

# Food Quality & Safety

FARM TO FORK SAFETY

## Cold Snap

**Mitigate pathogen risk in frozen foods**







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Letters should be no longer than 350 words.

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- Scientists to Study COVID-19 Transmission among Food Workers
- Appeals Court Upholds California Animal Housing Law



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# CONGRATULATIONS TO SARGENTO FOODS INC.

*Food Quality & Safety* magazine has recognized Sargento Foods Inc. for employing high product standards and expectations. For the complete story behind this company's success, turn to page 24.

# From The Editors

## A Tip from Sherlock Holmes

It's been more than 130 years since Sir Arthur Conan Doyle introduced his legendary detective, Sherlock Holmes, to the reading public in *A Study in Scarlet*. I would imagine that there are one or two of our readers who are fans of Mr. Holmes.

When Holmes met his biographer, Dr. John Watson, Watson was quite puzzled at the esoteric interests of Holmes and attempted to catalogue his knowledge—a catalogue that was cast into the fire in frustration. When Watson learned that Holmes did not know or even care that the Earth revolved around the sun, he was completely stunned and wanted to know why. Holmes then explained his thoughts on learning as follows:

*I consider that a man's brain originally is like an empty attic, and you have to stock it with such furniture as you choose. A fool takes in all the lumber of every sort he comes across, so that the knowledge which might be useful to him gets crowded out, or at best is jumbled up with a lot of other things so he has a difficulty laying hands upon it. Now the skillful workman is very careful indeed as to what he takes into his brain-attic. He will have nothing but the tools which may help him do his work, but of these he has a large assortment, and all in the most perfect order. It is a mistake to think that that little room has elastic walls and can extend to any extent. Depend upon it there comes a time when for every addition of knowledge you forget something that you knew before. It is of the highest importance, therefore, not to have useless facts elbowing out the useful ones.*



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# NEWS & NOTES

## Food, Beverage Groups Ask President for Priority Access to COVID-19 Vaccine

BY KEITH LORIA

There's some promising news on a possible COVID-19 vaccine, with Pfizer, Moderna, and AstraZeneca announcing that trials of their respective vaccines have proven to be between 70% and 95% effective so far. All seem headed toward quick approval through FDA's emergency use authorization.

In a November 11 letter to President Trump, 15 trade groups representing different parts of the food, beverage, and CPG industry have asked for priority access to the COVID-19 vaccine, once approved. Similar discussions have occurred with President-elect Joe Biden's transition team.

"Our members have been on the front lines of the response to the pandemic by continuing operations and ensuring Americans have access to safe, nutritious, and affordable food," says Adrienne Seiling, vice president of strategic communications for the American Frozen Food Institute, a group that has co-signed the letter. "We sent a letter to the President encouraging his administration—once a vaccine for COVID-19 is developed and approved—to have a

federally orchestrated vaccine distribution program and prioritization of vaccination among population groups including critical infrastructure employees, which include the food, agriculture, manufacturing, and retail industries."

According to CDC's vaccination program interim playbook, healthcare workers, non-healthcare essential workers, at-risk adults with underlying medical conditions, and those 65 and older could be prioritized for vaccinations if the supply is initially limited. The food groups that have asked for priority believe that they should be considered "essential workers" as well.

"Challenges have taxed the food supply chain over the past eight months, but the food, agriculture, manufacturing, and retail industries are resilient, and the supply chains have not broken," the letter stated. "Prioritizing vaccinations for food, agriculture, retail, and CPG workers will be a key intervention to help keep workers healthy and to ensure that agricultural and food supply chains remain operating."



Other groups that signed the letter include the United Fresh Produce Association, Consumer Brands Association, the North American Meat Institute, the International Dairy Foods Association, and the National Restaurant Association.

Recent data show that more than 72,000 people working in the food and beverage industry, including approximately 49,000 meatpacking workers, have tested positive for COVID-19.

## U.S. Seafood Industry Under Stress Due to COVID-19

The pandemic is putting a strain on the seafood industry, according to a new report focused on the impact of COVID-19 on U.S. fisheries. The study investigators suggest that American fishmongers may struggle without additional government aid.

The study, published in *Fish and Fisheries*, found that monthly fresh seafood exports declined up to 43% compared with 2019, while monthly imports fell up to 37%, and catches dropped 40% some months. Over the first six months of 2020, total U.S. seafood exports are down 20%, and imports are down 6%, compared with the same period last year. Further losses are likely as restrictions increase to address COVID-19.

"Seafood has been hit harder than many other industries because many fisheries rely



heavily on restaurant buyers, which dried up when the necessary health protocols kicked in," says lead author Easton White, PhD, a quantitative ecologist at the University of Vermont in Burlington. "Restaurants represent about 65% percent of U.S. seafood

spending, normally." For context, more than one million U.S. seafood workers regularly produce more than \$4 billion in annual exports, much of which is processed overseas and imported back to the U.S.

Aid for fisheries has been slow, partly because pandemics are not currently considered valid reasons for a fishery failure or disaster under current law. The CARES act has authorized \$300M for the sector. Even with increased demand for seafood delivery, which surged 460% for Google searches from March to April, some producers may not be able to recover without government assistance.

"Seafood is a seasonal business," adds White. "If you have a March to June season, and can't get funds until next year, you might have to quit. Support from policymakers will decide which producers can survive."

### FDA Issues Draft Guidance on Sesame Labeling

FDA has issued a draft guidance encouraging food manufacturers to voluntarily declare sesame in the ingredient list on food labels, due to the number of people with sesame allergies. “Many Americans are allergic or sensitive to sesame, and they need the ability to quickly identify products that might contain sesame,” said Susan Mayne, PhD, director of FDA’s Center for Food Safety and Applied Nutrition, in a prepared statement.

“While most products containing sesame declare it as an ingredient, there are

times when sesame is not required to be declared by name on the label, such as when it is used as a ‘flavor’ or ‘spice.’ Other ingredients, like ‘tahini,’ are made by grinding sesame into a paste, but not all consumers are aware that tahini is made from sesame. In these instances, sesame may not be declared by name in the ingredient list on a product’s label. We are encouraging food manufacturers to voluntarily list sesame as an ingredient whenever a product has been made with sesame.”



In 2018, FDA issued a notice inviting data and information on the occurrence and severity of sesame allergies in the U.S. and the prevalence of sesame-containing foods in the U.S. that are not required to disclose sesame as an ingredient. While the exact frequency of sesame allergies in the U.S. is unknown, it is estimated in some recent studies to be more than 0.1%, which is similar to allergies to soy and fish. The responses that FDA received indicated that some allergic reactions, such as hives, vomiting, wheezing, and anaphylaxis, may be occurring after ingestion of products with undeclared sesame or products that contain ingredients such as tahini.

Federal law requires that foods containing one of the eight major food allergens—milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybeans—declare the food source of the allergen using its common or usual name on the label. The Food Allergen Labeling and Consumer Protection Act (FALCPA) imposes strict requirements that foods containing one of these eight major allergens be clearly marked for the presence of these allergens.

While sesame is not one of the eight major allergens, FDA, through this draft guidance, is encouraging food manufacturers to voluntarily label their products if they contain sesame, even when not required to do so.

### FAO Sets Sights on New Food Safety Strategy

BY KEITH LORIA

The Food and Agriculture Organization of the United Nations (FAO) is preparing a new food safety strategy that will provide advice on managing unforeseen global challenges and crises that may impact the food supply. “Member states have tasked FAO with drafting a new food safety strategy to be prepared to act on the food safety challenges of today and tomorrow,” says Markus Lipp, PhD, senior food safety and quality officer for the FAO. “The new FAO food safety strategy will need to call to action all stakeholders in the food supply chains to do their individual parts to help ensure that all food for everyone is safe. Food safety is everyone’s business.”

The new strategy would act as a streamlined international guidance, policy, and advocacy platform to encourage increased investments and integration of food safety into the development of sustainable food

systems, food security and nutrition policies, and agriculture development strategies.

Delegations at the 27th Committee on Agriculture, which has more than 100 member nations, announced they will support the development of this new strategy. Most urged the FAO to ensure alignment of the strategy with the work of the World Health Organization and Codex Alimentarius. “In view of the increasing global importance of Codex standards, Switzerland strongly recommends FAO to ensure that the new FAO Food Safety Strategy clearly articulates FAO’s responsibility to support Codex standard setting procedure in order to ensure that Codex standards are based on science,” said the delegation from Switzerland.

“A new food safety strategy should further address health issues such as antimicrobial resistance, emerging zoonotic diseases, climate change, agricultural intensification,



new technologies, innovation, food fraud, digitalization of food systems and circular economies,” Lipp says. “The COVID-19 pandemic also demonstrates the increased relevance of food safety in emergency food assistance and humanitarian food aid. A new food safety strategy will align with new developments in food systems and provide advice on managing unforeseen global challenges and crises that may affect the food supply.”

FAO aims to present its members with the new food safety strategy by 2022, the next scheduled meeting of the committee.



# Washington Report



## Food Security Programs

Legislative efforts to protect the U.S. from food insecurity

BY MARY BETH NIERENGARTEN

In awarding the 2020 Nobel Peace Prize to the United Nations World Food Programme (WFP), the Norwegian Nobel Committee recognized and acknowledged the critical and central role food security plays in stabilizing societies by ensuring that one, if not the most, basic need is met. In a statement acknowledging the award, David Beasley, executive director of WFP, said, “Today is a reminder that food security, peace, and stability go together. Without peace, we cannot achieve our global goal of zero hunger, and while there is hunger, we will never have a peaceful world.”

This past spring, Beasley warned of the additional threat of food insecurity posed by the emergence of SARS-CoV-2, which he said could result in a “hunger pandemic.” That was in April. Now, in November, hunger rates are “skyrocketing around the world,” he said. Beasley noted that the socio-economic impact of the pandemic “is

more devastating than the disease” and is causing the loss of livelihoods for many people and moving many people into poverty. COVID-19 lockdown restrictions on mobility, trade, and economic activity are pushing millions of people into extreme poverty.

### Regulatory Measures

Caitlin Welsh, director of the Global Food Security Program at the Center for Strategic and International Studies cites the Global Food Security Act (GFSa) as one of the key laws addressing food insecurity. Passed in 2016 with bipartisan support, the law codifies the commitment by the U.S. government to “the productivity, incomes, and livelihoods of small-scale producers, particularly women, by working across agricultural value chains and expanding farmers’ access to local and international markets.” The law was reauthorized in 2018 and is up for reauthorization again

in 2023. It requires an updated global food security strategy per each reauthorization, the next one due in 2021, and Welsh says she will be looking specifically at a number of issues left unaddressed in previous versions.

One issue is a strategy to help poor urban residents who have suffered severe job and wage losses during the pandemic. “COVID is having an effect on food insecurity around the world, not because of food scarcity but because of lost jobs and wages that prevent people from accessing food,” she says. Although low-income people are being hit the hardest during the pandemic, Welsh cites a report from the International Food Policy Research Institute that showed an increase in poverty of 44% in urban areas of Africa during this time, compared with an increase of 15% in rural areas.

Other regulatory measures were discussed during the recent 2020 Ag & Food Policy Summit meeting held virtually in September. Sen. Pat Roberts, R-Kan, chairman of the Senate Committee on Agriculture, Nutrition, and Forestry, emphasized the extraordinary year for American agriculture and consumers. “Perhaps for the first time since the Great Depression, the significance of food security has resonated throughout the entire agriculture and food value chain, impacting nearly every kitchen table around the country and the world,” he said during a virtual session. “As COVID-19 has demonstrated, if any singular component in the food supply chain is vulnerable or harmed—the seeds, plants, feed, animals, workers, or infrastructure—significant challenges can result, and have resulted,” he said.

He listed a number of legislative efforts to protect the nation from threats to food security, including programs established within the 2018 Farm Bill to help USDA Animal and Plant Health Inspection Services (APHIS), including the new vaccine bank, the America’s Food and Agricultural Act enacted into law in March 2020, and the

*(Continued on p. 39)*

# Legal Update



## Election 2020

### How the Biden administration may impact the food industry

BY JOEL S. CHAPPELLE, ESQ.

**B**arring some dramatic and unforeseen event, President-elect Joe Biden will take office as the 46th President of the United States on January 20, 2021. What that means for the food industry will depend on some significant unknowns but, based on the results of the congressional races and Biden's stated goals and policy positions, we may still get a fairly clear idea of the types of changes likely to occur under a Biden administration.

By way of a civics reminder, Congress writes the laws, and the executive branch, led by the president, enforces those laws. In turn, the laws grant federal agencies the authority to issue regulations, which have the force of law. This is important because, although the executive branch cannot unilaterally enact laws, it does have broad discretionary authority to en-

act regulations based on its interpretation of the law. That can (and likely will) lead to substantial changes in the way federal agencies, from one administration to the next, enforce the law.

As with any political prognostication nowadays, I would be remiss not make certain disclaimers. To begin with, it appears probable—subject to the results of Georgia's senatorial runoff elections—that Republicans will retain control of the Senate. Thus, while the Biden administration will certainly pursue a more progressive agenda than the previous administration, its ability to enact legislation will be constrained by virtue of a split control in the legislature.

Additionally, this article is not an endorsement of any policy or administration. Rather, it is intended only to be an objective analysis of what the incoming administration is likely to do, and what may change.

**Workforce oversight.** In the immediate future, the ongoing pandemic will continue to govern the trajectory of our day-to-day lives. While it appears a viable vaccine is on the near horizon, the coming months are likely to be among the most challenging to date. Unfortunately, for many reasons, the food industry has suffered disproportionately in terms of the occurrence of illness.

As regards the pandemic, the Biden administration is likely to implement much more stringent measures to protect workers. Biden has advocated for enhanced protective measures. Last May, Biden said he supports coronavirus-related workplace safety regulations, even if they raise food prices. Biden has appointed worker advocates to teams responsible for overseeing the meat industry. In the near term, Biden is likely to implement stricter COVID-19 protective measures applicable to employees. In the longer term, Biden will likely re-staff agencies, such as the Occupational Safety and Health Administration, which will lead to increased oversight.

**Antitrust laws.** The Biden administration will likely be more focused on enforcing antitrust laws. During the campaign, Biden asserted that he intended to “strengthen” the Sherman and Clayton Antitrust Acts and the Packers and Stockyards Act. Generally, the argument goes that American food workers and small agricultural businesses are suffering due to increasing market concentration (e.g., monopolistic business practices), particularly in the meat industry. To level the playing field and promote competition, the new administration plans to significantly increase federal enforcement of antitrust laws. Such an approach would disfavor the largest food industry corporations. Biden's eventual choice for Secretary of Agriculture (unknown at the date of publication) will provide substantial additional insight into what the administration's approach ultimately will be.

**Regulation.** In terms of food regulation, the incoming administration plans



to streamline and reform existing regulations. What this means is not entirely clear, but we should not expect to see any type of major overhaul. Ideally, streamline and reform means fewer and more effective regulations. However, given the likely expansion of environmental regulations under a Biden administration, the food industry would be well served to begin preparing for more numerous and more stringent environmental regulations.

**Economic and infrastructural policy.** The Biden Administration has yet to articulate a comprehensive economic policy. In all likelihood, the administration's economic policy will be determined by how and whether the coronavirus pandemic affects the economy between now and January 2021. In the meantime, farmers across the country will continue to experience adverse impacts due to the imposition of tariffs on Chinese goods and the ongoing trade war. Although Biden has been critical of the prior administration's approach, his administration has not clearly articulated exactly how it will deal with the trade war.

