish a program for the testing of food in certain circumstances, to be performed by accredited laboratories as required under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Per FDA's summary of the LAAF final rule:

*Under the LAAF program, FDA will recognize accreditation bodies that will*

*accredit laboratories to the standards established in this final rule. Laboratories accredited to the LAAF standard ("LAAF-accredited laboratories") are authorized to conduct certain food testing as described in this rule. For purposes of this discussion, it applies to owners or consignees that must have certain food testing conducted by a laboratory accredited under this program. It's important to note that lab accreditation is granted on individual analyses, not to the lab in general.*

*This rule applies when food testing is conducted in certain circumstances. "Food testing" and "testing of food" include the*

*analysis of human or animal food, as well as testing of the food growing or manufacturing environment (i.e., "environmental testing").*

*Direct receipt of food testing results in these circumstances is of particular importance to the Agency and to public health. This rule applies to food testing conducted under specific testing requirements in the FD&C Act and implementing regulations that "address an identified or suspected food safety problem," and in directed food laboratory orders that we (FDA) will issue "as required by the Secretary, as the Secretary deems appropriate, to address an identified or suspected food safety problem."*

*If we [FDA] determine that the food testing results are valid and that they demonstrate the detained food product does not violate the FD&C Act, we [FDA] will release the food from detention and allow it to proceed into the United States. We [FDA] use the detention without physical examination (DWPE) procedure when there exists a his-*

tory of the importation of violative products, or products that may appear violative, or when other information indicates that future entries may appear violative.

Import alerts inform FDA field staff and the public that we [FDA] have enough evidence to allow for DWPE of products that appear to be in violation of FDA laws and regulations. Concerns periodically have arisen regarding importers' manipulation or substitution of the samples a private laboratory tests, and practices such as "testing into compliance," in which multiple samples from a shipment are tested, but only those results that would allow the shipment to enter the United States are submitted to us. See, e.g., "The Safety of Food Imports: Fraud & Deception in the Food Import Process; Hearings Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations."

### Who Is Covered Under the Rule?

The LAAF final rule applies to accreditation bodies (ABs) and food testing laboratories that wish to participate in the program. Their participation is voluntary for eligible entities. In certain circumstances, owners and consignees will be required to use LAAF-accredited laboratories to conduct food testing.

ISO 17025 is the international standard typically used to accredit laboratories and is a pre-requisite of the FDA LAAF program, as is participation in a proficiency testing program for each analysis in the scope of accreditation requested. However, they are not equivalent, so it is important to understand the distinction between the two. Many labs are already accredited to ISO 17025, and that will certainly give them a head start in preparation for LAAF accreditation. However, FDA has not done an equivalency comparison, and will only recognize the LAAF accreditation for testing in the situations described in the final rule.

In LAAF, eligible ABs apply to FDA for recognition under the LAAF program. A good portion of the rule is dedicated to establishing this process and the criteria an applicant AB must meet for FDA recognition. Conflict of interest is covered in detail: An applicant AB may not own or have a financial interest in a laboratory in accredits to LAAF. An accreditation body seeking to participate in the LAAF program must be a full member of the International Laboratory Accreditation Cooperation (ILAC) and a signatory to the ILAC Mutual Recognition Arrangement (MRA) that has demonstrated competence to ISO/IEC

17011:2017(E) with a scope of "Testing: ISO/IEC 17025." Once reviewed and recognized, laboratories seeking accreditation under LAAF can apply to the recognized AB directly.

The LAAF rule outlines all of the requirements the laboratory must meet for accreditation to a given analysis. This is worth repeating. An accredited laboratory is not accredited for every analysis it performs; only those analyses that are reviewed by the AB and listed in the scope of accreditation are covered. The other areas include requirements for conflicts of interest, reporting, and documentation for the analyses covered, including participation in a proficiency testing program within the previous 12 months. A recognized AB's assessment of LAAF-accredited laboratories involves onsite and remote assessments, with annual updates as the program describes. Laboratories must send testing results directly to FDA to comply with the program's requirements. Labs owned and operated by the owner or consignees of a food subject to testing are eligible to participate in the LAAF program provided all conflict of interest and impartiality requirements are met.

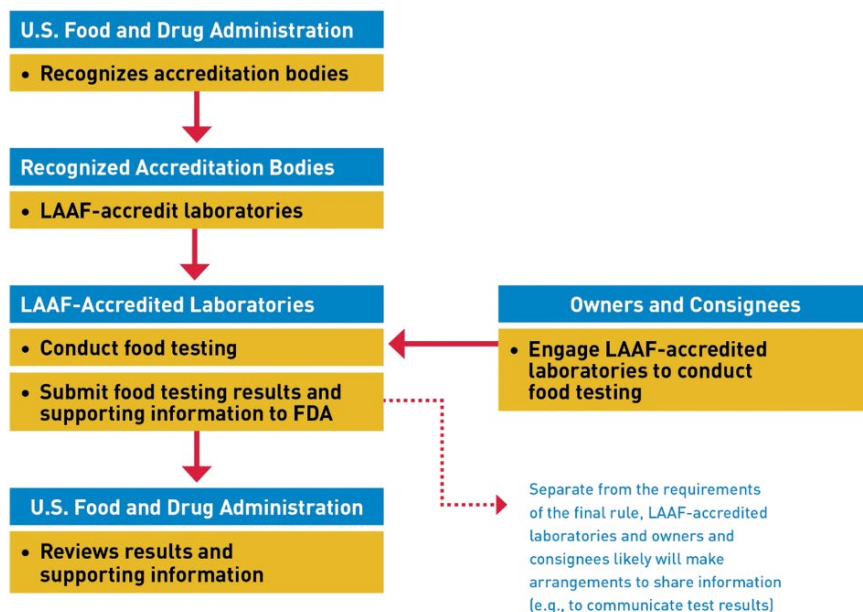
### What Testing Is Covered Under the Rule?

