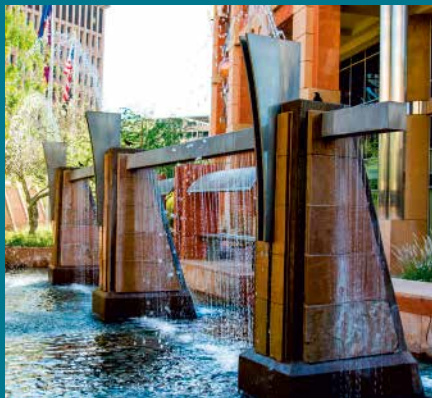


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From The Editors

Vaya con Dios 2020

Well, 2020 has come to an end. The year of COVID-19 is kaput! However, COVID has not gone away, and will remain with us for many months. People will still get the virus and there will, unfortunately, be more deaths, and probably more lockdowns and mandates to wear masks and social distance. But, we now have several vaccines—an amazing accomplishment when one considers the speed with which these were developed, evaluated, and approved. “Operation Warp Speed” was an incredible accomplishment. The means by which these were developed have the potential to benefit other programs such as acceptance of science, vaccines, and even genetically modified foods. As I write, more than 22 million Americans have been vaccinated. In addition, there are millions who have contracted the virus and recovered and, therefore, have some degree of immunity.



So, where do we go from here? The most important thing is that the world learn a few things that will prevent or minimize the effects of such a situation in the future. Perhaps the most important lesson to be learned is that good communication is essential. Would things have been different if the world had been given better information from China on the situation in Wuhan?

We in the food industry have learned a few lessons: the importance of good hygiene and proper handwashing and the need to adopt masks or facial protection as standard equipment for food plant workers. But, the lessons go far beyond the production floor. Many processors have taken a long, hard look at their supplier programs and realized that they needed to diversify their sourcing. Remember the early days of the pandemic? There was a scramble for certain ingredients such as non-nutritive sweeteners because the primary source was a nation with a serious virus problem, and exports had been curtailed.

My greatest fear for 2021 is that it will be the year of blame. Rather than moving forward, learning from mistakes and the events of 2020, and celebrating the roll-out of the vaccines and the end of lockdowns, my fear is that we'll see news media, politicians, and lawyers blame individuals, organizations, and companies for the events of 2020, including sickness, death, and other issues. And, with the blame will come the lawsuits.

I sincerely hope that 2021 will be the year of healing. Blame and finger pointing will do little when it comes to healing and repairing the ravages of 2020. Let's be sure to learn from the past, and not try to profit from it.

Richard Stier
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NEWS & NOTES

FDA Approves Genetically Modified Pork

FDA has approved a first-of-its-kind intentional genomic alteration (IGA) in a line of domestic pigs, referred to as GalSafe pigs, which may be used for food. This is the first IGA in an animal that FDA has approved for human food consumption.



The IGA in GalSafe pigs is intended to eliminate alpha-gal sugar on the surface of the pigs' cells. People with alpha-gal syndrome may have mild-to-severe allergic reactions to alpha-gal sugar found in red meat (e.g., beef, pork, and lamb).

As part of its review, FDA evaluated the safety of the IGA for the animals and people eating meat from them, as well as the product developer's intention to market the IGA for its ability to eliminate alpha-gal sugar on pigs' cells. FDA determined that food from GalSafe pigs is safe for the general population to eat. The agency's review also focused on ensur-

ing the effectiveness of the IGA through the evaluation of data demonstrating that there is no detectable level of alpha-gal sugar across multiple generations of GalSafe pigs.

FDA analyzed the potential impact that the approval of the IGA in GalSafe pigs would have on the U.S. environment and determined it is no greater than environmental consequences from conventional pigs. The conditions under which GalSafe pigs will be kept are far more stringent than those used for conventionally farmed pigs. Additionally, no animal safety concerns were noted for GalSafe pigs beyond those that would be expected in well-managed, commercial swine operations.

FDA also assessed the risk of the IGA to promote the emergence or selection of antimicrobial-resistant bacteria of human health concern in or on GalSafe pigs. FDA concluded that the microbial food safety risk is low and is mitigated by the low number of GalSafe pigs entering the food supply and the ongoing surveillance for antimicrobial resistance, among other factors.

Because the product developer's application to FDA did not include data regarding elimination or prevention of food allergies, FDA's review process did not evaluate food

safety specific to those with AGS, a recently identified type of food allergy to red meat and other products derived from mammals. In the U.S., the condition most often begins when a Lone Star tick bites someone and transmits alpha-gal sugar into the person's body. In some people, this triggers an immune system reaction that later produces mild to severe allergic reactions to alpha-gal sugar found in red meat.

The product developer indicated that it initially intends to sell meat from GalSafe pigs by mail order, rather than in supermarkets.