One interesting question involves the intersection between climate policy and economic policy. On the one hand, if the Biden administration lifts tariffs on Chinese products, that could be a significant boon to farmers by reopening Chinese markets to U.S. agricultural products. At the same time, the expected focus on reducing the use of and reliance on fossil fuel emissions could have a correspondingly negative effect on demand for biofuels, such as ethanol.

In terms of infrastructural policy, the Biden administration seeks to invest \$20 billion in rural broadband infrastructure, and to triple broadband access funding in rural areas. This reflects much needed and long overdue support to agribusiness, which is predominantly located in rural areas. A new stimulus package is also likely after the inauguration. As of late November, it appears unlikely that Congress will be able to pass a stimulus package before 2021.

**Climate and immigration.** Not surprisingly, immigration and climate change are two areas where the policy differences between the incoming and outgoing administrations are most apparent. Whereas the previous administration was known for being largely anti-immigration, Biden

is pressing for a more permissive immigration framework, especially as it relates to agricultural immigration. Biden seeks to work with Congress to enact compromise legislation between farmworkers and the agricultural sector that would grant legal

**Given the likely expansion of environmental regulations under a Biden administration, the food industry would be well served to begin preparing for more numerous and more stringent environmental regulations.**

status based on, among other things, agricultural work history. In the current political climate, and especially if the Senate remains under Republican control, it will be difficult to pass any meaningful legislation, much less immigration reform legislation, which remains anathema to the Republican base. Thus, we are most likely to see implementation of lesser reforms that are achievable through executive action.

While President Trump has historically expressed skepticism about climate change and the need to address it, Biden has made it one of his signature issues. Biden recently named former Secretary of State John Kerry as his climate czar. The administration aims to lay the groundwork for achieving a 100% clean energy economy and net-zero emissions by 2050, and to expand the federal Conservation Stewardship Program, a partnership between the government and farmers/ranchers to implement sustainability improvements and reduce emissions. Such a partnership would likely provide a host of new opportunities for small to mid-size agricultural interests but would also increase the industry's regulatory burden.

### **Change Takes Time**

I hope this article offers a better understanding of what the new administration will mean for the food industry. However, as momentous as a presidential

election is from a historical standpoint, it is important to maintain an appropriate amount of perspective. As a practical matter, it is important to note that significant change typically takes significant time. The United States government is a bureaucratic colossus. In recent decades, we have faced a nearly constant barrage of tribalistic, partisan-based fearmongering. With each election, we are made to believe we face tremendous danger; however, the reality is more mundane. Yes, the United States faces significant challenges, domestically and internationally. It always has. Democracy is loud and messy. But, whether you were happy with outcome of the election or not, the reality is that, for most people, our day-to-day lives are unlikely to significantly change as a result of any single presidential administration or who happens to control the House or Senate.

I am glad the election is behind us and for the temporary reprieve from the endless unsolicited political text messages and emails. Likewise, I welcome putting 2020 in the rearview mirror. It has been a tough year for everyone, and we have suffered unimaginable losses.

Yet, more than anything else, I am grateful. I am grateful to work with people from every imaginable background and socioeconomic status in places all across the country, in urban areas, and rural areas, and everywhere in between. In doing so, I have observed, without exception, that we are better than our politics, and have much more in common than our politics would suggest.

I am grateful to live in a country where I can count on my fellow citizens to roll up their sleeves and continue producing safe and plentiful food, even amidst a pandemic, despite great personal risk. I am grateful to all of you for your unheralded bravery, unwavering dedication to your communities, and your ability to work together to get the job done under the most difficult conditions imaginable. I only wish our elected leaders had your integrity, decency, and selflessness. Thank you for all you do.

Have a safe and happy holiday season and new year. ■

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# Allergen Control



## My Sample Tested Positive for Allergen Residues—What’s Next?

### Part 1: Confirm your results

BY STEVE L. TAYLOR, PHD, SHYAMALI JAYASENA, PHD, LYNN M. NEIMANN, DEBRA M. LAMBRECHT, SEAN KRAFT, AND JOE L. BAUMERT, PHD

**Editor’s note:** This is part 1 of a two-part series on allergen residue results. Part 1 focuses on how to confirm a positive result and Part 2, which will publish in our February/March 2021 issue, will focus on steps to take once a result has been affirmed.

**P**ositive results in allergen testing of food products can sometimes be quite unexpected and disconcerting. This is particularly true when testing finished food products ready for distribution and sales, or ingredients procured for a manufacturing run in the near future. Positive allergen residue results are not so surprising when testing to assess the effectiveness of cleaning pro-

ocols on shared equipment, especially when qualifying a new cleaning procedure, but a positive result is disturbing if the cleaning protocol has been assessed on numerous previous occasions with no positive results.

Oftentimes, ingredient or finished product samples are sent to external commercial laboratories to confirm that detectable allergen residues are not present. Swabs and final clean-in-place rinse waters are also sent to commercial laboratories, typically as a third-party check to demonstrate consistency with in-plant analysis using qualitative methods such as lateral flow devices (LFDs). In some cases, the product, ingredient, and/or process

have been checked on multiple occasions with no previous positive detection of allergen residues. Even in cases where allergen testing has not been performed previously or testing was sporadic, the positive result is still an unpleasant surprise. The situation becomes even more alarming if the testing was performed by a valued customer, an auditor, or a regulatory inspector.

What should you do when you get that unexpected positive result? First of all, take three deep, calming breaths, and step back from the ledge. Then, get into investigative mode. Sometimes, the recipients of an unexpected positive result will immediately wonder if the external laboratory made a testing error and/or claim that the result is a false positive. That possibility needs to be assessed but is not the only possible explanation. Other possibilities include a manufacturing error (cross contact), a contaminated ingredient, packaging error, or a failure of the allergen cleaning protocol.

We know from experience that recipients of unexpected positive results from an external lab report may immediately reach out to their external laboratory or reach out to the Food Allergy Research and



Resource Program (FARRP) for assistance. While we are okay with sharing your pain at this stage, know that our initial goal will be to put you into investigative mode to get enough information so that we might really be able to help you with a thorough root cause analysis and/or risk assessment.

### Carefully Examine That Laboratory Report

The laboratory report should, but will not always, contain critical information. First, double check the sample identification information on the report to ensure the laboratory report contains the test result for the sample(s) that you sent for analysis. The laboratory report will contain the analytical result(s), but most importantly, it should also contain the units, usually ppm for allergen analysis. However, these laboratory reports may not always list the calibrant. For example, when testing for milk residues, 10 ppm  $\beta$ -lactoglobulin (BLG) is not the same as 10 ppm non-fat dry milk (NFDM). In fact, 10 ppm BLG is equivalent to 286 ppm NFDM because BLG is roughly 10% of total milk protein and NFDM contains about 35% protein. The laboratory report should, but will not always, contain the identity of the method used to acquire the result. Many external laboratories use commercial enzyme-linked immunosorbent assays (ELISAs) for detection of allergen residues. Citing milk allergen analysis again as our example, at least six different ELISA kit companies (even more on an international basis) produce milk ELISA kits, and several of them make multiple milk ELISA kits with different targets (total milk, casein, or BLG) and different calibrators (non-fat dry milk, soluble milk protein, casein or BLG). The choice of the milk ELISA kit can make a difference for your results and will certainly affect the interpretation of the seriousness of the finding to the potential risk of the product.

If you have used this commercial laboratory on numerous occasions in the past, you may have confidence that they are excellent analysts; however, you need to find out which ELISA test was conducted and the units/calibrants associated with that method if this information is not clearly provided on the analytical report. If the laboratory report does not contain information on the method used or the calibrant, you will need to contact the lab-

oratory to get that information. The choice of the external lab can also be important. ISO-accredited labs must undergo an audit and approval process for specific methods to be included on their scope of accredited procedures. Be aware that ISO-accredited labs may not have all test methods within their ISO scope. If you want to use an ISO-accredited lab, make sure that the allergen test methods for your samples are included within their ISO scope or that that the laboratory follows a similar degree of care with procedures that are not under their ISO scope.

In addition to commercial ELISA kits, allergen analysis may also be performed by polymerase chain reaction (PCR), which detects DNA from the allergenic source, or by mass spectrometry, which detects specific proteins from the allergenic source. PCR typically has high specificity, but quantification of results and correlation to how much protein came from the allergenic source of concern can be difficult. Mass spectrometry methods hold great promise for the future, but few well-validated methods currently exist that can be

used in the wide variety of ingredient and food matrices that are commonly analyzed by the food industry.

Most allergen analysis is performed using commercial ELISA kits. The level of sensitivity of those kits is typically in the low ppm range but can vary between kits. It is important to remember that the choice of calibrant affects the result (10 ppm BLG = 286 ppm NFDM) as well as the choice of protein target(s) that the kit detect. Allergen ELISA kits also have a dynamic range associated with the quantitative standards supplied with the kits. For example, the dynamic range might be 2.5–25 ppm. Many commercial laboratories will not dilute the sample if the result exceeds the upper limit of the dynamic range. Thus, you might get a result of, for example, >25 ppm. Your first question will be: How much greater than 25 ppm? Some commercial laboratories will not answer or even be able to answer this question. Some external laboratories will dilute samples, but some of these laboratories charge extra for taking that step. The FARRP Laboratory immediately dilutes

*(Continued on p. 14)*



  
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samples that fall outside the dynamic range of the kit up to a maximum of 200-fold dilution (5000 ppm, or 0.5%). From a risk assessment perspective, knowing the specific, quantitative result is imperative for a thorough exposure assessment.

When you receive an unexpected result, you may want the laboratory to repeat the analysis. Some commercial laboratories will not be able to do that because they do not save any of the sample to use for a repeat analysis. Other laboratories will conduct a repeat analysis upon request, but some of them will charge again to do that test. For these reasons, we suggest that a best practice is to take duplicate or even triplicate samples, saving the extra ones at your place of business in case a repeat analysis is desired.

### Could the Result Be a False Positive?

Commercial ELISA kits are typically quite specific. The manufacturers of these commercial kits assess the likelihood of cross-reactivity across a range of foods and food ingredients. Significant cross-reactivity is not often encountered except for very closely related foods such as walnut and pecan (these two nuts are botanical cousins). ELISA kit manufacturers publish written inserts that are distributed with the kits and typically include information on cross-reactivity. Commercial laboratories should be aware of cross-reactivity issues and decline to test samples that might generate false positives due to cross-reactivity in that specific test. Alternative methods should be considered if available; however, the laboratories do not always know the compositional nature of the submitted sample. Often laboratories receive unknown, food-grade powders for analysis. It is impossible for the laboratory to know what the composition of a powder may be, so it is critical to develop a good line of communication with your external laboratory. For example, we are aware of a commercial peanut ELISA kit that yielded weak positive results on samples containing high amounts of pea protein, another legume, that were reported by another commercial laboratory. This situation prompted a recall before we had the chance to inform the company that the analytical result was likely a false positive. Another best practice

is to inform the external laboratory about the general composition of the test sample and ask them to verify that there are no known cross-reactivities in the ELISA kit being selected for the analysis that may affect the reliability of the results.

Beyond cross-reactivity, commercial ELISA kits can occasionally experience matrix interference. This is more common with foods or ingredients containing chemicals that might react with proteins in the sample or the antibodies used in the ELISA kits. For



example, spices containing high amounts of phenolic compounds can generate false positives, often due to non-specific binding to the proteins and antibodies contained in the ELISA wells. We have also observed false positives in several commercial peanut ELISAs when testing caramel color, especially the darkest class of caramel color. These matrix-associated false positives typically yield weak positive results—usually <10 ppm. If, after dilution, your sample gives a positive result of 50 to >5000 ppm, the result is rather unlikely to be a false positive. With a true positive sample, the absorbance values that are measured from the sample wells will decrease rather linearly with each additional dilution until the absorbance reaches the absorbance associated with the buffer control. When a matrix interference is observed, the absorbance values will remain stable with each subsequent dilution. When the dilution is factored into the calculation of the final concentration for each dilution, an increase in the ppm value will be observed with each additional dilution. This is counterintuitive and provides a good indication of a matrix interference.

If you suspect a false positive result, what steps can be taken? The FARRP Lab-

oratory has an investigational approach used for such situations, so it is prudent to contact us at this stage. First, we might repeat the analysis done by the original laboratory, because the result is more reliable if confirmed in two laboratories. This approach also examines the possibility that the original result was caused by laboratory error. Of course, this approach requires a duplicate sample and is dependent on the homogenous (non-particulate) distribution of the analyte in the sample. The original laboratory should be asked to do a repeat analysis if they have sample remaining that could be used for this purpose. If the original result is confirmed by the FARRP Laboratory, then we will recommend testing samples of this product or ingredient with multiple (3 to 4 if available) commercial ELISA kits for that analyte. This recommendation is generally predicated upon the original result falling below 10 ppm. In our experience, it is unlikely that higher concentrations are a result of a matrix interference but are rather true positive results. Since each commercial ELISA kit uses their own proprietary antibodies, extraction methods, and so on, they are not likely to experience the same matrix issues. If we find positive results in multiple ELISA kits, the likelihood of a true positive is enhanced. Conversely, if only the original ELISA kit gives a positive result, the possibility of a false positive is increased. We might also arrange for a PCR and/or a mass spectrometry analysis for confirmation of the positive result if such methods are available.

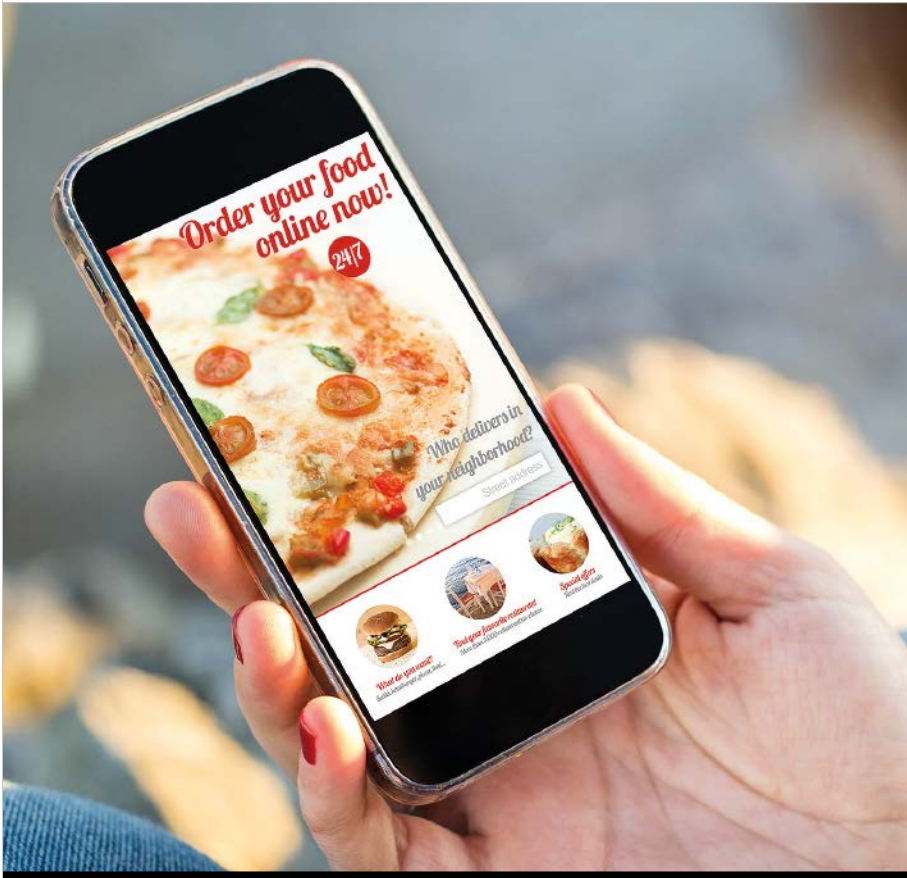
If the unexpected positive result was obtained by testing of an ingredient, the supplier may try to claim that the result was a false positive. Testing can readily demonstrate if that explanation is plausible. If testing is arranged on multiple lots (perhaps from multiple suppliers) of the same ingredient and only the suspicious lot tests positive, then matrix interference cannot be the answer. Matrix interference will be quite consistent if the test samples have a similar composition.