After the LAAF final rule is fully implemented, owners and consignees will be required to use a LAAF-accredited laboratory for food testing:

- To support removal of a food from an import alert through successful consecutive testing requirements;
- To support admission of an imported food detained at the border because it is or appears to be in violation of the FD&C Act;
- If required by existing FDA food safety regulations, when applied to address an identified or suspected food safety problem (i.e., certain tests of shell eggs, sprouts, and bottled drinking water);
- If required by a directed food laboratory order, a new procedure being implemented in this final rule that will allow FDA to require use of a LAAF-accredited laboratory to address an identified or suspected food safety problem in certain, rare circumstances; and

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## Structure of the Laboratory Accreditation for Analyses of Foods (LAAF) Program



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- If conducted in connection with certain administrative processes such as testing submitted in connection with an appeal of an administrative detention order.

Products to be tested are sampled by the LAAF lab or an appropriately qualified third party with arrangements to establish chain of custody. Owners and/or consignees will not typically perform sampling activities.

### What Testing Is Not Covered Under the Rule?

Food testing, including environmental testing, is only required to be conducted by a LAAF-accredited laboratory under certain circumstances as specified in the rule. Testing of these items for general food safety purposes, such as testing of ingredients, finished products, and/or routine environmental monitoring outlined in a food safety plan do not require the use of a LAAF-accredited laboratory.

For the purposes of this rule, “food” has the same definition as in section 201(f) of the FD&C Act. It includes articles used for food or drink for man or other animals, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)). In short, testing under LAAF is reserved for foods detained under an Import Alert or DWPE, or in cases where there is reasonable concern over the safety of a food such as during an FDA investigation.

### Implementation Timeline

FDA outlines a stepwise approach to implementation of the LAAF program on the



An accredited laboratory is not accredited for every analysis it performs, only those analyses that are reviewed by the AB and listed in the scope of accreditation are covered.

announcement webpage. On February 11, 2022, FDA launched the LAAF application portal (with a user guide) where interested accreditation bodies may apply for recognition under the program. Once FDA has recognized a sufficient number of ABs, the agency will announce that laboratories may apply to the recognized accreditation bodies for LAAF accreditation. When there is sufficient LAAF-accredited laboratory capacity for the food testing covered by the final rule, the agency will publish a document in the Federal Register giving owners and consignees six months’ notice that they will be required to use a LAAF-accredited laboratory for such food testing. The agency may issue more than one Federal Register document, as LAAF-accredited laboratory capacity is attained for various types of food testing described in the final rule.

This recognition and accreditation process is similar to the Voluntary Qualified Importer Program (VQIP) FDA launched several years ago. Based on the knowledge and experience gained during the development of that program, FDA has provided ample time for each step of the process to avoid bottlenecks arising from lack of capacity.

### Impacts of the Rule

The LAAF does not establish any new testing requirements for covered foods—these foods all have testing requirements today. LAAF establishes the criteria for ABs and laboratories that want to participate in the program and have their results accepted by FDA to release product under detention. While participation in the LAAF is voluntary for ABs and labs, owners or consignees that have foods subject to the LAAF rule are required to use a laboratory LAAF accredited for the analysis requested. This is an important detail to verify when selecting a laboratory to use in these circumstances. FDA will provide a list of recognized ABs on their website, and these will be required to

publish a list of accredited labs and their scope of accreditation.

Importers, shell egg producers, and those already familiar with the testing requirements for DWPE should already have a fundamental understanding of the circumstances for which the LAAF rule will apply.

Most of the comments received on the proposed LAAF rule were favorable. In the preamble to the final rule, FDA addresses comments received and provides responses where warranted. There was general support for the transparency and consistency of test results generated by accredited laboratories, with some suggestions for an expanded use of labs accredited under this program. FDA declined those suggestions, and the LAAF rule remains applicable to the situations described in the existing rule.

Some comments expressed concerns that labs not already ISO 17025 accredited may have difficulty meeting the requirements in a timely manner. In particular, shell egg producers noted that many of the labs servicing that sector weren’t ISO 17025 accredited, which could create a bottleneck for those producers requiring LAAF testing. FDA acknowledged those concerns and pointed to the step-by-step implementation process as a solution to this and other capacity-related concerns.

The final rule specifies the eligibility requirements that ABs and laboratories wishing to participate in the program will need to satisfy, as well as procedures for how the FDA will manage and oversee the LAAF program. It also contains new definitions and terminology that many would find it helpful to become familiar with.

By and large, the LAAF final rule is seen as an upgrade to the existing FDA testing requirements that will take some time to implement. ■

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## Testing for Dairy Processing

Five trends currently affecting the dairy industry, and how to capitalize on them

BY WOPKE BEUKEMA

**W**hile dairy has maintained a strong presence throughout the history of human diets, its nearly universal appeal in the modern world was not inevitable. Milk—and dairy products in general—have only maintained their consumer appeal through a constant cycle of innovation in line with market demands.

Even today, we are discussing a radically different dairy landscape than the one that existed 30 years ago. Dairy, a product that was once predominantly centered around Europe and North America, has seen massive growth in production and consumption across the world, especially in Latin America and Asia. It has also seen a transformation in how it is perceived, re-inventing itself as a health food to target contemporary consumer concerns and evolving to encompass plant-based milk products that extend the market “beyond the cow.”

This traditionally dynamic marketplace has only been made livelier by the

COVID-19 pandemic, accelerating trends that were already underway and introducing new challenges to processors.

All of these changes and the “new normal” of the last two years during the pandemic have highlighted the need for novel and advanced testing and analysis technologies. Equipped with these, processors can adapt and seize new opportunities presented by this ever-evolving marketplace.