"Today's first ever approval of an animal biotechnology product for both food and as a potential source for biomedical use represents a tremendous milestone for scientific innovation," said FDA Commissioner Stephen M. Hahn, MD, in a statement. "As part of our public health mission, the FDA strongly supports advancing innovative animal biotechnology products that are safe for animals, safe for people, and achieve their intended results. Today's action underscores the success of the FDA in modernizing our scientific processes to optimize a risk-based approach that advances cutting-edge innovations in which consumers can have confidence."

Researchers Create New Form of Cultivated Meat Using Layered Cells

Researchers at McMaster University in Hamilton, Ontario, Canada, have developed a new form of cultivated meat using a method that they say promises more natural flavor and texture than other alternatives to traditional meat from animals, according to a new study published in the journal *Cells Tissues Organs*.

The investigators devised a way to create the meat by stacking thin sheets of cultivated muscle and fat cells grown together in a lab setting. The technique is adapted from a method used to grow tissue for human transplants.

The sheets of living cells, each about the thickness of a sheet of printer paper, are first

grown in culture and then concentrated on growth plates before being peeled off and stacked or folded together. The sheets naturally bond to one another before the cells die. The layers can be stacked into a solid piece of any thickness "tuned" to replicate the fat content and marbling of any cut of meat, an advantage over other alternatives.

The researchers proved the concept by making meat from available lines of mouse cells. Though they did not eat the mouse meat described in the research paper, they later made and cooked a sample of meat they created from rabbit cells. "It felt and tasted just like meat," says Ravi Selvaganapathy, PhD, one of the study researchers



and a professor in the university's School of Biomedical Engineering.

There is no reason to think the same technology would not work for growing beef, pork, or chicken, and the model would lend itself well to large-scale production, Dr. Selvaganapathy says. *(Continued on p. 8)*

(Continued from p. 7)

England Proposes Gene Editing for Plants, Livestock

BY KEITH LORIA

During the virtual Oxford Farming Conference, held earlier this month, George Eustice, Secretary of State for Environment, Food, and Rural Affairs in England, announced that a comment period has commenced regarding gene editing of crops and livestock in the country.

The Department for Environment, Food and Rural Affairs (Defra) comment period will be in effect for 10 weeks, ending on March 17. If there's enough interest, this could lead to legislative change in the next two years.

In gene editing, organisms produce changes that can be made slowly using traditional breeding methods. For instance, farmers can plan to breed stronger, healthier animals or plants so that the next generation contains these beneficial traits.

Currently, gene editing in Europe is regulated in the same way as genetic modification, but because the UK is no longer part of the European Union, that can be changed. Defra's opinion is that organisms produced by gene editing or other genetic technologies should not be regulated as genetically modified organisms (GMOs) if they could have been produced by traditional breeding methods.

David Acheson, MD, strategic advisor and food safety chair for PathogenDx, Inc., notes that gene editing is not a new concept and is essentially a process by which genes can be edited in very specific ways to cut out sections of the genetic material, with the goal of altering a characteristic of a food item, such as a plant.

"The pros of such an approach is that one can edit in or out specific characteristics, such as drought tolerance, which is seen by some as valuable in environments where water supply is scarce," he tells *Food Quality & Safety*. "The approach is not that different conceptually from GMO, bio engineering, and even conventional breeding—although the latter is considered as 'natural' vs. 'man made.'" The cons, Dr. Acheson says, are as with any genetic manipulation, ensuring one does not create a new variant with deleterious consequences and the bigger issue of acceptance by consumers.

"There are already regulations in place around genetic modifications and approval processes before genetically edited/modified foods can be sold to consumers," Dr. Acheson says. "While there are economic and societal opportunities, there will be continued pushback on the concept of GMO



by some. Likely, this will only change when the benefits outweigh the risks."

"As with all novel foods, gene edited foods will only be permitted to be marketed if they are judged to not present a risk to health, not to mislead consumers, and not have lower nutritional value than existing equivalent foods," says Robin May, the Food Standards Agency's chief scientific advisor.

This type of technology is not unique to England and is being looked at in other countries, including the U.S., to improve the properties and resilience of crops. "The U.S. is already using gene editing tools such as CRISPR, and these tools are regulated by both USDA and FDA," Dr. Acheson says. "The same hurdles exist for use in the U.S. as the UK. It is likely that this technology will be used globally in time as populations grow and the need to feed more people with fewer resources continues to become a priority."

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Leafy Green Traceability Pilot Programs Show Value in Sharing More Product Information



A group of food industry organizations has released a report that outlines four months of leafy green traceability pilot programs with supply chain partners, including growers, distributors, and independent and chain retailers. The researchers found that investigations into foodborne illness outbreaks could be streamlined and conducted more effectively when supply chain members provide extended product information during tracebacks.

Additionally, the investigators found that the use of a standard template to exchange pertinent product information enhanced the speed of tracing procedures. All of the pilots were successful in tracing the source of the affected product.

The pilots tracked romaine lettuce through three separate supply chains, starting with actual consumer purchases made with loyalty cards or credit cards. Small teams of industry experts mimicked FDA's role in conducting the traceback, including determining which data was to be requested and how to format the requests for such data. Supply chain members used the template to provide key data elements that allowed an item to be traced back to its source.