Sub-sampling can also contribute to analytical uncertainty. If the analyte is present in particulate form—e.g. chopped peanuts or whole sesame seeds—the analyte may not be present in every sample taken for analysis. In this case, the unexpected

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# Global Interests



## Eating In a Pandemic

Consumer food purchasing and eating behavior during COVID-19

BY AURORA A. SAULO, PHD

A cluster of pneumonia illnesses in Wuhan City, Hubei Province, China, from an unknown cause was first reported in December 2019. In January 2020, the cause was identified and, later, designated by the World Health Organization (WHO) as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) resulting in an infection named COVID-19.

WHO declared a global pandemic on March 11, 2020, and by November 2020, 218 countries and territories were affected by

the illness. Since April 2020, many of these countries have instituted strategies to control virus spread so that sudden and large increases in infections needing hospitalization would not tax their medical care capacities. A study published in the *Journal of Infection* in April 2020 reported that this attempt at “flattening the curve” will reduce case fatality rates. Countries highly encouraged—and mandated in some areas—physical distancing of at least six feet between people, wearing face coverings when physical distancing is not guaran-

teed, strict hand hygiene, avoiding touching the eyes, nose, and mouth, and good respiratory hygiene (sneezing or coughing on a disposable tissue or bent elbow).

Additional practices include avoiding contact with symptomatic persons, sheltering those who are highly vulnerable (i.e., the elderly, especially those with compromised immune systems), limiting crowd sizes, identifying risky venues and activities, and other strategies, depending on the operations and policy makers. These restrictions reflected and magnified real consumer fears about their personal health and safety, and financial health. Consumers continue to eat during a pandemic, but consumption of food and beverage is also impacted by the virus.

In April 2020, The Hartman Group ([hartman-group.com](http://hartman-group.com)) conducted their “Eating Occasions Compass” survey recruiting approximately 2,500 U.S. adults aged 18 to 73 from the major demographics. Several studies were completed to determine the impact of COVID-19 on eating relative to their cultural values/beliefs, social/political/economic forces, the different media and social networks, what people need for food and beverage, and their behaviors and habits. This article focuses on consumer eating and buying behavior during the pandemic as primarily reported by this organization.

### Eating Occasions

For the majority of consumers prior to the pandemic, dinner was the meal most frequently eaten (80%), followed by lunch (70%) and breakfast (64%). Some consumers also ate an afternoon snack (38%) or an after-dinner snack (32%). American consumers retained the same eating occasions during the pandemic, and at approximately the same frequency. In consecutive order during the day, the eating occasions are the early morning snack, breakfast, morning snack, lunch, afternoon snack, dinner, after-dinner snack, and late-night meal/snack.

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### Effects of Isolation

To arrest the spread of the coronavirus, most countries isolated themselves from other countries, and residents were instructed or mandated to follow quarantining practices. Most office workers were told to work from home. Venues with high close-contact activities (such as restaurants, fitness centers, salons, travel, banks, schools, and houses of worship) were closed, and residents were severely restricted from using many services. A new term—“untact”—was introduced in South Korea to describe services that minimize direct person-to-person contact, such as online purchasing and payment, self-service counters, videoconferencing, and distance learning. Buffets and hot bars were quickly converted to untact services such as complete meal kits and take outs.

### At-Home Eating

Before the pandemic, approximately 76% of consumers ate at home, and the remaining 24% ate at work, in restaurants, and at other locations outside the home. During the pandemic, eating at home increased to 88%, reducing eating anywhere away from home to 12%, half of what it was before the pandemic. Morning snack, lunch, afternoon snack, and dinner are eating occasions that now happen significantly more at home, due to increased unemployment and work-at-home strategies or mandates. Generation X (those born from 1965 to 1976) experienced the largest decrease in eating at work during the pandemic.

### Alone Eating

Before the pandemic, U.S. consumers were more likely to eat alone during early morning snack, breakfast, morning snack, and lunch times when they hurriedly prepared to go to work or were already at work. Although about 43% still ate alone during the pandemic, U.S. consumers are more likely to eat with others (e.g., family, significant others) at these eating occasions. Approximately 88% of snack consumption now occurs at home, and snacks are mostly ready-to-eat items.

Interestingly, about half of all snacking occasions involve adults who are alone, and approximately 53% of these snack foods and beverages are planned and bought more than eight days before con-

sumption. Millennials (those born from 1977 to 1995) ate alone more than they did before the pandemic.

### Shopping Trips

As eat-at-home occasions surge, the U.S. consumer is shopping more efficiently, conducting fewer shopping trips for the major eating occasions because stores are considered to present higher risks of contracting COVID-19. An exception to this statistic are the Boomers (those born from 1946 through 1964), who significantly increased their stock-up trips during the pandemic. Shopping trips are conducted at least three days in advance for food and beverage consumed at home (especially dinners), for snacks and meals that had been purchased from food service before the pandemic, and for possible food shortages and other needs resulting from new sheltering orders. Generation Z (those born from 1996 through 2010), the first generation to grow up completely in the digital age, and Millennials are more likely than Gen X and Boomers to purchase their dining options on the same day of consumption. Even before the pandemic, Gen Z used delivery and takeout options more often, especially for last-minute dining decisions.

Online shopping revenue grew significantly, from 10.5% of all grocery spending in 2019 to 14.5% in February 2020 to almost double that in March and April of 2020 (27.9%). All generations, both with and without children, used online grocery shopping, according to The Food Marketing Institute. In addition to citing safety and health as the top reasons for online shopping, the U.S. consumer likes the time saved, its ease, and the fact that it includes delivery. As of August 2020, however, 39% of all generations still prefer in-store to online (26%) grocery shopping.

### Food Categories

The U.S. consumer retained the same predominant food categories eaten before the pandemic—breads/rolls/tortillas (13%), cheese (12%), eggs (11%), dairy products other than cheese (10%), fruit/fruit snacks (9%), meat cuts (9%), and common breakfast items (7%), according to The Hartman Group. During the pandemic, more than twice as many breads/rolls/tortillas as potatoes (6%), and more than three times the amount of rice and other starches (4%),

have been eaten. A November 2000 study published in *Psychosomatic Medicine* reported that emotional eaters, when stressed, increased their consumption of “sweet high-fat foods and a more energy-dense meal,” foods that quickly supply energy.

But there’s a concern that stress and anxiety induced by the pandemic and quarantine mandates may also lead to “the quarantine 15,” the term coined for the 15 pounds that some people may gain during isolation. Pizza/pasta/Italian food, sweets, and burgers, which were mostly outsourced to restaurants and other away-from-home locations before the pandemic, have been consumed less during the pandemic because consumers preferred not to replicate the foods at home, even when they decided not to purchase the same foods from providers outside the home.

### Cooking at Home

Because of nationwide shelter-at-home orders during the pandemic, about 40% of U.S. consumers cook at home more often. Approximately 49% of this group expects to keep cooking at home after the pandemic, according to The Hartman Group. The novelty of cooking at home during the day is enjoyed as a recreational activity, especially among the younger generations, resulting in some meals not usually eaten pre-pandemic for the same eating occasions.

For example, while lunches were consumed mostly away from home before the pandemic, approximately 81% of lunches are now prepared at home for families and from “scratch,” entailing a moderate increase in time and effort using “fresh, less processed,” and “special health” foods and ingredients. Lunches during the pandemic look more like pre-pandemic dinners.

Before the pandemic, many dinners were outsourced to food service. During the pandemic, approximately 93% of dinners are prepared at home for the same persons involved pre-pandemic but with “heavy preparation” and increased planning time. Approximately 42% of consumers bought the food supplies during their usual shopping trips, not as last-minute decisions.

### Food Pick-up and Delivery

Although most restaurants converted from dine-in to solely takeout and delivery,



about 24% of all eating occasions entail restaurant-prepared foods. For 35% of Gen Z, 36% of Millennials, 19% of Gen X, and 11% of Boomers, eating occasions involve such restaurant-prepared foods. Third-party delivery services are more important to Millennials than to the other generations. Lower-contact ordering significantly increased during the pandemic for restaurant pick-up, drive-throughs, and other options such as orders by phone, app, or on-site. Both the Millennials and Boomers prefer drive-through pick-up of restaurant-prepared food, and Boomers order more via phone, app, or on site.

About 37% of the eating occasions using foods outsourced to restaurants are planned by parents and 19% by non-parents. The planning time to purchase these foods during the pandemic has increased significantly to about a day before consumption (17%), so many eating occasions are now planned ahead.

Before the pandemic, there was high consumer awareness in promoting sustainability by decreasing single-use plastics. COVID-19, however, reintroduced the use of non-recyclable food plastic ware and packaging to limit the spread of the virus. It will be interesting to see how plastics are used after the pandemic.

### Buying Behavior

In 2017, according to Retail Dive, food and beverage shopping in the U.S. was influenced by price, taste, convenience, and a “meaningful and memorable” “stress-free experience.” Other factors such as less processed food, ethically produced, healthful qualities, and fair labor treatment also influenced their buying behavior. Although one would have expected price to remain the leading factor when shopping for food and beverage during the pandemic because of a negatively impacted economy, “price was no object” to the U.S. consumer, because the primary concern during the early stages was to secure groceries and supplies, according to The Hartman Group. People stockpiled, creating shortages. A report published in August 2020 in the journal *Food Security* explained that stockpiling or hoarding is an indicator of panic buying in response to risks that may not even be known, but that have potentially catastrophic results.



Because of nationwide shelter-at-home orders during the pandemic, about 40% of U.S. consumers cook at home more often. Approximately 49% of this group expects to keep cooking at home after the pandemic.

Interestingly, the pandemic caused an increase in disposable income for the U.S. consumer, especially for those whose jobs and wages were not affected by the virus; this is likely due to reduced spending on food and beverage outside the home, fewer options in recreational activities, and restricted travel. Thus, “trading up” to food and beverage with health and wellness qualities becomes possible and is seen as justifiable; food is treated as medicine. Romanian consumers in the quarantined area of Suceava mirrored this buying behavior of fresh and less-processed food, opting for the online purchase of fresh vegetables delivered directly by producers.

According to The Hartman Group study, the most important considerations for the predominant number of eating occasions during the pandemic are “fresh and less processed,” followed by “convenience.” Approximately a third of eating and drinking occasions are focused on basic health and well-being issues, particularly snacks before and after breakfast. This results in an increased demand for functional foods and beverages that address weight management, energy,

hydration, digestion, and the cardiovascular system, especially those products benefiting the immune system. The focus diminishes, however, from lunch to afternoon snack to dinner and to after-dinner/late night snack.

By July 2020, after several months of the pandemic, the enthusiasm for cooking subsided and “cooking fatigue” set in. The U.S. consumer is now searching for new ways to plan meals and foods that are convenient to serve, reasonable in price, and have new exciting flavors without compromising quality. There is increased interest in new cooking methods, culinary skills, flavors, and sauces. Foods, other than those usually consumed for a particular eating occasion, are now served at other times. For example, macaroni and cheese instead of eggs and bacon is breakfast. Millennials, more than the other generations, are searching for these new flavors.

### Where Do We Go from Here?

A Nielsen Company study of consumers in 100 countries reported that changes in consumer behavior occur in six common stages. Consumers first focus on strengthening their health and immunity. Next, they purchase protection products to manage their health, prepare for isolation and quarantining, and hoard certain supplies in anticipation of additional restrictions. Consumers then try to live their now drastically altered daily life. When the presence of the coronavirus is finally considered manageable, consumers enter the sixth stage, which is the return to some semblance of pre-pandemic living conditions familiar to them. Although moving from one stage to another occurs at different speeds from country to country, worldwide consumer behavior seems to follow these stages.

Living through the crisis brought on by COVID-19, the highly destructive invisible pathogen, taught us ways to manage the illness through health and well-being practices. But, are we developing behavior that is crisis-specific only? Or are we learning that at least some of these practices are lifelong behaviors that we must keep for everyone’s safety? If so, which practices would those be?

Let’s see what the consumer will do. ■

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# Cannabis Corner



## The Challenge of Potency Testing

Testing food items for cannabinoid potency runs from complicated to extremely complicated

BY JESSE STANIFORTH

Approximately five years ago, Canadian cannabis edibles pioneer Brandon Wright ran up against a testing problem. He was producing cannabis brownies following a 2015 decision by the Supreme Court of Canada that guaranteed licensed medical patients the right to produce and possess edible cannabis products, and he wanted patients to be certain that each brownie he served contained the same very high dose of 200 mg of cannabinoid tetrahydrocannabinol (THC).

Yet, despite sending three brownies per batch for testing, his labs reported wildly different results, which confounded Wright. “I later found out they were breaking off a corner of each brownie, [reducing it to powder], and testing that,” Wright says. The problem, he eventually figured

out, was “hot spots,” which may be acute in non-homogenous cannabinoid products such as brownies. Wright warns that the lack of homogeneity within a food product containing 200 mg THC means that the end product “is likely going to have micro-hot spots, even with a production process that is excellent at mixing and homogenizing.”

Cannabinoids are fat soluble and likely to cluster in small deposits within a baked good rather than being uniformly distributed, so even in an extremely potent product (200 mg is 20 times the 10 mg-per-serving limit imposed by some U.S. states), one part of such a food item may contain more or less THC than another.

Because of hot spots, a brownie containing 200 mg of THC has the cannabinoid distributed only somewhat uniformly. To get the readings Wright was looking for,

his lab needed to reduce each complete brownie to homogenous powder and sample from that powder. “I could then analyze those results to determine the milligrams of THC per gram of brownie and adjust production processes accordingly,” he says.

### What Makes Testing Edible Potency Difficult

For food and beverage producers who pivot into cannabis-infused products, traditional food-safety testing practices remain essentially the same. Yet producers of cannabis edibles and beverages face an important test particular to their industry: potency. Potency is generally measured in milligrams of active cannabinoids, such as the best-known THC (responsible for cannabis’s psychoactive effects), the popular non-impairing cannabinoid CBD, and other less-understood cannabinoids such as cannabigerol (CBG), cannabinol (CBN), and cannabichromene (CBC).

Mike Hennesy, director of innovation for Colorado edibles producer Wana Brands, notes that, in its plant form, cannabis is a very pharmacologically diverse. “You have cannabinoids; you have terpenes. Some growers have used pesticides, and it also soaks up things like heavy metals and microbials. No one piece of equipment is perfect for [testing for] any one of them,” he says. And, that’s just for testing cannabis flower. Depending on your product, testing food items for cannabinoid potency runs from complicated to extremely complicated.