In this article, we will break down five key trends currently affecting the dairy industry and explore how, backed by robust testing technologies, dairy processors can best capitalize on these trends.

### Plant-Based Products

A growing number of people, predominantly in Europe and North America, are identifying as vegan or attempting to reduce animal product consumption. This intensifying demand, paired with the novel formulation technologies that allow processors to better simulate the

taste and feel of dairy products, has led to plant-based milk products commanding a growing market share.

As with any novel product, safety and quality assurance should be at the top of the agenda for any processor. While ensuring safety in all milk products is critical, it introduces some distinct challenges for plant-based offerings.

For example, plant-based milk products tend to hold more suspended particles than their animal counterparts, which can lead to processing difficulties in instrumentation originally designed for animal-based products. Plant qualities such as stickiness can lead to processing disruption and an increased need for maintenance. The suspended solids also cause issues in characterizing these products when using certain analytical techniques. The nature of these formulations means that the density of the products is not always clear, making it difficult to judge which products are fit to be used in specific instrumentation.

When analyzing a plant-based sample, we can apply what we know in traditional dairy products, where formulations higher than 30% solids require near-infrared instrumentation. Therefore, in solid-rich plant-based milk products, near-infrared is usually best suited. Alternatively, in those lower than 15% total solids, Fourier transform infrared (FTIR) liquid analyzers can test samples in less than 30 seconds and with lower than 1% coefficient of variation (CV). Furthermore, diode array-based instrumentation, which can fit directly across a belt or pipeline, can provide rapid spectra of a product sample within six seconds. And for high-detail analysis, Fourier transform near-infrared (FT-NIR) can separate wavelengths in the near-infrared range within 30 seconds.

This is an area that is rapidly growing in response to market demands, with many instrument manufacturers beginning to roll out calibrations specific to plant-based milk products.

### Testing Is Traveling Upstream

Across the broader dairy industry, testing technologies are being applied further upstream in the supply chain by proces-

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sors. With more stringent global food regulations, a growing clean-label product demand, and rising competition between brands, processors are requiring or intensifying early stage and raw ingredient testing in order to have more control of product quality.

The change to upstream testing can be most clearly seen in antibiotic residue testing. Veterinary drugs, such as antibiotics, are used on farms to prevent infections and promote health in cows. To prevent antibiotic residues from accumulating upstream and seeping into dairy supplies, processors rigorously test samples to ensure compliance.

Lateral flow strip tests, for example, can be used to test throughout the dairy creation process: from field and farm to contract and in-house processing labs. This easy-to-use, accurate technology can detect a broad range of antibiotics found in cow's milk both at or below European Union and Codex Maximum Residue Limits. Better yet, they often require almost no sample preparation and produce results within minutes.

FTIR is also being applied more widely at milk collection points. Using solutions that ensure easy installation and minimal moving parts for easy transportation, these instruments can test for both composition and untargeted adulterants.

By routinely applying these technologies, processors can more easily adhere to regulations and continue to provide consumers with safe products. They can also more confidently assure safety in their products, as well as prevent the large-scale losses incurred when contaminated ingredients are mingled with healthy supplies. As testing continues to move upstream, easy-to-use and transportable technologies such as these will be important.

### Intuitive Instrumentation

The food processing industry generally sees high staff turnover. With broader labor shortages across several industries, dairy processors are also seeing more intense staff shortages. The specific and lengthy training requirements within the dairy processing industry in particular means that these shortages are leading to workflow breakdowns and reduced productivity. To keep profit margins stable,

processors need to embrace technologies that can help remedy these issues.

Intuitive instruments and software that delivers real-time learning can reduce training times and keep workflows optimized, even as staffs change. Through clever design, manufacturers can integrate useful features like touch screens, one-button operation, and automation to lower barriers to use for operators and scientists alike. They can also ensure that maintenance on the equipment is simple to perform, thereby minimizing downtime. These collective modifications can add up to big benefits in workflow efficiency.

### Responding to Regulation

A hallmark of the modern food industry is tightening regulation. Across the world, the Food and Agriculture Organization of the United Nations is driving higher standards. This, combined with greater customer expectations of ingredient transparency, means that dairy farmers, collectors, and processors need to understand their product compositions and safety profiles better than ever before. To do this, the dairy industry needs robust instrumentation that can help provide proper antibiotic, mycotoxin, and pathogen detection across a wide range of products.

By leveraging FTIR and FT-NIR systems, for example, processors can perform adulterant pass/fail screening in one minute or less; using liquid chromatography with tandem mass spectrometry (LC/MS/MS), processors can thoroughly test for antibiotics and veterinary drug residues in milk; and with inline NIR systems, they can understand their dairy powder compositions in less than 10 seconds with no sample prep.

For efficient mycotoxin testing in complex dairy matrices, processors can also use DON ELISA kits, in which the workflow is designed for users to “set it and forget it,” minimizing manual intervention and manual error. Solutions like these are also highly efficient, helping lab teams process up to 192 samples in fewer than 90 minutes.

Equipped with the latest instrumentation and assay kits, manufacturers can best inform customers as to what's inside their products, as well as help keep them safe from any possible adulterants.

### Data in Dairy

While testing data solutions are currently being rolled out across almost every industry, they remain generally underused in the dairy industry, offering processors an opportune chance to get ahead.

One way data solutions can help processors is through synchronization of their workflows to achieve improved efficiency. Some solutions can give access to visualizations and predictive analytics, helping to provide a more complete overview of workflows, ingredient quality, and product performance. Modern software tools can also pull out areas where workflows can be made more efficient, with the overall goal of leveraging data to help managers make more informed and faster decisions that can reduce time, cost, and waste demands while increasing product quality.

Data solutions in dairy are undoubtedly going to scale up in the future. As sensors become more sophisticated, two areas within data solutions in particular will see advancement. First, more user-specific visualizations and information will be available for processors, and second, tailored automation when leveraging data will become widespread.

### Looking to the Future

As with many industries, the dairy industry is currently undergoing a period of change. Adapting to this is fundamental if the industry wants to maintain dairy's near-global appeal as a popular, reliable, nutritional, and tasty product. From plant-based milk products to tightening regulations, there are no signs that the dynamic dairy industry is slowing down. Further, with milk becoming ever more global and differences in product demands continuing to diverge, it's highly possible we will see an even more varied and distinct marketplace in the future.

Smart, robust testing and analysis technologies are key when trying to stay on top in the quickly changing landscape of dairy. With innovative testing and analysis solutions and best practices, processors can add new firepower to their value and quality and continue to create competitively exciting and customer-driven products to the global marketplace. ■

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# Manufacturing & Distribution

FOOD PACKAGING



## How COVID-19 Changed the Packaging Industry

During the pandemic, demand for sustainable and single-use containers has flourished | BY LORI VALIGRA

**W**hen the COVID-19 pandemic took hold in the United States in early 2020, shutdowns and business curtailments hit supermarkets and other food sellers quickly, rippling back through the supply chain to food producers and packaging makers.

For Aaron Anker, who is CEO and owner of small granola company Grandy Organics in Hiram, Maine, it meant a major pivot early in the pandemic away from selling bulk foods to health food stores, including Whole Foods, and to universities, when these buyers closed their bulk granola bins. Bulk foods, which were half of his business, have since recovered, but the experience led the company to broaden its products, including selling smaller packages to retailers and subscription services such as Imperfect Foods, which sells the granola in its food boxes. “When bulk food sales shut temporarily, it forced us to diversify our businesses,” says Anker.

While the bulk business still dominates sales now, Anker continues to sell smaller packages to retailers. He also sells directly to consumers via the Grandy Organics website, and while this part of his business accounts for only a small percentage of his overall sales, it lets him test new packaging such as compostable bags, part of the consumer demand for more sustainable products and packaging that has grown during the pandemic.

Although a small company, Grandy Oats had to take on the challenges the pandemic laid onto larger companies and the food system as a whole. A large shift in demand from consumers, who early in the pandemic were stuck at home and hoarded items, including canned soup and pasta, led to shortages of some products and their packaging. Supply chains were disrupted as manufacturers scrambled to make enough products. Costs rose and international trade issues added to the pressure.

“There was a massive shift from commercial and institutional packaging to retail home use,” says Craig Robinson, global vice president of business development and innovation at PTI, a packaging and inspection company based in Holland, Ohio. “People stopped going to restaurants and large venues [during the pandemic], so the large five-gallon containers of food became unnecessary.” Demand for single-use and takeout containers flourished.

### Retail Packaging Surges

At the same time, retail packaging surged as more consumers bought their food online instead of at grocery stores and got take-out containers from restaurants. E-commerce accelerated to 17% of grocery sales in the pandemic, compared with 3% of food purchases before it, and it could reach 20% of purchases in the next four years, according to consulting firm McKinsey & Co.

E-commerce changes the demand for packaging, which needs to be stronger, says David Feber, MBA, partner and head of McKinsey’s global packaging practice in Detroit. Amazon has a 17-angle drop test, compared with five angles at retailers, he adds, and some package designs are sustainable to meet consumer demand. One example is detergent in a strong plastic bag within a box that is shipped as is, he says.

Robinson says that early in the pandemic, e-commerce websites such as Amazon Pantry sold flour wrapped in plastic and glass spaghetti bottles double bubble-wrapped and taped. He says a lot of that secondary and tertiary packaging will be replaced by more rugged packaging. “A lot of glass, because of the breakage and weight, doesn’t lend itself well to some of the e-commerce rigors,” he adds.

Efforts are underway to convert some of the heavier packaging to polyethylene terephthalate plastic, but this push is being hampered by the freeze that shut down large parts of Texas in February 2021; some PET resin producers are still not fully back

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online. This delay has caused resin prices to skyrocket.

Food producers and packagers also were affected by shutdowns of factories in China, which meant that glass and plastic bottles, as well as ingredients, were not coming to the United States. Efforts to produce smaller packages—for example, a half-gallon compared with a five-gallon drum, use more material and slow down production because it takes more time and packaging materials to make 10 smaller drums than it does to manufacture one large one. “There’s no buffer built into a lot of these companies because that’s just wasted resources,” Robinson says. “The production for consumers is running at capacity, and companies just can’t respond.”

The pandemic, the Texas freeze, factory shutdowns in China, supply interruptions, product shortages, and consumer demand changes all contributed at some level to a situation in the industry that nobody has ever seen before, Robinson says.

### Innovation Delayed

With most companies focused on getting items through the supply chain to consumers, innovation in packaging, which is driven by advances in food, has hit pause to some degree, Feber says. “The focus shifted to making sure products were available for consumers,” he adds.

But packaging companies need to respond to changing consumer behaviors, especially among younger buyers who are seeking purpose, quality, and novelty, he says. This includes developing packages for e-commerce that don’t get damaged and that decrease transportation costs. In some cases, designing packages with different barrier properties, including those with gases between different layers of plastic packaging, is providing the thickness needed to preserve cheeses without adding much weight or bulk.

Feber cites three packaging trends that did accelerate during the pandemic: sustainability, e-commerce, and hygiene concerns. In order for packaging to be sustainable, it must reduce the carbon footprint, eliminate leakage, increase recyclability, and use recycled content. One example is a trend toward packaging food in flexible

plastic pouches instead of heavier bottles. The food can be prepared using an extra retort or heating it until it is sterile.