For Amber Wise, PhD, the scientific director at Seattle’s Medicine Creek Analytics, the next question is this: homogenous or non-homogenous? “A gummy is really homogeneous. It’s well mixed,” Dr. Wise says. “But a chocolate chip cookie, for instance, is not.” As infused-food producers try to concoct a winning combination of cannabinoid dose and flavour profile, her lab has received a wide variety of food products to test. “We’ve received jalapeno ranch-flavored pretzels [and] caramel popcorn.”



With complex foods featuring multiple ingredients, Dr. Wise encourages producers to submit a significant number of the items for individual testing. “If you’re making cookies or brownies, sending in 20 of those and paying for 20 individual tests, [you can] see the spread of the lab you’re using,” she says. “That gives you a better idea of, if I send in any random cookie, are they going to give me a number that is a narrow range? It gives you a sense for the spread of your product and that lab together.”

### The Power of Test Prep

Hennesy says that the way a lab conducts preparation for potency testing will determine the accuracy of the results. “Test prep cannot be underestimated as one of the most important variables from lab to lab,” he adds, noting that ingredient differences among products must be reflected in how labs prepare their samples for testing, or the results may be corrupted.

“But there’s no such thing as a standard sample prep,” Hennesy says. “Those are considered, essentially, trade secrets for every different lab. Every lab will have a different test prep.” So it falls to producers to work with labs to develop “robust, internal validation programs, [meaning] the lab uses several different processes to check and double-check [that] the results they’re providing you are accurate.”

Every lab can create its own validation processes, and Hennesy warns against labs that do little validation. “Everyone’s equipment is different, and everyone’s test prep is different,” he says. “A lab really should do validation on their test prep and do validation on the individual equipment they’re using. Most importantly, they should have a different validation procedure for every type of product.”

Dr. Wise agrees, calling this process “matrix-specific testing, meaning crackers are treated differently than meat is treated differently than fruit.”

To test cannabinoids, labs must extract the molecules from the food products in which they appear, but Dr. Wise says the ingredients of any given product may affect the extraction process. “It’s important that the lab you’re working with either has tested your kind of food product previously or you’re able to work with them and send them an uninfused sample and then an infused sample,” she notes. “They

can run background tests to ensure that they’re getting all of the cannabinoids out of your specific product.” (She adds that producers should avoid any lab using the outdated and unscientific division of cannabis products into “Indica” and “Sativa.”)

Hennesy stresses that, if a lab doesn’t have a validation process for the specific product in question, it should work with the producer on developing validations for the exact product the producer needs tested. This is particularly important, Dr. Wise says, for beverage producers working with water-solubilized cannabinoids, such as those in nanoemulsions. Producers must be clear with their labs when they are using such cannabinoids in order to get accurate results—but the more labs know about how the product is made, the better.

“You should also be providing information to them,” Hennesy says. “The more the lab knows about what they’re actually testing and what barriers you might have created within the product-development process that could hinder testing, the easier it is for them to tailor their procedures to give more accurate results.”

### Pushing the Upper Limits

In many cases, producers testing for potency are simply looking to determine the cannabinoid content of their food or beverage products so they can list it on their packaging. Yet, in some states, producers are testing against edibles potency limits. In the states of Washington and Colorado, for example, THC is capped at 10 mg per edible or beverage serving, with a maximum of 100 mg THC per package. (Under far more stringent Canadian law, THC is capped at 10 mg per package.)

In theory, the chief challenge producers should face when testing against upper limits on THC is making sure their products don’t exceed the THC limits. However, Washington-state cannabis business-intelligence expert Jim MacRae, PhD, who has published a series of reports showing “friendly labs” allowing companies to “pay for potency” in multiple states, warns that some labs are willing to fraudulently undercount cannabinoids, allowing products onto the market with more than 10 mg of THC per serving.

However, Dr. MacRae notes that, unlike falsely inflated cannabinoid content, products that are labeled 10 mg per serving

but that deliver a much stronger dose are actually more desirable to many experienced consumers. He adds that increasing the THC dose in infused products—and particularly in high-end infused products with expensive ingredients, such as Belgian chocolates—might cost producers very little. “A very small fraction of the cost of the thing is the cannabinoids,” says Dr. MacRae. “If you can double that, that’s doubling the cost of only a small proportion of your product cost.” If consumers discover a product is “a stronger 10 mg per serving,” that might increase its appeal among those looking to consume more THC.

While an excess dose of cannabinoids can’t kill a consumer, the experience of consuming too much THC is acutely uncomfortable and sometimes terrifying. Because of the enormous variation in tolerance between seasoned consumers and new users, THC doses that have negligible effects on regular cannabis consumers can provoke truly unpleasant experiences for some novices. Though some consumers would welcome a “strong 10 mg” product, new users run the risk of mistakenly consuming THC at a level that could leave them in a state of discomfort, and sometimes panic.

Hennesy believes that companies can avoid being caught up in such circumstances by setting high standards for researching and selecting the labs with which they work, and not skimping on best practices—even if there isn’t yet a uniform standard for such practices. “In reality, the cannabis industry has created a lot of low-cost providers that are working to produce the cheapest, fastest test results possible,” Hennesy says. “They’re certified by a state lab, which means they’re in the clear to give you those results—even if they’re not the most accurate results out there.”

Lab testing is one of the final steps before a producer’s food item goes to market. Hennesy says it’s up to producers to treat selecting a lab with the same care they put into developing their products. In the long run, the trust will run both ways. “It’s important to have a strong relationship with your lab,” he adds. “They’ll be able to help you troubleshoot and problem solve, and even identify when test results don’t make sense.” ■

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# Cold Snap

Strong and secure measures within food processing and manufacturing facilities are needed to ensure the safety of frozen foods

BY MARY BETH NIERENGARTEN



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**D**emand for frozen food products are on the rise. By one recent analysis, the size of the global frozen food market will reach \$185.28 billion in 2027, up from \$146.79 billion in 2019, representing a compound annual growth rate (CAGR) of 3.1%. The market research analysis by *Fortune Business Insights*, published November 10, 2020, found that an expanding workforce population, a rise in women's employment rates, a change in lifestyles among younger generations, and increased consumer awareness of the health benefits of frozen foods are among the current and predicted drivers of increased demands for frozen food and ready-to-eat (RTE) products as people increasingly want food that requires less effort and time to make and is more convenient to consume.

Although acknowledging the downturn in demand and drop in frozen food market sales during the COVID-19 pandemic, after an initial increased demand when SARS-CoV-2 first emerged, the report highlights the recent demand for online shopping occasioned by the pandemic as increasing consumer awareness about new apps for online shopping are expected to drive growth in the frozen food market going forward. When looking at the type of product, the report predicted that frozen vegetables and fruits would lead in consumer demand, followed by frozen RTE meals.

What this report underscores, similar to several other analyses predicting similar or even higher growth in consumer demand for frozen food products, is the need for strong and secure safety measures within food processing and manufacturing facilities to ensure the safety of frozen food products.

For food processors and manufacturers, a number of pathogens may pose a risk to frozen food products. Among the most concerning is *Listeria monocytogenes*. The seriousness of this pathogen on human health, particularly on more vulnerable populations such as pregnant women, neonates, people older than age 65, and those with chronic illnesses, is well documented. As reported in a recent review by Farber et al., published in October 2020 in the journal *Food Control*, the populations of people at risk of acquiring listeriosis, the foodborne illness caused by *L. monocytogenes*, is growing and may represent up to 30% of the general population.

Not only is the population at risk growing, so too is the incidence of listeriosis. Using data from FoodNet from 2004–2009 to estimate the rates of listeriosis by subpopulation, the study's authors predicted that the overall listeriosis incidence rate would increase from 0.25 per 100,000 in 2010 to 0.32 per 100,000 in 2030. When looking at the specific vulnerable population of pregnant women, that number jumps to 4.0 to 4.4 per 100,000 women in the same time span.



To place that number in another context, the authors of the report estimated it would require a 48% reduction in exposure or infectivity to *L. monocytogenes* in the overall US population (or 89% for people >70 years old) to achieve the Healthy People 2020 goal of a one-third reduction rate of listeriosis.

The review, authored by an international expert panel commissioned by the American Frozen Food Institute (AFFI), was conducted to develop a scientific basis and rationale for regulatory policies governing *L. monocytogenes*. Currently, the “zero-tolerance” approach by FDA is challenged by many within the frozen food industry who do not believe it is the best approach to mitigating or preventing the presence of the pathogen, particularly in

## Frozen food facilities inherently present optimal harborage environments for *Listeria* growth.

— SANJAY GUMMALLA, PHD  
American Frozen Food Institute

low-risk foods, given the impossibility of completely eliminating the pathogen in RTE foods, including frozen foods.

Martin Wiedmann, PhD, the Gellert Family Professor in Food Safety in the department of food science at the College of Agricultural and Life Sciences at Cornell University in Ithaca, N.Y., an author of the report, emphasized that “total elimination” of *L. monocytogenes* is impossible. “There always is a residual risk of contamination even if all food safety systems work according to plan and regulation,” he says. As such, the report advances the argument and provides a number of recommendations on a risk-based approach to mitigating and preventing *L. monocytogenes* in low-risk foods based on a scientific and rational approach.

Dr. Wiedmann emphasized, however, that in frozen food, the vast majority of food safety issues are due to improperly designed or inconsistently or incorrectly implemented food safety systems. As such, food processors and manufacturers can and do need to have a good food safety system in place to prevent and mitigate as much as possible the potential of selling contaminated products to consumers.

For food processors and manufacturers of frozen food products, the first step is recognizing the prevalence of *L. monocytogenes* and understanding how this pathogen can be introduced into frozen food products.

### A Ubiquitous and Persistent Pathogen

John Butts, PhD, founder and principal of FoodSafetyByDesign, LLC, advisor to Land O’Frost and a member of the *Food Quality & Safety* Editorial Advisory Board, underscored that food processors

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really need to understand the risks of the problem. “Just because it’s frozen doesn’t mean the organism isn’t present,” he says. He also emphasized the persistent nature of the pathogen, citing an experience in a meat plant in which *L. monocytogenes* contaminated a product 12 years after the same pathogen had resulted in the first fatality from a contaminated turkey frank.

Dr. Wiedmann detailed two primary ways pathogens can be introduced into frozen foods. The first is through the raw material if it does not go through a “kill step,” such as blanching, to inactivate the pathogen in vegetables and fruit. The second is through environmental exposure at the processing facility, which, he said, can lead to contamination of products after the “kill step” or heat treatment.

Drilling a bit deeper, Sanjay Gummalla, PhD, senior vice president of scientific affairs at the AFFI, emphasized the risk of repeated entry of *L. monocytogenes* as raw produce comes from fields into facilities, allowing for the potential spread within the production environment due to movement of personnel and vehicular traffic. “Frozen food facilities inherently present optimal harborage environments for *Listeria* growth,” he says, emphasizing the need for food manufacturers to continually address ways to prevent and limit the pathogen by improving sanitation practices, environmental monitoring programs, and investments in hygienically designed equipment and facility infrastructure. He underscores, however, the fact that food can still be contaminated in the post-lethality environment, making it imperative that facilities establish and implement good manufacturing practices.

## Environmental Monitoring

Dr. Wiedmann also stresses that a key component of a well-designed and implemented food safety system is effective environmental monitoring and “seek and destroy” programs, as well as effective root cause analysis for every time a problem is detected. He emphasized the need to verify consistent implementation of validated safety practices, which means ensuring that these practices are followed consistently day in and day out.

Dr. Butts, who developed the seek and destroy process in the early 1990s, says that the process separates verification samples from process control samples. “A positive process control sample is an opportunity to celebrate because the plant has the opportunity to intervene before product or contact surfaces are involved,” he says. “The application of process control sampling helps eliminate “firefighting” and enables preventive and predictive pathogen control.”

Dr. Gummalla also emphasizes the need for kill steps (or lethality steps) to effectively reduce the presence of *L. monocytogenes* in facilities, and the requirement to validate these processes as mandated by the Food Safety Modernization Act.

The need for environmental monitoring accompanied by verification programs as key components of a food safety plan was recently discussed and highlighted in an article published in the *Journal of Food Protection*, in which investigators surveyed food safety professionals working in frozen food manufacturing facilities. The survey found that floors, walls, and drains were the major areas of reported concerns in facilities for finding *Listeria*-positive results, and that most food safety

**In frozen food, the vast majority of food safety issues are due to improperly designed or inconsistently or incorrectly implemented food safety systems.**

programs within the facilities surveyed focused their attention on identifying the presence of *Listeria* in the processing environment and mitigating product contamination while few focused on testing active raw material and finished products for *Listeria*. Along with environmental monitoring, the survey also reported the need by industry to improve and develop verification programs to reduce the prevalence of *L. monocytogenes* in environments in which frozen food products are processed.

To help food processors and manufacturers achieve these goals, AFFI developed ways to assist companies to validate their lethality processes, particularly for frozen foods. For example, Dr. Gummalla points to research that established a correlation of key time and temperature parameters with significant log reduction of *L. monocytogenes* when blanching frozen vegetables. “Blanching was originally intended to be a way to stabilize the quality of the raw materials prior to freezing, but appropriate time and temperature treatment can also serve as an effective anti-microbial step,” he says.

He cites this and other research at AFFI that is available to help food manufacturers develop and implement food safety practices for their operations. Found on its Food Safety Zone website at [affifoodsafety.org](http://affifoodsafety.org), resources and downloadable tools developed by food safety professionals for food safety professionals offer manufacturers an easy way to search, access, and incorporate food safety practices. The site also includes a *Listeria* Control Program



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with more than 100 recommendations to help prevent and control *L. monocytogenes*.

John Rusiniak, vice president of quality and product safety at Lakeside Foods, Inc., in New Richmond, Wisc., reiterates the importance of seek-and-destroy principles as a key best practice for mitigating pathogen contamination. “We employ aggressive environmental monitoring and testing practices based on pathogen seek-and-destroy principles, supported by focused corrective actions when needed,” he says.

That said, Rusiniak, who is a member of AFFI’s Scientific and Regulatory Affairs Committee, underscored the idea that the challenge faced by frozen food manufacturers to ensure safe food products is the same for all food manufacturers and is based on the essential principle of “Safe Food Always.”

“How we get there differs in terms of managing the four Ms: methods, materials, machines, and manpower,” he says. “I would also add a fifth M for “money,” because food safety only happens with commitment during the budgeting process to financially support all aspects of food safety.”

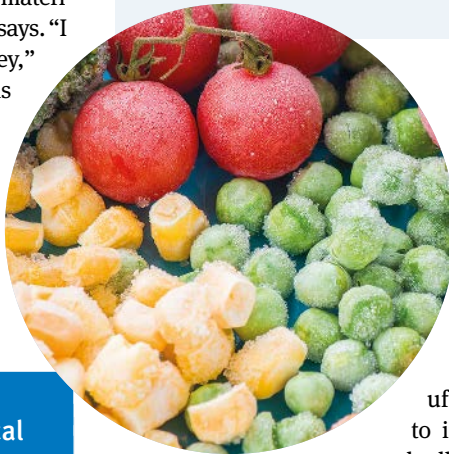
### Food Safety Culture

Basically, what Rusiniak is describing is the need for food man-

### Consumer Education

- Use simple, practical labelling instructions on products.
- Effective and consistent science-based education of consumers and healthcare workers on avoiding high-risk foods for at-risk populations and helping people to select lower risk food options, which, along with making wise food choices, includes education on handling and preparing food safely.
- Frozen foods labeled with cooking instructions, in general, should be considered as not-read-to-eat (NRTE) foods with instructions on the need to be cooked prior to consumption.