Early in the pandemic, when little was known about how the virus was transmitted, demand for recycled packaging dropped significantly because no one wanted those packages going back into a retail environment, Robinson says. “We

**There was a massive shift from commercial and institutional packaging to retail home use [during the pandemic]. People stopped going to restaurants and large venues, so the large five-gallon containers of food became unnecessary.**

—CRAIG ROBINSON

didn’t understand what was happening with transmission of the virus, so retail outlets didn’t want post-consumer materials,” he adds.

### Smarter Packaging

Health concerns also led to wider use of antimicrobial coatings on paper and sulfur dioxide pads on blueberry containers, which can permeate gasses to help keep blueberries from decaying too quickly if there is a three-day delay to the retailer. Other health-related packaging turned up in single-use packets aimed at controlling the virus spread.

As supply chain issues lengthened the time from the manufacturer to the consumer, smarter packaging designed to control moisture and other factors that can spoil food also accelerated. Intelligent packaging is coming on board quickly, says Clair Sand, PhD, owner and founder of Packaging Technology and Research in Stillwater, Minn. “Consumers and retailers want to know if the product is still good because products are sitting out longer than before,” Dr. Sand says.

While intelligent packaging, which can communicate shelf life with a time and temperature indicator, is being tested

mostly in Europe, she expects it to become popular in the United States as well. Intelligent elements such as sensors can be stamped onto current packaging, or the packaging can be made with integrated sensors that can change color as the pH changes or communicate its shelf life so retailers can rotate the stock in their store, she says. Such packaging technology already is used when shipping vaccines in cold packages, she says.

Dr. Sand says supply chain issues remain, so such technology will be needed going forward. She also expects more investment in packaging to resume.

To meet the sustainability demand from consumers, some food and beverage businesses are moving to reusable packaging, she says. Just Salad has a reusable polypropylene bowl program for takeout that can be returned and reused. Dr. Sand says it has higher thermal resistance than PET to withstand sterilization temperatures and reuse. Consumers participating in the program get discounts. Additionally, Starbucks is pushing a program to have reusable cups in place by 2025 in an effort to reduce waste. “Reusable packaging is really of interest now because of our supply chain issues,” Dr. Sand says. “With reuse, there is a material shift driven by the supply chain.”

Going through the pandemic and having to worry about food supplies, consumers have a healthier understanding of food sources and food sustainability, Dr. Sand says. “We came out of the pandemic with a much more mature understanding of sustainability, that it’s not just ‘Is this package sustainable?’ but making sure we reduce food waste,” she says. “It’s focusing on the whole food system.”

Packaging makers still are not free of the effects of the pandemic, which in many geographies has slowed before an expected surge in the fall. Inflation and the conflict in Ukraine also will play into packaging demand from consumers and supply issues. “The strife in Europe is going to start having an effect, and oil prices will affect the cost of raw materials for packaging,” Robinson says. “It’s one thing after another for the brands, and they’re trying to figure out where they should go and what they should do.” ■

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# Promote Food Safety Through Stainless Steel Conveying

Stainless steel belts and conveyor belt systems can help make food processing safer, more efficient, and more sanitary

BY DENIS GAGNON, BA, MBA

**M**ultiple major food recalls stemming from contamination have made headlines recently, including one instance in October 2021 when the Centers for Disease Control and Prevention issued a warning after nearly 900 people contracted *Salmonella Oranienburg* from onions. The contaminated onions were shipped to 38 U.S. states and forced the hospitalization of more than 180 people. Despite the widespread nature of the event, the contamination was linked to one processing facility, suggesting a food processing issue.

This is not an isolated incident; approximately 48 million people become sick from eating contaminated food each year, and an estimated 3,000 of those peo-

ple die. It's not just a handful of illnesses at the source—there are actually more than 250 diseases that are spread through food alone. In addition to attracting the attention of FDA and endangering consumers, the intense, negative publicity can be hard to recover from for many producers; not many people have forgotten the deadly 2018 *E. coli* outbreak traced to tainted romaine lettuce. At the same time, events such as the *S. Oranienburg* outbreak, in which the contamination is linked to a facility, are almost entirely avoidable with the right precautionary measures and sanitary cleanroom production elements.

There are many facets to consider within the overarching topic of hygienic food preparation: understanding the in-

herent microbial risks in certain foods, using the proper materials for the design and infrastructure of a facility, and following best practices for cleaning and disinfecting equipment are just a few. One key element to consider is the material used for conveyor belts and systems, and how this material can support a facility's commitment to hygienic food processing. Although they are popular, polymer, plastic, and metal mesh conveyors are limited in their hygienic capabilities and may actually increase the risk of food contamination. Conversely, the specific attributes of stainless steel belts and conveyor belt systems make food processing safer, more efficient, and far more sanitary.

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### Hygienic Advantages

Conveyor belts pose a particular challenge for industrial food processing manufacturers, as the need for flexibility and an ability to pass through different environments can limit the number of viable material options. Stainless steel conveyor belt systems are ideal for the cooking, freezing, and handling of edible products because their versatility allows customization for any automated food processing system with exceptional results.

So, what are some of the specific advantages these systems possess over the alternatives? To answer this question, it's important to understand what constitutes food contamination during the production process. It can be broken down into two separate categories: bacterial/microbial based and particulate based. Stainless steel belts are adept at prevention in both areas.

First, due to their flat and nonporous surface, stainless steel belts are resistant to bacteria, making them easy to clean and compliant with even the strictest USDA requirements. Stainless steel is a derivative of steel with an elevated level of chromium, which creates an oxide layer on the surface to prevent further oxidation. Furthermore, if the surface is at all damaged or scratched, the newly exposed metal oxidizes almost immediately, in a self-healing capacity. Other belt materials can't compare, allowing bacterial buildup in crevices and small holes, or even in the gaps between belt components.

In addition to this microbial resistance, stainless steel belts don't generate particulate like flat neoprene or polymeric alternatives do, so they won't create dust that could impact production in a cleanroom environment. These alternatives often incorporate fibers for added strength, which may rub against conveyor guides or rough edges, detaching small particulates which may then be embedded in food products. Unlike mesh belts (made up of miniscule chain links), metal belts made up of a single element won't generate any friction between component parts that may require lubrication. Not only does the use of a single-unit system reduce overall maintenance, but the lack of required lubrication also means there is no risk of contamination to the flavor or quality of the foods being processed.

The advantages of stainless steel belts go beyond their inherent hygienic nature. Regardless of how resistant they are, all belts need to be cleaned and cleared of food debris to prevent contamination—and no material is easier to clean than solid stainless steel. Due to their resistance to chemical corrosion, stainless steel belts can be cleaned-in-place (CIP) with almost

**Due to their flat and nonporous surface, stainless steel belts are resistant to bacteria, making them easy to clean and compliant with even the strictest USDA requirements.**

any cleaning or sterilization method, such as high-powered steam, chemical cleaning solutions, and high-pressure wash. On the other hand, plastic and mesh conveyors require more intensive cleaning measures beyond CIP—either periodic removal from the production equipment to immerse in chemical solutions or the installation of complex cleaning systems and brushes.

This superior cleanability was confirmed by Finnish food laboratory VTT Expert Services Limited. Their research found that stainless steel belts are not only easier to clean than plastic alternatives, but, in addition, their advantages were compounded over time as the plastic belts became worn or damaged. A 2012 study published in *Poultry Science* found higher levels of formation of *Listeria* biofilm on polymeric materials than on stainless steel, with the authors noting that “plastic conveyor belts exhibited stronger bacterial adhesion compared with stainless steel.”

### Thermal Conductivity

One of the major aspects of food production is the heating or cooling of products as they make their way down the conveying line. Food products are moved through ovens for drying, baking, or cooking, and through cooled zones for solidification or freezing. This is a difficult hurdle for most materials, as most plastic conveying ma-

terials are not able to withstand temperatures above 100°C. Metal mesh conveyors have been adopted by some for their ability to pass through different temperatures, but these conveyors can pose other problems; the mesh may become fatigued and fracture, possibly resulting in metal particles within the food.

The ability of single-surface, solid stainless steel products to transmit energy in the form of heat, cold, and electricity is another factor that makes them the perfect solution for food processing; the superior thermal conductivity results in a more uniform heating and cooling process. Further, metal belts and conveyor systems can withstand cooking and freezing processes to which food products are frequently subjected during production. This means that facilities using metal belts on their production line can more easily automate their processes, so they don't have to manually handle the food, thereby reducing potential contamination points.

Stainless steel is incredibly customizable, allowing for the creation of several alloys that resist distortion and perform well in applications with elevated temperatures. For instance, Invar will not distort when operating in environments up to 400°F, compared to 300 Series stainless steel, which can start to see distortion at temperatures below 400°F. Taking it even further, Inconel 625 and 718 can operate in environments with temperatures up to 1,600°F. Polymeric belts and those made of other materials simply cannot withstand such variable temperature conditions without suffering belt damage or distortion. In addition to its extreme heat tolerance, stainless steel is ideal for use in freezing temperatures that can cause serious wear and tear to traditional materials.

### Creating Custom Solutions

The selection of a proper hygienic conveyor belt can go a long way toward preventing contamination in a food processing facility, as demonstrated through the hygienic and thermal advantages of stainless steel products. Beyond these key benefits, metal belts possess many other properties that are advantageous for everyone in the food industry, including superior precision, control, longevity, and cost effectiveness. ■

**Gagnon** is CEO of Belt Technologies Inc., and is based in Massachusetts. Reach him at [dgagnon@belttechnologies.com](mailto:dgagnon@belttechnologies.com).



# NEW PRODUCTS



## Checkweigher for Packaged Foods

The Raptor Checkweigher series from Fortress Technology Ltd. is now available for North American food producers. The system helps food manufacturers meet legislative weight requirements and targets operational inefficiencies, including upstream product giveaway, non-conforming food packs and packaging waste. The regular system and its XL version have modular electronics, which allows them to be integrated with a Fortress metal detector and upstream packaging equipment. The series also features an HMI touchscreen panel, which can be pre-programmed to calibrate numerous SKUs. **Fortress Technology, Ltd., [fortresstechnologies.com](http://fortresstechnologies.com).**

## Autoclavable Paddle Blender Bag

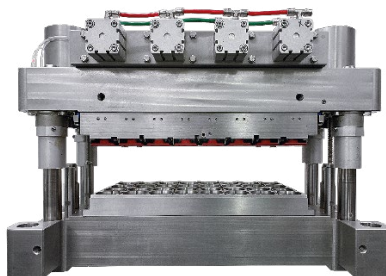
Seward has launched the Stomacher 3500 autoclavable paddle blender bag. Its material composition makes the new autoclavable bag the first paddle blender bag that can survive irradiation, stomaching, and the autoclave disposal cycle without losing its integrity. The bag prevents bursting and spillages after autoclaving, ensuring the contents can be disposed of where and when intended, rather than being accidentally dumped onto the floor. The single chamber autoclavable bags are ideal for sample sizes ranging from 400-4,500 mL and irradiated sterile for use in laboratory blenders. They are available in packs of 250 in five sachets of 50 and sterility assured and made from food-grade materials



and suitable for all microbiological applications. The bag's wide range of applications also includes small batch media preparation, which can then be sterilized in an autoclave. **Seward, [seward.co.uk](http://seward.co.uk).**