Source: Food Control.  
Published October 13, 2020.  
DOI: 10.1016/j.foodcont.2020.107601.



ufacturers to invest in and adhere to a food safety culture.

“The bottom line is that manufacturers must build a food safety culture, which boils down to awareness, education, and commitment,” he says.

Dr. Wiedmann also stresses the need for food processors to take seriously the risk of pathogen contamination of their frozen food products and not adopt a “we never had a problem so everything must be fine” attitude. “There is a need for continuous improvement and regular re-assessment of food safety systems,” he says, citing, for example, the need to continually monitor sanitation procedures. “Often, problems can be traced back to sanitation procedures that do not include sufficient disassembly before cleaning and sanitation, which is essential to make sure

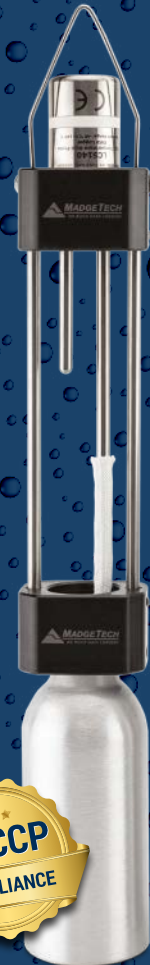
(Continued on p. 40)

### Determining a Cultural Maturity: Three Hierarchical Levels

- Level 1: Organizational climate is the outermost, visible layer observed and verified during audits and inspections.
- Level 2: Organizational climate includes the organization’s espoused values and guides employees’ attitudes and behavior toward authority, regulatory, and market standards compliance.
- Level 3: Organization’s core culture reflects the invisible and assumed core values of what the organization is about.

Source: Comprehensive Reviews in Food Science and Food Safety.  
Published April 9, 2020.  
DOI: 10.1111-1541-4337.12548.

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# The Big Cheese

Sargento Foods wins the 2020 *Food Quality & Safety Award*

BY LORI VALIGRA

An investment in technology and a strong culture that promotes food safety and quality distinguish Wisconsin-based cheese company Sargento Foods Inc. from the crowd. The family-owned and operated company was recently named winner of the prestigious 2020 *Food Quality & Safety Award*.

The award, presented annually by *Food Quality & Safety* magazine, honors the dedication and achievement of an organization that makes significant contributions to uphold the highest food standards supported by quantifiable results. This year, our panel of judges, composed of food quality and safety experts, determined that Sargento Foods demonstrated a comprehensive food safety and quality management program that included a robust focus on technology and training.

Founded in 1953 and headquartered in Plymouth, Wisc., Sargento Foods employs nearly 2,000 people and has taken in \$1.4 billion in net sales. The company's business philosophy began with its founder, Lenoard A. Gentine. Sargento successfully introduced America to sliced and shredded pre-packaged natural cheese, says Portia Young, the company's director of corporate public relations. He believed in treating people like family—not only employees, but also the company's consumers, business partners, and neighbors in the community; this philosophy forms the foundation of the company's commitment to food safety and quality and demonstrates its history of upholding high standards and making investments for the long term, she says.

Two highlights of the company's recent investments are a multimillion-dollar enterprise resource program (ERP), completed in 2018, and a central microbiology laboratory expansion, completed last year. The lab will also include a new software that should be completed in the first half of 2021. The company, which is one of the largest cheese companies in the United States, also has invested in ongoing employee training at all levels, from the production line through management. One of the company's 20 principles that comprise the corporate culture is career and personal development, which is why training and continuing education are investments it willingly makes.

Vijay Krishna, Sargento Foods' vice president of food safety and quality, says that the keys to mitigating risk and improving and maintaining top-notch products lie in the company's culture, its employees, and its processes. "I think what makes us special is our ability to continually innovate and invest in the area of food safety and quality. This is not just something we started doing in the past few years; our values as a company keep us firmly on the side of putting people first. Our quality systems protect the integrity of our products, not just because it's the right thing to do, but because that's what anyone would do for their own family."

With more than 1.1 million square feet of factory space across three plants, the company creates approximately 300 million pounds of sliced, grated, string, stick, and custom cheese products per year for the consumer and food service industry markets. The company also includes a technology center in Elkhart Lake, Wisc., and is run by third-generation CEO Louie Gentine II and third-generation executive vice president of operations Mike McEvoy.



## Bridging the Digital Divide

The ERP conversion was one of many significant technology upgrades in the company's 67-year history. Adopting a digital system has made it easier for the Sargento team to pull relevant information and data together to help them make the right decisions at the right time when it comes to food safety and quality.

Krishna says the move to the SAP platform was a major endeavor for the organization, and it took a while for employees to adapt and learn the new system. But, at this point, he says the company is exceeding its expectations for quality using the system. "The philosophy is, 'How can we be predictive and find or detect problems before they become problems?'" he says. That's why the company is investing ample time and financial resources in food safety and quality initiatives, he adds.

About a year ago, the company expanded the size of its corporate microbiology laboratory so it could consolidate testing in one location. The company also invested in a laboratory information management system to further enhance data integrity for the micro lab.

(Continued on p. 26)





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Another multi-million-dollar investment across all Sargento Foods facilities enhanced the separation between high care and low care manufacturing zones. High care areas are where the cheese is exposed in some way or when it is converted, for example, from a block of cheese into slices.

The company typically purchases 40-pound blocks of cheese, converts them into different shapes, and then packages them. It works closely with suppliers to provide the high-quality cheeses when it comes to taste, texture, and freshness. A set of Wisconsin-licensed cheese graders sit on the quality team, professionals unique to the state, who assess inbound cheese for key attributes such as color, flavor, pH level, and appearance. They also ensure that the cheese has the right knit or body to withstand the conversion process. When the cheese arrives, it often has secondary packaging that has to be removed. It is then taken to a room where it can be shredded, sliced, or converted into sticks. The highest

opportunity for microbial, physical, or chemical cross-contamination occurs when the cheese doesn't have packaging protection, so conversion and packaging are performed in the high-care areas. "We have to make sure we have the right protocols in place to protect the product at all times during the entire manufacturing process," Krishna says.

### Food Safety Plans

Sargento Foods has established several distinct food safety plans to ensure that biological, physical, chemical, and radiological issues are controlled and that the products it produces are safe and in accord with the Food Safety Modernization Act, says Young. The company's food safety plans are based on the Codex Alimentarius principles of food hygiene established by the World Health Organization and the United Nations Food and Agriculture Organization in 1963.

Sargento Foods also has comprehensive preventive programs in place, including (but not limited to) environmental monitoring, pest control, preventive maintenance, sanitation, allergen control, food safety and quality training, supply chain control, and recall.

When it comes to pest control, for example, Jennifer Weber the company's quality systems manager, says that Sargento Foods conducts a shadow audit with an employee who makes sure that everything is checked by the third-party agent. The company randomly checks pest traps by placing a business card inside them to make sure the pest-control operator is actually checking every trap when he or she is on site.

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The plans have helped lead to improved Global Safe Food Initiative audit ratings by the BRC in 2020. “In 2020, all of our manufacturing facilities received an ‘AA’ BRC rating,” says Kerry Kremer, the company’s senior vice president of manufacturing and engineering. The “AA” is the highest BRC rating for a planned audit.

Krishna says that the company’s food safety plans are robust and comprehensive. “It’s a dynamic document, which means we continuously pressure test it against new risks that come up, and we do an audit against that plan,” he says.

The company shares the audit across the organization and shares important information with its suppliers. It has a program called “Audit Ready All Year” so that employees and factories are ready for an audit at any time. Protocols for managing the food safety plans also are in place. A cross-functional team at the plant level meets at least once a month to discuss any issues and corrective measures. Also, a corporate-level committee, which Krishna, Kremer, and others sit on, reviews food safety and quality initiatives and investments at least on a monthly basis. “I think we have a great check-and-balance. [We] make sure ... our plan is doing what it’s designed to do, which is to protect the food, protect the brand, and exceed stakeholder expectations,” Krishna says.

He adds that the company works on a lot of relationship building and strategic partnerships with its suppliers. “Obviously, we do an audit with them on product formulation and specifications, but what might separate us from other companies is that we have a personal relationship with many of our suppliers. We’ll share information that we’ve discovered because we do not believe food safety is a competitive advantage. We rise together as an industry and the more best practices we can share, the better off we will be,” he says.

### Employee Training

Training is another important aspect for food safety at Sargento Foods, says Krishna. He says the company spends a lot of time and energy to build the right skill sets and technical awareness across the organization. “When you work in food safety and quality you have to work collaboratively with other groups,” he says. “One of the things you need to do is be able to influence groups.”

Weber says the company has been using the Alchemy learning management system geared toward food and employee safety for a



number of years. More recently, it incorporated that software into its SAP base learning management system. “That really helped enhance our training for our employees,” says Weber. “We have a one-stop shop where they can go into something we call ‘My Learning,’ and all their training is in that one spot.”

Weber says the training approach also enhances Sargento Foods’ reporting capabilities so that the company can track what courses employees have taken. “We really worked on tailoring our training to specific roles and responsibilities in the organization,” she says. In the past, the company had more PowerPoint-based training and offered courses less frequently than it does now. The combined Alchemy and SAP education platform lets it offer more micro-learning options so it can focus in on a specific course; for example, process technicians would receive general food safety refresher training but also very specific training on critical control

## The philosophy is, “How can we be predictive and find or detect problems before they become problems?”

—VIJAY KRISHNA, *Sargento Foods Inc.*

points, preventive controls, and their work area. “Providing this more detailed training to the employees to make the right decisions and choices really helps enhance our safety,” says Weber. While there is an area with computers at the company, the pandemic has caused more e-learning than is typical. A few of the sessions are more hands-on or classroom-type sessions.

Beyond the more basic training, Kremer says the company is in its third year of providing Six Sigma Yellow Belt continuous improvement training to employees, which she says helps provide some foundational understanding of tools for continuous improvement. “It really helps with new skills within our employee base,” she adds. “It’s about the engagement and involvement of our workforce.” Weber says that the programs help Sargento Foods to better track who has received training and who still needs it. Since 2016, the company has offered additional training through a third party on preventive controls, which is based on the company’s food safety plans.

Krishna says there is always room for improvement, and the company plans to continue to invest in food quality and safety technology and education, as it has done since 1953. “Excellence in food safety and quality isn’t a destination,” he says. “It’s a journey.”

We couldn’t agree more. ■

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# Safety & Sanitation

ENVIRONMENTAL MONITORING



## Bridging Environmental Monitoring Program Results to Sanitation Practices

Part 2: Sanitation recommendations after receiving an OOS microbiological result

BY VIRGINIA DEIBEL, PHD, AND KARA BALDUS, BS, MBA

**Editors' note:** This is part 2 of a three-part series on environmental monitoring. Part 1, which explored the first steps in implementing a cleaning/sanitation process, was published in the August/September 2020 issue of FQ&S, and part 3, which will cover procedures for use during extenuating circumstances, will publish in the February/March 2021 issue.

**I**n Part 1 of this three-part series, we discussed the basics of sanitation, soil, and chemical identification, in addition to basic procedures and applications for routine cleaning and sanitation. In this article, we will discuss root cause analysis and intensified cleaning and sanitation activities to perform after receiving an out-of-specification (OOS)

microbiological result during routine environmental monitoring.

Let's begin by stating that OOS results are an expected, albeit perhaps not welcome, outcome of a robust microbiological environmental monitoring program (EMP). Usually, we find that cleaning and sanitation procedures are a common scapegoat, if you will, for an OOS. While this may be part of the story, we have found that OOS results signify that the EMP is working as intended, meaning that the results will detect whether there is a gap or drift between procedures as they are written versus what is occurring on the plant floor; if the written procedures do not address circumstances that lead to cross-contamination; or if there is a situation festering that, if not addressed, could lead to a major production disturbance. Taken together, OOS results are a shot over the bow and encourage bridging the food safety and sanitation departments in performing augmented procedures.

So, what do we mean when we say augmented? Let's start by giving an example. A company is enjoying an increase in sales and the plant is producing 30% more product, which undergoes a thermal lethality step. To meet the production demands, the second shift is running late and encroaching into nightly sanitation time. Months into this schedule, trending of the coliform counts shows the quality team increasing counts on equipment during the second shift. Two weeks later the increased counts are then noted during first shift and then at pre-op, where <10 cfu/sponge is the specification. Microbial analysis on retained product identifies swelling packages before the end of shelf life, and coliform counts are well above specification.

The quality manager takes five 360° vector sponges surrounding each of the equipment sites with OOS coliform counts and identifies three pieces of equipment where the vector sponge counts are high. The HACCP team determines that, on the next down day, maintenance will disas-



semble the equipment to the frame. During disassembly, sponges are taken, and there are copious amounts of accumulated product residue tucked deep inside numerous crevices, all with a rank odor. Sanitation performs an intensified cleaning of the area. After sanitation, verification samples are taken and sanitation is determined to be effective. The equipment is then reassembled by maintenance and the equipment sanitized again.

While waiting for results, the sanitation records are reviewed. Records indicated that due to second shift time overruns, the sanitation team does not disassemble the equipment or sanitize all equipment in order to save time. As preventive actions, the sanitation manager shift is changed to overlap with production so she can verbally report activities or issues to the HACCP team in morning meetings. Further, checklists are devised to capture each step in the sanitation standard operating procedures (SSOP), including equipment disassembly, chemical concentrations, and applications on each piece of equipment. Additional sanitation personnel are hired to allow for SSOP adherence.

Let's unpack this scenario. What went right?

1. We'll assume that a risk assessment identified coliforms as a risk for product spoilage.

2. Organisms identified in the risk assessment were added to the EMP, which, as one of its purposes, is a tool to identify gaps in sanitation (or other food safety) programs.

• **Suggestion:** Sampling frequency, timing (first, second, or pre-op shift), sampling sites, zones, and organism selection should be predetermined and based on risk assessment of the facility and product.

3. EMP specifications were set and samples were taken during pre-op, first, and second shift of operations.

• **Suggestion:** Specifications are based on collection of baseline data, which are accumulated over an extended period (i.e., at least six months to account for seasonality) and trended to understand the normal concentrations of microorganisms in that specific manufacturing facility and during each shift (accounting for building age, equipment condition,

products, number of employees). After specifications are set, exceeding their limits results in investigation and corrective actions.

4. The results were trended and noted to increase.

5. Retains were saved and tested for the organism found to be OOS.

6. Vector samples were taken to assess origination and scope of OOS results.

• **Suggestion:** Root-cause analysis should include additional sampling to determine the location of the source, or harborage site, which is often different from the sample site. This is called vector sampling, which includes sampling beyond the OOS point to other locations in the vicinity. Vector samples are those taken in a 360° radius, up to 30 feet from the original OOS site, including the ceiling, walls, and floors. Water droplets from cleaning, air currents, cross-contamination from tools, hoses, utensils, and people are all means of translocation from a harborage site to external locations. Harborage sites are those locations that are difficult to inspect, reach, or clean. In this regard, they are usually not product contact areas (Zone 1); rather, they are areas further removed (Zone 3). They usually have access to water and a food source, typically product build-up. Harborage sites allow bacteria to accumulate, grow, and then excrete back out into the environment. Harborage sites can be present for weeks, months, or even years. Eventually, the bacterial concentrations will build to a point high enough that they will be detected on nearby equipment or product.