## Cutting Tool

IMA Dairy & Food USA has made enhancements to the cutting tools used for its recently introduced ZERO Technology, which helps food brands easily use sustainable monomaterial cup packages. Highlighted by an extractable central cutting unit (CCU) design, the innovation drastically reduces production downtime for change-outs,



minimizes spare part costs, and raises the number of punches between sharpenings. Ideally suited to IMA's Erca, Hassia, and Intecma brands of form-fill-seal (FFS) machines, the technology uses a punch process to provide cutting and pre-cutting of eco-conscious materials such as PET, PP, and PLA. The enhanced cutting tools overcome other longstanding obstacles: production downtime and cost of ownership. By using an interchangeable cutting elements setup that allows individual tools components to be expediently replaced onsite, line stoppage can be reduced to 20 minutes. **IMA Dairy & Food, [imadairyfood.com](http://imadairyfood.com).**



## Wastewater Monitoring System

Food processing plants require large amounts of water for washing, rinsing, cooking, disinfecting, bottling, canning, and packaging, and both incoming and discharged water must be treated to ensure product quality and environmental safety. To help food facility water and wastewater system operators conveniently monitor equipment and environmental conditions, Sensaphone has released the cloud-based Sentinel PRO system with supporting iPhone/Android applications. The system interfaces with any water or wastewater processing equipment that uses a PLC with Modbus sensors and can read values over 2-wire RS485 or Ethernet/TCP. The system immediately notifies users when sensor readings move outside of preset parameters, which can indicate potential threats to pumps and systems. The system sends alerts via text, email, or phone call. Users can view data values in real time, set alarms, acknowledge alerts, review data, and generate reports from their mobile device, tablet, or computer. **Sensaphone, [sensaphone.com](http://sensaphone.com).** *(Continued on p. 40)*

*(Continued from p. 39)***Clean-In-Place Acid**

Madison Chemical ProClean CIP ACID is a concentrated, low-to-moderate foaming blend of acids and surfactants that penetrate and remove films, oxide, milkstone, and other soil from dairy and food processing equipment. This product can be used as an acid cleaner on all surfaces in and around food and beverage processing areas and is not intended for direct food contact. It can be used in most circulation systems to clean tanks, pipes, and equipment-in-place. It can also be used as a neutralizer and brightener following alkaline cleaning of high temperature-short time pasteurizers. It is safe to use on stainless steel metals when used as directed and rinses easily with potable water and without streaking.

**Madison Chemical Co., Inc., madchem.com.**

**Chlorine Dioxide High Range Test Strips**

Industrial Test Systems, Inc. (ITS), introduces the WaterWorks chlorine dioxide high range test strips. This product is safe and easy to use since there are no chemicals to mix. The test strips achieve results in less than 35 seconds, detecting high levels of chlorine dioxide from 0-2500 ppm in increments of 0, 10, 25, 50, 100, 250, 500, 750, 1000, and 2500. The strips don't color bleed and come in a quantity of 50 strips, stored in a plastic bottle. The strips provide monitoring of chlorine dioxide levels, including residuals.

**Industrial Test Systems, Inc., sensafe.com, its@sensafe.com.**

**Label Liability** *(Continued from p. 15)*

some cannabinoid-infused foods are already subject to federal labeling rules.

Cannabis in the U.S., Millard says, is “a weird federally legal marketplace where the consumer product is not legal federally and you’re only allowed to possess it in different states. But the labeling requirements are federally established, and so you have to follow NIST Handbook 130, Part 4, on Uniform Packaging and Labeling Regulations. That’s law in 46 states; no matter what you do, if you’re manufacturing a cannabinoid product, you should be following those rules because those are the federal labeling rules. Just like in any food you’d see anywhere—the style, the format, the way you see [nutritional] information—that’s a defined labeling regulation in the NIST Handbook 130 under Part 4. There’s

also specific FDA regulations on labeling that coincide with the NIST handbook.”

This approach of building upon existing criteria guides Millard and others hoping to establish a voluntary consensus standard to create nationwide uniform labeling for cannabis. While there would be no federal agency to enforce such standards, operators could sign on voluntarily as a show of commitment to standardizing the industry.

“We’re not trying to reinvent the wheel,” Millard says. “If you already have the principal display panel—the front panel most likely to be displayed when that product is being sold—with the name, net weight, and a few other things—those are defined specifications. All we did was say that if your product contains cannabi-

noids, you have to follow the same rules as everybody else.”

For Mabugat, creating labels that mirror FDA and NIST compliance is an ideal best practice. But even for those modeling their work on federal guidelines, she stresses the necessity of getting a lawyer to sign off on the final copy. “The only thing I would say is that, whenever a client has a new product they’re going to bring to market, they should run all their labeling and designs past a lawyer. It’s a big burden for smaller companies, [and] the mistakes I see in cannabis labels come from even the most sophisticated of cannabis businesses.” ■

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**Hand and Personal Hygiene for Food Safety** *(Continued from p. 22)*

Q&A sessions can help make the training more dynamic and interesting. A written quiz at the end of the training helps evaluate the trainee’s knowledge and readiness. As with any training, refresher training courses are important to help improve the effectiveness of the initial training.

Once training is complete, schedule your next training to help ensure that your employees retain all the information they learned the first time.

**The Impact of the Pandemic on Hygiene Best Practices**

The pandemic impacted best practices by placing an emphasis on hand sanitizer that we have never experienced before. By mid 2021, soap orders continued to be strong, indicating that facilities are using more soap, which is notable because hand washing seemed to be overshadowed by hand sanitizing early in the pandemic. Both hand washing

and hand sanitizing play an important role and work best when used together to reduce pathogens on hands.

According to the CDC, practicing proper hand hygiene is an important and effective way to prevent the spread of the novel coronavirus, making hand hygiene trainings more crucial than ever. ■

**Nelson** is a national sales manager with Best Sanitizers, Inc.

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## Events

### MAY 2022

**4-6**  
**European Symposium on Food Safety**  
 Munich, Germany

Visit [foodprotection.org/europeansymposium](http://foodprotection.org/europeansymposium).

**9-12**  
**Food Safety Summit**  
 Rosemont, Ill.

Visit [food-safety.com/food-safety-summit](http://food-safety.com/food-safety-summit).

**18-19**  
**DairyTech Conference**  
 Austin, Texas

Visit [dairytechconference.com](http://dairytechconference.com).

### JUNE 2022

**6-7**  
**Mexico Association for Food Protection Annual Meeting**  
 Virtual Event

Visit [amepal.com](http://amepal.com).

### JULY 2022

**10-13**  
**FIRST Annual Expo and Virtual Experience**  
 Chicago, Ill.

Visit [ift.org/events](http://ift.org/events).

**July 31-Aug. 3**  
**IAFP**

Pittsburgh, Penn.

Visit [foodprotection.org](http://foodprotection.org) or email [info@foodprotection.org](mailto:info@foodprotection.org).

### AUGUST 2022

**Aug. 26-Sept. 1**  
**AOAC Annual Meeting and Exhibition**  
 Scottsdale, Ariz.

Visit [aoac.org/annual-meeting-exposition](http://aoac.org/annual-meeting-exposition).

### OCTOBER 2022

**17-19**  
**Cannabis Quality Conference and Expo**  
 Parsippany, N.J.

Visit [cqcxpo.com](http://cqcxpo.com).

**19-21**  
**Food Safety Consortium Conference and Expo**  
 Parsippany, N.J.

Visit [foodsafetyconsortium.org](http://foodsafetyconsortium.org).

**23-26**  
**Pack Expo International**  
 Chicago, Ill.

Visit [packexpointernational.com](http://packexpointernational.com).



### NOVEMBER 2022

**2-4**  
**Dairy Practices Council Annual Conference**  
 Bloomington, Minn.

Visit [dairypc.org/dpc-conferences](http://dairypc.org/dpc-conferences).

**3-4**  
**International Food Safety Congress**  
 Istanbul, Turkey

Visit [foodsafetycongress.org](http://foodsafetycongress.org).

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# SCIENTIFIC FINDINGS

For access to the complete journal articles mentioned below, go to “Food Science Research” in the April/May 2022 issue at [foodqualityandsafety.com](http://foodqualityandsafety.com), or type the headline of the requested article in the website’s search box.

## Roast Level and Brew Temperature Affect the Color of Brewed Coffee

Beverage color significantly affects perceived sensory quality and consumer preference. Although the color of coffee beans is well known to vary strongly with roast level, little work has examined how roast level and brewing conditions affect the color of the final beverage. These authors report that the color of full immersion brewed coffee is significantly affected by both roast level and brewing tem-



perature. Coffees from three different origins were each roasted to three different levels (light, medium, and dark) and then brewed at three different temperatures (4°C, 22°C, and 92°C). Each sample was brewed toward full extraction and then diluted to precisely 2% total dissolved solids so that differences in concentration would not confound color measurements. Absorbance spectra (UV-vis) and color tristimulus values ( $L^*a^*b^*$ ) were then collected and analyzed. The authors concluded that roast level had the strongest impact on brew color, and that brew temperature had a significant impact on color for light and medium roasts, with less impact on dark roasts. Qualitatively, the cold brewed coffees tended to be redder, while the hot brewed coffees were blacker. The results suggest that there is an opportunity to manipulate and brand brewed coffee color through judicious choices of roast level and brewing temperature. **Journal of Food Science. Published online ahead of print March 29, 2022. DOI: 10.1111/1750-3841.16089.**

## Production of Non-Alcoholic Beer via Cold Contact Fermentation

The use of non-conventional yeasts is increasingly seen as an option for the production of low and alcohol-free beers. In this study, four non-conventional yeasts (*Kazachstania servazzii*, *Kluyveoromyces marxianus*, *Pichia fermentans*, and *Torulaspora delbrueckii*), originally isolated from sourdough cultures, were assessed by screening their ability to reduce wort aldehydes at a fermentation temperature of  $1.0^\circ\text{C} \pm 0.5^\circ\text{C}$ . Of the evaluated yeasts, *T. delbrueckii* was found to be most promising, being capable of the removal of wort-derived aldehyde off-flavors, while being sufficiently sensitive to low temperatures to limit the formation of ethanol. Despite the different alcohol by volume (0.07% vs. 0.28%), the beers produced via cold contact fermentation at 10 L scale with *T. delbrueckii* and a reference lager yeast strain were similar, with no major differences found after sensory analysis. The results suggest that *T. delbrueckii* could be used in cold contact fermentation to produce non-alcoholic beers with alcohol content at, or close to, 0%. **Journal of The Institute of Brewing. 2022;128:28-35.**



## Sodium Reduction Strategies in Foods

In response to health concerns generated by increased sodium intake, many new approaches have been studied to reduce the sodium content in processed food. It has been suggested that reducing sodium in the food supply may be the most appropriate solution. The aim of this review was to establish what sodium reduction strategies are effective in maintaining acceptable sensory qualities for various food industry applications. Studies that evaluate and report on the effectiveness of a sodium reduction strategy relevant to food and included outcomes detailing how the strategies were received by human participants using sensory data are included, as well as book chapters, literature reviews, and patents focusing on sodium reduction strategies. Only those published in English since 1970 were included, and 277 primary studies, 27 literature reviews, 10 book chapters, and 143 patents were selected for inclusion. Data extracted included details such as analytical methods, broad and specific treatment categories, significant outcomes, and limitations, among other material. Sodium reduction methods were categorized as either salt removal, salt replacement, flavor modification, functional modification, or physical modification. Although salt removal and salt replacement were the focus of most of the studies included, future research would benefit from combining methods from other categories while investigating the impact on sensory characteristics, technological aspects, and consumer perception of the strategy. **Comprehensive Reviews in Food Science and Food Safety. 2022;21:1300-1335.**



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