7. The HACCP team met to discuss the EMP results and determine next steps.

8. Maintenance disassembled the equipment to the frame and, *before any cleaning of the equipment*, coliform samples were taken and a visual inspection conducted.

9. Sanitation was present during the disassembly process and conducted an intensified sanitation procedure. They were able to witness where in the equipment the soils were accumulating. An intensified cleaning procedure (deep clean) includes a number of steps that are expanded from routine cleaning. These include:

• **Equipment disassembly:** Do this to the framework or as close as possible.

• **Manual scrubbing:** Although this is the hardest method to control and monitor, this may be the most effective way to clean in areas that are difficult to access. Two rounds of detergent application, which involves the use of alternative chemicals (i.e., apply chlorinated alkaline first, rinse, then apply alkaline) or the same cleaning chemicals but in higher concentrations than used in the routine process, should be conducted. These stronger chemistries should be used with caution and only on an intermittent basis due to potential damage to the equipment or environment and strict enforcement of personal protection equipment. Consultation with a chemical supplier is suggested prior to conducting any type of change. The best practice for small parts removed during disassembly is using two buckets: one bucket with detergent and one with sanitizing solution. Small parts may then be left in the sanitizing solution until retrieval for reassembly. Use non-scouring pads, single time only.

• **Sanitizer application:** After rinsing detergent, apply an environmental strength (the high end of a chemical supplier's recommended parts-per-million) sanitizer. Rinse and apply a second round of sanitizer, which may be a different compound than the first. Rinse food contact surfaces. At this juncture, swab equipment, assemble, and apply a third round of sanitizer (food contact concentrations for Zone 1 and 2 and environmental concentrations for Zone 3). Although sanitizers are effective across a broad spectrum of microorganisms and have proven efficacy per EPA standards, certain sanitizers have greater efficacy against specific types of organisms than others. For example, chlorine dioxide is extremely effective against Gram-negative and Gram-positive bacteria, but weak against yeasts. A facility applying chlorine dioxide may experience yeast contamination in the environment, meriting a switch to peroxyacetic acid, which has efficacy against yeasts. Chemical substitution should

(Continued on p. 40)



## Employee Hygiene During COVID-19

How to develop and manage health measures to protect your workforce | BY PEG RAY

**A**t the beginning of 2020, how many operations in the food and beverage supply chain included employee health measures as part of their business continuity planning? Based on the number of employees who fell ill due to the pandemic and the ripple effect this had across the industry's workforce, not enough. This has forced the entire supply chain to take a focused, proactive look at how to effectively protect the workforce against contracting and spreading the disease. Implementing protective measures to maintain a healthy workforce is a key component of any business continuity plan, especially during a pandemic.

Where should development of a plan that prioritizes employee health begin? First, gather the facts about how the virus

spreads from person to person. Second, choose and develop health mitigation measures required for workforce protection. And third, manage these strategies so that they will remain effective.

### Understand How the Virus Spreads

The scientific community, as reported through WHO, CDC, and other agencies, has identified numerous facts about SARS-CoV-2. This information includes how the virus is transmitted, how long its incubation period is, what symptoms it causes, and when an infected person is contagious.

The primary mode of transmission is through close contact, which is defined as being within six feet of an infectious individual for 15 consecutive or cumula-

tive minutes. Respiratory droplets and smaller particles that contain the virus are expelled from an infected person through breathing, talking, sneezing, or coughing into the air around the infected person. Any uninfected person in close contact may then inhale enough of the virus to also become infected.

The secondary mode of transmission is through contact transfer, such as shaking the hand of an infected person. Contact transfer can also include touching a surface where the virus is viable, as the coronavirus can remain viable on various types of surfaces for between 24 and 72 hours. An infected person can expel the virus onto these surfaces through respiratory actions or transfer it from a hand used to cover a cough or sneeze. An uninfected person who touches a surface with the virus on it and then touches their mouth, nose, or eyes could potentially inhale enough of the virus to become infected.

Also critical in understanding how to prevent transmission of the virus is its incubation period of five days, with a range of two to 14 days prior to the onset of symptoms. The virus is believed to be most infectious in the 24 to 48 hours before an individual experiences symptoms, and this may last for up to 10 days after symptoms subside. Some individuals remain asymptomatic for the entire time they are infected with the virus, which means they can infect others without ever showing any symptoms of the illness themselves.

Knowing the facts makes it easier to tailor plans and mitigate the transmission risks among workers in facility operations.

### Develop Health Mitigation Measures to Protect the Workforce

The first opportunity to control risk is at the entrance to the facility. Screening employees, visitors, and contractors prior to site entry for evidence of fever and illness symptoms will stop symptomatic sick and infectious people from entering the site. Another beneficial tool is a health questionnaire that asks about symptoms and exposure to people who have tested positive.

The pre-entry screening process will eliminate site access to those individuals who represent a clear risk for disease transmission. However, these steps do



not eliminate those who are carrying the virus but are not yet showing symptoms or those who will remain asymptomatic. This scenario requires additional measures to protect the workforce against contracting the disease while at work.

Because the virus is expelled into the air, it is logical to implement measures to contain respiratory droplets. This is best done by requiring all employees and others who are onsite to wear face masks. Unless they are medical grade, face masks do not contain all respiratory droplets, nor are they meant to protect the wearer. Wearing a mask will help protect others from someone who is shedding the virus. Some individuals may be unable to wear face masks due to health conditions; consider having them use full face shields instead to help contain their respiratory droplets.

Not all respiratory droplets will be contained by a mask or face shield, so the implementation of six feet or two meters of distance between employees is another mitigation measure. The crisis management team should carefully evaluate the site to determine where people work in close contact with one another and how distancing can be managed. In manufacturing, slowing line speed may allow for fewer employees on lines to maintain distancing. When this is not possible, construction of food-safe, cleanable barriers between employees might be the answer. Marking traffic patterns in the site to promote social distancing is another strategy. Employing the use of technology for clocking in and out can eliminate congregation and unnecessary contact with the time clock. Managing employee density in break rooms, restrooms, laboratories, and elsewhere is another mitigation measure to be employed. Using staggered shift times and break times will also help prevent employees from being in close contact with one another.

The combination of wearing masks and social distancing helps mitigate the risk of airborne transfer between members of the workforce. The choices the crisis management team makes will need to be tailored to each specific operation.

Next, consider the contact transfer risk. Human hands have long been known as a vector for the introduction of pathogens to food and food contact surfaces.

Therefore, an emphasis on effective hand-washing should already be in place to maintain food safety, preventing the transfer of pathogens from hands into food. Though coronavirus has not been identified as transmissible through food, our hands can transfer the virus to ourselves

## Maintaining frequent and transparent communication will keep everyone in the facility informed of the steps taken to keep them healthy and the business operational

through contact with our face, mouth, nose, or eyes. A thorough, 20-second wash with soap and water will not only help ensure food safety, but also help decrease the transfer of coronavirus.

Operations can further mitigate the risk of contact transfer by identifying and implementing a plan to frequently disinfect all touchpoints in the worksite. The chemical used for disinfection should be labeled as effective to destroy the coronavirus, which can be verified by checking the label or the EPA List N.

Other strategies for managing contact transfer include the assignment of pens, forklifts, and other tools to individuals for the duration of the workday, followed by disinfection at the end of the day. Kick plates can be installed on doors to eliminate the use of doorknobs. Some internal doors can be left open, if practical. The crisis management team can identify other opportunities to manage the touchpoints in the facility.

### Manage Effective Mitigation Strategies

Once strategies have been selected, they must be properly managed to be effective. The order of donning PPE like face masks, face shields, gloves, and any other gear the team has chosen to accompany hairnets, aprons, and outer garments already in place is important. Check CDC guidelines for donning and doffing instructions.

Control of face masks and any reusable gear provided to employees is crucial. Any worn gear must be considered contaminated, as you don't know who may be asymptomatic. Disposable masks must be discarded at the site in clearly labeled and lined containers, designated for this purpose only. Personnel who remove this trash need to be protected and instructed on how to handle this debris. Reusable face masks must be held captive at the plant to undergo defined washing and disinfection processes prior to reuse. Allowing employees to provide and manage their own reusable face masks means that the site has lost control of this protective measure.

When an employee reports that he or she is sick and/or has tested positive for the virus, steps are needed to protect the remaining workforce. This includes contact tracing for those who were in proximity with the infected individual, quarantining and disinfecting the worksite, and setting up symptom-based, time-based, or test-based strategies for the affected individual to return to work. These strategies have been defined by the CDC.

Once health mitigation measures are established, training everyone on what to do and showing them why it is important to maintain their health will ensure understanding and buy-in. All employees must be fully committed to the program for their own health and for the health of those with whom they work.

The effectiveness of any health mitigation measures implemented in an operation relies on management's ability to monitor and enforce the measures for everyone's protection. Maintaining frequent and transparent communication will keep everyone in the facility informed of the steps taken to keep them healthy and the business operational.

There has never been a better time than during the pandemic to develop, implement, and manage such employee health measures. For additional guidance and a standard that can be audited against, AIB International's Pandemic Prepared Certification further defines these and other measures that will help keep your workforce safe and business operational. ■

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# Quality



## The Importance of Halal Foods

Why halal certification matters

BY ALISON DEGUIDE

**A**ccording to the Pew-Templeton Global Religious Futures Project from the Pew Research Center, there are currently more than 1.9 billion Muslims in the world, representing a little less than 25% of the global population. This number has grown steadily over the past 10 years, and

the same survey estimates that by 2030, there will be more than 2.2 billion Muslims worldwide.

Even more impressive is the sheer financial power of this demographic. The State of the Global Islamic Economy 2019/20 Report by DinarStandard reports that Muslim spending in the areas of food,

pharmaceuticals, and lifestyle made up a total of US\$2.2 trillion in 2018, with estimates that this number will grow to US\$3.2 trillion in 2024. The report also anticipates exponential growth in the halal food sector, with spending jumping from approximately US\$1.37 trillion in 2018 to US\$1.97 trillion in 2024. This means that by producing halal-certified products, a manufacturer can appeal to more consumers, especially in countries with predominantly Muslim populations.

Despite this exponential growth, the global economy is still struggling to catch up. There is a staggering lack of access to halal foods, whether that be on grocery store shelves or in college campus dining halls. In fact, in the joint National Campus Dining Services Survey by the Islamic Food and Nutrition Council of America (IFANCA) and the Muslim Students Association National, 64% of respondents reported that the lack of halal options was a factor in their decision not to use campus dining services. If we apply this logic to other foodservice venues, it becomes clear that the Muslim population seeking halal options is critically underserved in the United States.

### What Is Halal?

“Halal” is an Arabic word meaning “permitted” or “allowed.” It describes food that is acceptable for consumption according to Islam, and it is an obligation—not a choice—for Muslims. The term “haram,” on the other hand, denotes foods that are forbidden, such as pork products, alcoholic beverages, the meat of carnivorous animals (such as birds of prey), and blood.

Although the aforementioned items are expressly forbidden in Islam, they do not make up the entire list of haram foods. Other foods may not be permissible, depending on their origin or how they were produced. For example, meat such as beef and poultry can only be considered halal if slaughtered by a Muslim in accordance with the following rules:

1. The animal must not be dead before the time of slaughter.
2. The animal must die by bleeding, with one cut resulting in loss of life for the animal.
3. God’s name must be invoked at the time the animal is cut.



It is impossible to determine simply by looking at an item whether halal requirements such as those listed above have been met, which is where the need for halal certification arises.

### Why Is Halal Certification Necessary?

The goal of halal certification is to make it easier for Muslim consumers to know which foods are halal or haram and diminish confusion surrounding questionable items. It is impossible to compile a full list of permissible ingredients without knowing the source of an ingredient or a company's manufacturing process, which is where halal certification comes in.

Saeed Hayek, PhD, a food scientist and quality manager at IFANCA, notes that some of the ingredients that impact the halal status of a food, depending on where they were sourced, include gelatin, glycerin, mono- and diglycerides, enzymes, vitamins, amino acids, fatty acids, natural flavors, and colorings. "Most ... food products will contain at least one ingredient from this list," says Dr. Hayek. "These ingredients can be sourced from [animal-based] materials and, thus, bring ... doubt to the halal status of the product. Except for gelatin, other ingredients can also be sourced from [plant-based] and/or synthetic materials, which would be suitable to halal."

For gelatin to be considered halal, it must come from cows slaughtered according to halal requirements and, according to Dr. Hayek, "must be traced from the cow to the final product to avoid any possible [cross-contamination] throughout the production chain." Cross-contamination is a substantial concern when it comes to halal certification, especially when a facility produces both halal and haram products. Halal certifiers are responsible for acting on behalf of the consumer by conducting facility audits to ensure that no cross-contamination has occurred.

Dr. Hayek notes that, even if a company uses only ingredients that are low risk, such as plant-, mineral-, or petroleum-based ingredients, there can still be issues with the manufacturing process. A facility that processes haram materials or uses haram cleaning chemicals, processing aids, lubricants, or packaging materials cannot be considered halal. For

example, if a company uses the fat of cows or pigs to lubricate its food machinery, the product will not be halal even if all the individual product ingredients are halal.

As supply chains become more and more globalized each day, ingredient tracing becomes even more complicated. When all the materials in a product came from the same place, food production was simpler. Bread, for example, is no longer made up

**By getting a product certified, a company sends a signal to consumers that it is determined to maintain continuous standards of quality and is open to additional monitoring by external organizations.**

simply of flour, yeast, and water. Now, a loaf can include numerous other ingredients, making it even more difficult to determine whether or not it is halal.

According to Muhammad M. Chaudry, PhD, president and CEO of IFANCA, the task of deciphering all the information about a product's inputs to determine its halal status is too complex for the average consumer. This is where the role of technical organizations as halal certifiers comes in. Without halal certification, the burden falls on consumers to contact a company directly to learn whether or not a product is acceptable for them to eat. Imagine doing that for every item in your grocery cart, and you can see why halal certification is crucial to Muslim well-being.

Halal certification also provides an added layer of quality control, and it can be easily integrated into programs such as Hazard Analysis and Critical Control Points (HACCP), quality management system ISO 9000, and good manufacturing practices (GMPs).

It is also the responsibility of these technical organizations to act in tandem with national governments to determine the halal status of local products for export so that a halal-certified product in one country is certified in another. Anything

that provides added peace of mind in our turbulent world, or simplifies the import/export process, represents a path to gaining more consumers, which makes halal certification good for business in more ways than one.

### How Does the Certification Process Work?

Obtaining halal certification requires equal participation from both a company and the organization certifying it. Though we cannot and do not speak for all halal-certifying organizations, the following is an overview of IFANCA's process:

1. A business requests a halal certificate by submitting an application for halal certification.
2. The completed application and all information are evaluated against halal requirements by food scientists and process experts.
3. An agreement is signed by both parties, spelling out the obligations of each.
4. A facility audit is conducted to evaluate the process, associated services, and personnel competence with halal production.

5. A decision on halal certification is made by the halal certification committee. If the product qualifies for halal certification, a halal certificate is issued.

Once the entire process has been completed, the company can use the Crescent-M service mark on products that have officially been certified halal by IFANCA. Each certificate is valid for one to three years; however, the plant must be re-audited each year. This allows IFANCA to make sure that a company is maintaining the same quality year after year and that neither the manufacturing standards nor a product's ingredients have changed in a way that renders the product impermissible.

Halal certification represents an important step forward in serving the Muslim market. By getting a product certified, a company sends a signal to consumers that it is determined to maintain continuous standards of quality and is open to additional monitoring by external organizations. As the number of adherents to Islam continues to grow, so too will the demand for halal products. ■

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# In The Lab



## Organic Pathogen Reduction for Spices

Consumer demands for foods that are fresher, safer, and healthier continue to challenge spice manufacturers and processors to find innovative food safety technologies

BY MATTHEW YOU

Spices are important food commodities and are growing in consumption. A 2017 USDA report showed a more than 260% increase in spice consumption by U.S. consumers over an 18-year period.

Spices belong to a group of low-moisture foods that are often assumed to be low risk in terms of food safety; however, these foods can be contaminated with harmful pathogens such as *Salmonella*. Within the 40-month period between January 2007 and April 2010, FDA reported 457 laboratory-confirmed illnesses, 68 hospitaliza-

tions, and one death in the United States caused by pathogen-contaminated spices. While the safety of spices is of the utmost concern to the spices industry, spice-associated recalls and outbreaks continue to make headlines.

*Salmonella* is the most common bacterial pathogen associated with spices. In a 2017 FDA study, investigators collected spice samples from retail establishments and from the import entry point to the U.S. to test for *Salmonella* prevalence. The study showed that the pathogen's prevalence in shipments at import was signifi-

cantly higher than in retail spices—6.6% and 0.25%, respectively.

These findings support the industry guidance by the American Spice Trade Association (ASTA) to apply a pathogen reduction treatment to products prior to their placement in retail stores. The study holds an even greater significance for the U.S., as most spices consumed here are imported. So, whether a spice is imported or grown domestically, it is crucial for the spice industry to continue to focus on food safety to protect consumers.

Once the Food Safety Modernization Act was signed into law, the spice industry changed course to focus on preventive-based controls to ensure food safety. Spice companies are required to conduct a hazard analysis, identify hazards that are reasonably likely to occur, and establish preventive controls for such hazards. The rules apply to both domestically produced and imported food. Many spice companies have demonstrated good corporate citizenship by implementing preventive food safety measures.

Now, more than ever, food safety is top of mind for today's consumers. According to an international consumer study from the Mars Global Food Safety Center (GFSC), more than half of respondents identified food safety as a top-three global issue. Consumers also indicated that the issue has been exacerbated by the current global COVID-19 pandemic. Consumer demands for foods that are fresher, safer, and healthier continue to challenge spice manufacturers and processors to find more innovative food safety technologies.

### Conventional Pathogen Reduction Technologies

Spices are primarily used for flavoring and coloring food. Therefore, it is essential to preserve the natural sensory and nutritional qualities of spices while achieving food safety. Currently, the most common pathogen reduction processes are:

- Irradiation;
- Fumigation with ethylene oxide (EtO); and
- Steam treatment.

Irradiation works by exposing food to radiant energy such as gamma rays and X-rays. EtO is a flammable, colorless gas that is widely used for sterilization, mainly for medical equipment. Steam treatment



exposes food to very high temperatures for a predetermined time period.

A study published in the *Journal of Food Science* in 2017 assessed these three methods to determine if spice quality was affected (2017;82:1208–1215). After an analytical assessment, the results showed that all three processing technologies negatively impacted the quality and sensory integrity of spices. Irradiation affected the color of onion powder and resulted in the nearly complete loss of measured volatile compounds. EtO processing altered the visual and odor qualities of cumin seeds. Steam processing of black peppercorn resulted in a change in odor, supported by altered levels of volatiles. Steam processing also created visual differences for cumin seed.

In addition to changes in food quality, there are other factors to consider when using conventional technologies. The global pandemic has triggered a sharp increase in demand for irradiation and EtO supply for pharmaceutical and medical purposes, which has caused an interrup-

**The global pandemic has triggered a sharp increase in demand for irradiation and EtO supply for pharmaceutical and medical purposes, which has caused an interruption in the supply chain for spices, with a significant delay in microbial reduction treatment.**

tion in the supply chain for spices, with a significant delay in microbial reduction treatment. This trend is expected to continue as the world navigates through the pandemic.

Consumer acceptance of irradiation has been very low, given the general perception that it can pose harm to humans

and the fact that it is not organic. Furthermore, consumers are concerned about the impact of irradiation on taste and nutritional value. FDA requires all irradiated products to be labeled with a “Treated with irradiation. Do not irradiate again” statement. Also, irradiation has limited use, as the U.S. National Organic Program prohibits irradiated ingredients in certified-organic products.

Fumigation with EtO in food processing has been a controversial topic. According to the U.S. Centers for Disease Control and Prevention (CDC), exposure to EtO has been reported in some human and animal studies to be associated with cancers. It is a substance that is banned in Europe and in other countries. In the U.S., public pressure on EtO processing has caused several EtO facilities to shut down, causing further disruption in the supply chain.

Steam processing is considered unsustainable for business operation, as it requires high investment and energy costs. Also, steam processing is difficult to

*(Continued on p. 37)*



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# Manufacturing & Distribution

## Reduce Food Spoilage with Mobile IoT Sensor Systems

How the technology can cut food waste on the road from farm to market

BY RAY ALMGREN



**M**any farms and restaurants are facing financial peril during the current economic climate. The trucking industry has been heavily disrupted as well. With the economy so variable by country, state, and city, no player in the farm-to-market chain can afford losses caused by waste in transit. Here's how the remote, mobile Internet of Things (IoT) can reduce losses in transit and help restaurants get what they need to stay in business.

What's at stake for farmers, restaurants, and truckers? Operators in all three industries are cutting costs and trying to find efficiencies that will allow them to stay in business. In the U.S. House of Representatives, some lawmakers from both parties say small farms need more federal help to cope with the reduction in demand from schools, restaurants, and farmers' markets. Restaurants hit hard in the spring by closures are facing another round of shutdowns in many areas. And in May, Reuters reported that new freight contracts were down 60% to 90% world-

wide, forcing many small trucking firms to compete hard on rates in order to keep their drivers on the road.

### Reducing Food Spoilage with Remote Mobile Cold-Chain Monitoring

Approximately one-third of the world's food is lost or wasted yearly. According to the U.N. Food Program, up to half of temperature-sensitive produce is ruined after harvest, "primarily because of lack of or inadequate access to cold-chain logistics." As produce exports from developing countries increase, and as climate change creates new temperature management challenges for distributors and transport companies, the need for affordable, easy-to-implement cold-chain monitoring technology will keep growing.

Transportation temperature monitoring solutions are already available, thanks to mobile IoT technology. It only takes a few minutes to outfit a reefer trailer with wireless temperature sensors that feed real-time readings to a mobile data gateway.

Trucking company managers can then view a continuous feed of data on their phones, tablets, or computers that shows the temperature inside the reefer at any time, to make sure the cold chain remains in effect.

Managers can also set thresholds for each sensor, based on the correct temperature range for the items in transit, so that they get alerts if the temperature inside the reefer rises or falls outside the acceptable level. These immediate notifications allow managers to reach out to the driver to try to solve the issue or to pull the items if they've been out of the proper temperature range too long, to avoid a costly and damaging recall later.

Transit companies can also, if they choose, allow clients such as restaurant managers or chefs to log in to see data on their incoming shipments, to demonstrate quality control. Aside from tracking real-time temperature data, this cold-chain monitoring technology builds a database of historical sensor readings that managers can review to spot areas where im-



provements are needed to maintain the right temperature. This ability to monitor and continuously improve cold chain compliance—with the data to back it up—gives trucking companies a competitive advantage with clients who need to ship temperature-sensitive food items.

### Protecting Fragile Food Products with Remote Vibration Sensors

Out-of-range temperatures aren't the only threat to produce in transit. Physical shocks caused by rough roads, sudden stops, or lane changes and containers shifting inside the trailer can crush or damage food items. But even an uneventful haul can harm the quality of produce, due to persistent vibrations of lower amplitude in the truck that can change the appearance or taste of foods such as lettuce and berries.

There's a mobile IoT solution for this problem, too: wireless vibration sensors that relay data to a mobile gateway in the

same way that wireless temperature sensors do. Both types of sensors can operate on the same network in a trailer to provide a clearer picture of conditions in transit. As with temperature sensors, vibration sensors can send alerts when vibrations are out of range for optimal produce quality. The historical sensor data can help managers determine which kinds of trailers, routes, and packaging provide the best protection from damaging shocks and vibrations, and which need improvement.

### Tracking Shipments and Total Transit Time with GPS

Timing of deliveries is important for restaurants. It's also important for quality control, as longer transport times increase the likelihood of food waste. Knowing exactly when items will arrive allows chefs to plan menus that maximize available food when it's freshest, to reduce food and financial waste.

When location tracking data is appended to real-time temperature and vibration readings, transport company managers can see where problems with shocks and cold chain compliance happen. That can allow them to address problems on their end or work with farmers to come up with a solution.

### Less Food Waste, More Savings—and a Competitive Advantage

With mobile IoT-enabled cold-chain, vibration, and location data available in real time and in graphs and reports, trucking companies can see and share their metrics for produce quality protection on the road. That proof of quality can help small trucking firms gain a competitive edge, help farmers get more product safely to market, and help restaurants get more value for their food budget. ■

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## Organic Pathogen Reduction for Spices *(Continued from p. 35)*

validate as different steam applications produce varying degrees of efficacy and food quality. As such, the spice industry is actively looking for a more effective and widely available pathogen reduction technology for spices.

### An Organic Pathogen Reduction Process for Spices

Spice manufacturers and processors need a new pathogen reduction process that provides consistent efficacy and food quality. One emerging technology is an organic pasteurization technology called

Neo-Pure. Neo-Pure has been providing validated food safety for nuts, seeds, and grains companies for many years. Today, Neo-Pure-treated food products can be found in many national grocery chains across North America.

Agri-Neo Inc., a Toronto-based food safety technology company, has been working in partnership with key stakeholders in the spice industry to validate Neo-Pure for spices. "Our goal is to provide an organic pathogen reduction process that is effective on different forms and types of spices, and be very cost efficient and easy to operate," said Rob Wong, president of Agri-Neo. "Our unique approach with certified-organic components allows us to achieve the highest food safety standards without compromising the natural taste, aroma, and texture of spices."

The technology provides a validated, up to 5-log (99.999%) reduction of harmful pathogens such as *Salmonella*, *E. coli*, and *Listeria* without compromising nutrition and quality of food. Its process uses a blend of organic acids to eliminate pathogens in a dedicated, continuous processing system. Precisely controlled, it is applied uniformly

to cover all food surfaces, including cracks and crevices, that can harbor pathogens. The treatment is activated to kill pathogens by penetrating the cell walls of the pathogen cell on contact. Afterward, the organic solution biodegrades completely, leaving spices safe and ready to eat.

Neo-Pure is certified-organic to the standards of the U.S. National Organic Program and the Canadian Organic Regime. Because Neo-Pure biodegrades completely, it is approved by FDA, EPA, and Health Canada as a processing aid, which means spice companies do not need to declare its use on food packaging. The process is also certified kosher and halal.

Neo-Pure for spices is expected to launch in the first quarter of 2021. The company is also working on a solution to reduce aflatoxins and pesticide residues in spices. Emerging technologies such as Neo-Pure not only support the spices industry's continued dedication to consumer protection, but also serve as a competitive differentiator for spices companies. ■

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# Food Service & Retail

## The Challenges of Sourcing Food-Safe, Single-Use Gloves

How current glove supply chain problems can affect food safety

BY LYNDA RONALDSON

**T**he global shortage of single-use gloves due to the demands of the coronavirus will continue well into 2021. Malaysia, the leading manufacturer of single-use gloves, is supported by its country's glove manufacturers body, Malaysian Rubber Glove Manufacturers Association (MARGMA), which recently stated that, while glove prices have soared and demand is overwhelming, the industry's supply is fully booked until early 2021.

MARGMA is warning buyers to be vigilant to fraudulent agents and distributors offering what it calls "ridiculous" prices with a promise to cut short delivery time. The shortage is also causing a flood of poor and reject quality gloves to hit the market, causing potential food safety implications.

Single-use gloves should provide the wearer with a barrier protection against food and pathogens, thereby playing an important role in the prevention of cross-contamination. Within the food industry, however, pre-COVID-19 scientific data implicates glove cross-contamination in 16% of all foodborne illness cases in the U.S. and, as more poor quality gloves flood the market, food safety risks will likely increase.

Here are several recommendations to mitigate the current and future food safety and supply chain risks of single-use gloves.

### Ensure Gloves Are Compliant for Food Handling

FDA-compliant food contact gloves must consist of "substances generally recognized as safe for use in food or food packaging." However, letters of compliance and guarantee on the glove submitted for

testing are not necessarily for the glove you have purchased.

There are few controls required for glove manufacturing relating to the reliability and consistency of raw materials, manufacturing processes and factory compliance. In addition, glove manufacturers are able to achieve FDA certification and then alter manufacturing and hygiene practices and raw materials to save costs. Cheap raw materials lower glove strength and durability, increasing the rate of glove failures (ripping), and can contain toxic compounds that can migrate to glove users' skin and food products.

These cost-saving alternatives are more prevalent than ever. Pressure to meet manufacturing demand has also led to the repacking of reject quality gloves, which previously were either disposed of or recycled for raw materials.

Purchase from a reputable supplier with quality systems in place to ensure glove quality consistency and FDA-compliant requirements.

### Purchase with Quality, Not Cost, in Mind

Purchasing decisions made on glove cost alone can threaten food safety programs. As glove suppliers let their customers down, either due to being unprepared for the sudden increase in demand or upselling to other buyers at greater margins, sourcing a quality glove is challenging, yet paramount for food safety.

Several glove types are available for food handling, each with varying degrees of barrier protection. The most commonly used are vinyl gloves due to their cheap price point. Vinyl gloves, however, have

limited durability and rip and puncture easily compared to nitrile, increasing the risk of bacterial and viral cross-contamination. Vinyl gloves are not a food-safe choice.

Price should not be the only determining factor for glove selection; scientifically based food safe selection is essential. Purchase quality nitrile gloves to help protect against pathogen cross-contamination and, with reduced usage, you will not necessarily increase your overall glove costs per month.

### Labor Violations in Glove Manufacturing

Labor rights abuse in disposable glove manufacturing has been regularly reported for many years. With added pressure on glove manufacturers to meet the current increase in demand, reports of labor abuse and exploitation against some of the biggest global manufacturers is making news again.

Because of forced labor concerns, the U.S. banned the import of surgical gloves from two subsidiaries of the world's largest glove manufacturer, as of July 15, 2020. The ban affects about half of the company's sales to the United States, products which will likely be sent to other countries without anti-slavery laws.

Consumers and businesses have the power to change supply chain violations with their purchasing. Ask for firsthand proof and partner with a fully transparent disposable glove supplier to protect your brand.

The current challenges in the glove supply chain have the potential to affect food safety. Sourcing a truly food-compliant glove is challenging but possible. Partnering with an established and trusted supplier will help to mitigate the current glove supply chain challenges mentioned in this article. ■

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## Food Security Programs *(Continued from p. 9)*

creation of the National Bio and Agro-Defense Facility (see “Regulatory Programs that Address U.S. Food Insecurity,” below).

According to a USDA spokesperson, the programs through the 2018 Farm Bill

### Regulatory Programs That Address U.S. Food Insecurity

2018 Farm Bill—This legislation includes three programs to support animal disease prevention and management:

- National Animal Disease Preparedness and Response Program
- National Animal Health Laboratory Network
- National Animal Vaccine and Veterinary Countermeasures Bank

2019 Protecting America’s Food and Agricultural Act—This increases resources directed to U.S. Customs and Borders Protection to help prevent the introduction of pathogens, biological threats, and agricultural goods.

National Bio and Agro-Defense Facility (NBAF)—This facility, which is under development in Kansas, will house diagnostic equipment and possess training capabilities to help protect agriculture, farmers, and the public against emerging, zoonotic, and foreign animal diseases.

to fund animal health programs are aimed at keeping foreign animal diseases out of the US to keep the livestock healthy and protect export markets for U.S. livestock producers. For example, the National Animal Vaccine and Veterinary Countermeasure Bank, the only vaccine bank in the U.S., will allow the stockpiling of animal vaccines and related products for use in case of an outbreak of high-impact animal diseases such as foot-and-mouth disease. “Vaccines are an important part of our strategy to eradicate any incursions of the disease [foot-and-mouth], and they can be a critical tool to allow American farmers and ranchers to get back on their feet more quickly,” said the USDA spokesperson. “While an outbreak would temporarily disrupt international markets, vaccination would allow animals to move through domestic production channels.”

On July 8, 2020, APHIS made an initial purchase of a vaccine for foot-and-mouth disease. “This purchase will significantly enhance the number of vaccine doses already available to the U.S. through the North American Foot and Mouth Disease Vaccine Bank, providing critical support for the U.S. livestock industry,” said the spokesperson.

Going forward, other issues may move toward legislative consideration, given the stresses on the food supply chain and in-

dustry during COVID-19. Becca Jablonski, PhD, assistant professor of food systems extension economics in the department of agriculture and resource economics at Colorado State University in Fort Collins, thinks there will be more discussion about the trade offs in food manufacturing and processing between efficiency and resilience. “We have favored efficient systems in our policies that have led to more consolidation in our food processing and manufacturing sectors in the U.S.,” she says, adding that the policies make sense, given the desire to provide consistent quantity and quality affordable food products.

However, citing major disruptions to the food supply chain with, for example, the closure of meat packing plants during COVID-19 that led to reduced access to products, she thinks more people will be looking at whether policies that support small and mid-sized plants that can pivot more quickly in a time of emergency or disaster make more sense. Important considerations will need to be made about the implications of such policies on product pricing, which, she emphasizes, has major food security implications. “I think what is going to happen now, particularly with a Biden administration, is more discussion around these issues,” she says. ■

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## My Sample Tested Positive ... *(Continued from p. 14)*

positive result may not be confirmed in every subsequent test. The only solution to this possibility is to test multiple samples. If you suspect that potential cross-contact allergens may be particulate in nature, taking multiple samples at the outset is an excellent strategy.

Sample preparation can further contribute to analytical uncertainty, especially with certain types of particulates. For example, whole sesame seeds are difficult to break apart. If laboratories are using blenders to homogenize the sample before sub-sampling and extraction, they may find that the sesame seed remains intact. In that case, the sesame proteins will not be well distributed within the sample.

Every commercial ELISA kit has a stated dynamic range such as 2.5 to 25 ppm in the earlier example. The kits should come supplied with a standard curve and one of those standards should be the lowest concentration from the dynamic range—2.5 ppm in our example. In that situation, 2.5 ppm would be the lower limit of quantitation (LLOQ) of the ELISA method. But ELISAs also have lower limits of detection (LOD) that are below the LLOQ. The LOD is typically determined in a very passive matrix such as buffer. Some commercial laboratories will report positive results between the LOD and the LLOQ. This practice is questionable in our opinion because the matrix interference from the food being

tested can generate weak low positive results between the LOD and LLOQ. Thus, it is important to find out the LLOQ of the ELISA method being used on your samples by the external laboratory and be mistrustful of any positive result reported below the LLOQ. These results could be false positives that will be very difficult to confirm. ■

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## Cold Snap (Continued from p. 23)

cleaning agents and sanitizers reach all spots where *L. monocytogenes* may ‘hide,’” he adds.

Talking about food safety culture in terms of the level of cultural maturity of an organization, Dr. Butts underscores questions that companies can ask themselves in terms of their commitment to food safety: What are our values? Are we going to apply our values to our production process? “The culture of an organization drives what they are going to do,” he says.

An article recently published in the journal *Comprehensive Reviews in Food Science and Food Safety* describes in detail how organizations can look at food safety culture in terms of moving from a compliance-oriented organization to a more integrity-oriented, and the ways

to determine the cultural maturity of an organization (see “Determining Cultural Maturity,” p. 23).

One outgrowth of organizations moving to a food safety culture built less on compliance and more on integrity (or a higher maturity level) may lead to a more risk-based regulatory approach and away from the more stringent FDA “zero tolerance” approach. Some argue that this in turn will actually improve food safety more than a “zero tolerance” approach, in which a food product is recalled if it is found to have any finding of *L. monocytogenes* regardless of the product’s risk profile, by reducing the disincentive to companies to regularly sample foods in fear of a recall.

Calling the “zero tolerance” approach a “significant impasse confronting the

food industry,” Dr. Gumalla says that a more risk-based approach to regulating *L. monocytogenes* as laid out by the expert panel in the *Food Control* article will “enhance food safety management and improve public health.” Among the risk-based approach recommendations are the use of alternate sampling approaches for foods that are at low risk of *L. monocytogenes* contamination and the use of big data to improve microbial risk assessments. Among the other recommendations is the need for clear communication to consumers on safe food handling and avoidance of high-risk foods for at-risk populations. ■

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## Bridging Environmental Monitoring Program ... (Continued from p. 29)

not be implemented without a risk assessment and a discussion with a chemical provider.

10. After sanitation, verification sponges were taken to verify that the sanitation procedures were effective. There are times when the harborage is longstanding. One intensive cleaning and sanitation event may not be effective and another is needed. After maintenance reassembled the equipment, it was sanitized again to avoid contamination during assembly process.

11. Preventive actions were identified and implemented. Cleaning records provide an additional awareness of breaches in protocol. For example, insufficient concentrations of cleaning

compounds lead to product build-up and potential biofilm formation. Records give indication of trends in microbiological creep data. If equipment is not being cleaned according to the SSOP, bacteria counts tend to increase over time.

Equipment that may not have been fully disassembled in the past will now be put on a disassembly schedule and dismantled to the framework (or as close to this state as possible). By removing parts, hollow areas and or damages are exposed that would otherwise be impossible to reach, see, or sample. During disassembly, use a designated mat with specific top and bottom identified or a dedicated rack to contain parts. Do not place parts directly onto the floor. Always clean mats

after use and hang up in a designated location to allow drying.

While a one-size EMP or cleaning and sanitation regimen does not fit all, there are baseline tasks that can be incorporated into all programs to set up your integrated food safety program for success, regardless of changes that will inevitably occur. Incorporating predetermined steps into an EMP program when there are OOS results, and using the strength of the entire HACCP team will aid in a successful approach for bacterial management. ■

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# NEW PRODUCTS



## Remote Monitoring System

Regularly monitoring and maintaining food cold storage units is essential to protecting product safety, ensuring consumer health

and meeting regulatory compliance. To help industry professionals responsible for the proper cold storage of food products, Sensaphone offers the Sentinel monitoring system. This device uses cloud technology to provide supervised 24/7 remote monitoring of temperatures inside industrial food refrigerators and freezers and other conditions that can affect the operation of cold storage units. The system is ideal for food manufacturing, processing and storage facilities, research and testing laboratories, food service establishments and retail locations. In addition to monitoring refrigerator and freezer temperature, the system lets

operators track conditions such as ambient room temperature, humidity, vibration, carbon monoxide, carbon dioxide, water leaks, power failure, and unauthorized access. When the Sentinel system detects that a sensor reading has moved out of the preset range, it sends a notification via phone call, text, or email to designated personnel. This immediate alert helps staff take fast corrective action. Personnel can remotely check real-time condition status from anywhere through a mobile app. They can also change settings, disable alarms, and readjust temperature limits. **Sensaphone, sensaphone.com.**



## Hand Sanitizer Dispensing Station

Keep one step ahead of preventing the spread of germs and virus with Sani-Spire's sturdy foot-operated hand sanitizer dispensing station that offers contact-free hand sanitization. It's durable and waterproof for indoor and outdoor usage. It was designed for high-traffic industrial, commercial, and retail areas. This free-standing sanitizer station is simple and reliable to use. It contains no expensive batteries or sensors. A locking cap keeps the sanitizer safe and secure. The Sani-Spire comes pre-filled with 32% of hand sanitizer gel and can be refilled with any sanitizer on the market. **Sani-Spire, sanispire.com.**

## Evaporative Light Scattering Detector

Shimadzu Scientific Instruments introduces the ELSD-LT III evaporative light scattering detector. This next-generation ELSD uses a high-power semiconductor laser as the light source, which enables sensitivity approximately 10 times higher than that of conventional products. The detector achieves a wide dynamic range of five orders of magnitude, providing simultaneous determination of high-concentration and trace components without gain switching. This eliminates the need for dilution and preparation of samples, cumbersome sensitivity settings, and the waste of samples due to failure to set sensitivity when considering methods. Capable of highly sensitive detection of non-chromophoric components, the ELSD-LT III meets a wide range of needs, such as impurity analysis and comprehensive detection. In addition, it can detect semi-volatile compounds and heat-labile compounds with high sensitivity. The ELSD-LT III can also be used as a detector for preparative LC. The detector's temperature-ready function ensures the reliability of the data because it executes analysis after confirming that the temperature of the drift tube has reached the set temperature. This function detects a decrease in gas pressure and stops the system with an error. The compact design reduces instrument height by 30% compared with conventional products, so it can be installed on the column oven, saving installation space. **Shimadzu Scientific Instruments Inc., ssi.shimadzu.com.**



## Antimicrobial Cleaning Tools

Specialist food safe brushware manufacturer Hillbrush Inc. has launched a range of premium color-coded antimicrobial cleaning tools, specifically for use in high-risk hygiene areas at food processing sites. The tools have been specifically designed to prevent the growth and reduce the risk of bacterial cross contamination, minimize foreign body contamination, and support HACCP and 5S best practice with color-coded segregation. A key feature of the tools is Biomaster technology, a silver-ion based additive designed to inhibit bacterial growth, which is proven to be up to 99.99% effective against harmful pathogens. All plastics in the cleaning tool products, including the brush filaments and resin, are infused with the additive. All components are FDA food-contact approved. The tools are available in six colors, making it even easier for users to avoid potential cross-contamination. Bacteria that is transferred onto the cleaning tools from a soiled surface will be reduced by 80% in 15 minutes and by up to 99.99% in two hours. **Hillbrush Inc., hillbrush.com or info@hillbrush.com.**



# SCIENTIFIC FINDINGS

For access to complete journal articles mentioned below, go to “Food Science Research” in the December 2020/January 2021 issue at [foodqualityandsafety.com](http://foodqualityandsafety.com), or type the headline of the requested article in the website’s search box.

## Co-Crystallized Honey with Sucrose: Evaluation of Process and Product Characterization

Honey is a commercial product that presents difficulties in the food industry related to crystallization inside packaging. Dry ingredients are easy to handle. Honey co-crystallized with sucrose is a dry product that can be used in



the food industry as long as it fulfills safety and sensory requirements. The objective of this work was to produce and characterize honey co-crystallized with sucrose using nine different samples of honey. The process of co-crystallization of honey (15%) with sucrose resulted in products with water activity from 0.38 to 0.51, moisture values ranging from 1.25% to 2.04% (wet basis), good fluidity (repose angles from 23.40° to 32.28°), and apparent density from 0.46 to 0.55 g/cm<sup>3</sup>. The products presented morphological structure characteristics of co-crystallization products. The final products showed good overall sensory acceptance, which opens the possibility of using co-crystallized honey in food industries. *Journal of Food Processing and Preservation*. 2020;e14876.

## Individual Effects of Enzymes and Vital Wheat Gluten on Whole Wheat Bread Properties

The objective of this research was to determine effects of five enzymes on whole wheat bread properties, particularly loaf volume, bread texture, and staling. Enzymes containing conventional  $\alpha$ -amylase ( $\alpha$ -amyl), cellulase (cel), glucose oxidase, maltogenic  $\alpha$ -amylase (m amyl), and xylanase (xyl) were added at three levels. Vital wheat gluten (VWG) was added as an additional, separate treatment at 2.5% (flour weight basis). Enzymes had minimal effect on water absorption and mixing time. Each enzyme increased specific loaf volume for at least one of the usage levels tested. Among the enzyme treatments, the greatest loaf volume was seen for xyl at the medium and high levels. No enzyme was as effective as VWG at increasing loaf volume. Overall, enzymes did not significantly change cell structure. The greatest reduction in fresh bread hardness was obtained for the high level of xyl. VWG, m amyl, and xyl reduced the rate of bread firming over seven days.  $\alpha$ -Amyl, cel, and m amyl decreased starch retrogradation at day 7 as measured by differential scanning calorimetry. M amyl nearly eliminated the endothermic peak for recrystallized amylopectin. This study demonstrated the specific application of enzymes in whole wheat bread to increase loaf volume and decrease initial crumb hardness and bread staling. *Journal of Food Safety*. Published November 10, 2020. DOI: 10.1111/1750-3841.15517.



## A Rapid Method for Detecting Hygiene Indicators, *E. coli*, and Coliforms in Dairy Products

This investigation was designed to develop colorimetric tests for rapid detection of *Escherichia coli*/coliforms. These test(s) for *E. coli* and coliforms were developed using the modified *E. coli* selective medium (M-ECSM) and coliform selective medium, respectively. The selective media contain a combination of group-specific marker enzymes and selective agents. The marker enzymes were screened using chromogenic substrates wherein  $\beta$ -D-glucuronidase and glutamate decarboxylase were found specific for *E. coli*, while  $\beta$ -D-galactosidase was found for coliforms. The selectivity of the media was achieved using different concentrations of ampicillin and gentamicin. The optimized test procedures enabled sensitive detection of  $0.35 \pm 0.10$  log cfu/ml of *E. coli* and  $0.57 \pm 0.15$  log cfu/ml of coliforms at 37°C within  $14.30 \pm 0.45$  and  $12.15 \pm 0.30$  hours, respectively. M-ECSM selectively inhibited major Enterobacteriaceae contaminants (*Salmonella*, *Shigella*, and *Yersinia*) up to 6 log cfu/ml. Moreover, better selectivity of M-ECSM was reported against tested commercial chromogenic media. Field evaluation of the developed test(s) reported prevalence of *E. coli*/coliforms as 57.29/88.54% in 96 raw milk and 16.28/51.16% in 43 pasteurized milk samples. Further, test components were vacuum dried in the form of miniaturized point-of-need tests for field application in dairy farms and industries with minimal infrastructural requirements. *Journal of Food Safety*. 2020;e12839.





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