Notably, the data that enabled each of the teams to independently and successfully identify the finished product lot purchased by the consumer is not currently captured

by the template, according to a statement released by the organizations. "These data included business intelligence such as sales data, stock rotation, inventory controls, and delivery schedules. These were critical in bracketing the scope of the traceback."

"The pilots provided valuable insights that will inform future outbreak response and recall protocols, helping industry to work together to support the FDA's focus on tech-enabled traceability," said Bryan Hitchcock, executive director of the Institute of Food Technologists Global Food Traceability Center, in the statement.

The organizations that led this activity included FMI-The Food Industry Association, GS1 US, the International Foodservice Distributors Association, the Institute of Food Technologists, the Produce Marketing Association, and the United Fresh Produce Association.

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Washington Report



Food Safety Under Biden

Industry experts weigh in on how the President's views may shape food policy, and what they'd like to see him address

BY KEITH LORIA

In the December 2020/January 2021 issue of *Food Quality & Safety* (p. 10), we took a look at some ways that Joe Biden's presidency might impact food safety and the food sector as a whole. Here, we asked several food industry experts to weigh in with their opinions on what they think the implications of a Biden-Harris administration may be on food policy in the U.S., and areas they think should be a priority in the years to come.

David Acheson, MD, former chief medical officer at the FDA Center for Food Safety and Applied Nutrition (CFSAN), notes that Democratic administrations are generally more stringent on food safety regulation, so he anticipates more enforcement and more activity from the Department of Justice related to food than occurred under

President Trump. "Trump largely let food safety move along unhindered," he says.

Farida Mohamedshah, director of food, health, and nutrition at the Institute of Food Technologists, notes that climate change is expected to threaten food and agriculture production, including food safety and nutritional quality, food security, food prices, and distribution. Therefore, she says, embracing new digital technologies and distribution channels, public-private partnerships, including government, industry, and NGOs, are critical, and this needs to be a priority for the Biden administration.

"The need for traceability to strengthen consumer trust and confidence in food safety and [the] source of [our] food supply is critical," she adds. "Further, the

COVID-19 pandemic has exposed the vulnerabilities of our food system and calls for increased public investments in research to develop an agile and resilient food system to provide safe, sustainable, nutritious, affordable, accessible, palatable, and culturally/socially acceptable food products to maintain and/or improve health outcomes."

Joe Maxwell, president of the Family Farm Action Alliance, notes that the Biden administration is heavily focused on climate change, including how agriculture can be part of the solution, which provides the opportunity to advance policies that support a resilient local and regional food system built on regenerative agriculture practices. "We are encouraged but will remain vigilant in our efforts to ensure this is their course of action," he says. "We are hopeful that the Biden administration will move on farmer and rancher protections within the Packers and Stockyards Act by advancing new rules addressing monopoly abuses within the market."

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Regulation

While the incoming administration plans to streamline and reform existing regulations, we should not expect to see any type of major overhaul, says Joel S. Chappelle, a food industry lawyer and consultant at Food Industry Counsel, LLC. 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 should likely begin preparing for more numerous and more stringent environmental regulations, he adds.

Hunger in the U.S.

In 2020, more than 54 million Americans, including more than 18 million children, struggled with food insecurity, more than a 50% increase from the year before.

Noreen Springstead, executive director of WhyHunger, a national nonprofit organization focused on hunger issues in the U.S., notes that food policy advocates are optimistic that the Biden administration will prioritize anti-hunger policies, ensuring that Americans have access to nutritious food, and that it will address the growing inequity and hunger crisis that

Workforce Oversight under COVID-19

For the immediate future, the ongoing pandemic will continue to govern the trajectory of our day-to-day lives. While the vaccine is already being distributed to some food workers, the food industry has suffered disproportionately in terms of occurrence of illness.

As regards the pandemic, the Biden administration is likely to implement much more stringent measures to protect workers. The President has advocated for enhanced protective measures. Last May, he said he supports coronavirus-related workplace safety regulations, even if they raise food prices. He has also appointed worker advocates to teams responsible for overseeing the meat industry. In the near term, President Biden is likely to implement stricter COVID-19 protective measures that are applicable to employees. In the longer term, he will likely re-staff agencies, such as OSHA, which will lead to increased oversight.
—Joel S. Chappelle, *Esq.*

have occurred as a result of the COVID-19 pandemic. “President Biden has said he will raise SNAP benefits and expressed support for the emergency food relief bill, the FEMA Empowering Essential Deliveries (FEED) Act, which is backed by bipar-

I would like President Biden to encourage food companies to use technology such as whole-genome sequencing without the fear of regulatory action. That would improve food safety for ready-to-eat foods.

—DAVID ACHESON, MD

tisan lawmakers,” she says. Additionally, Doug Emhoff, husband of Vice President Kamala Harris, has pledged his support to champion anti-hunger policies.

What remains to be seen, she says, is whether the new administration will be able to create bipartisan support for bold efforts to not just alleviate hunger, but also work to end it. “From raising the federal minimum wage to a living wage, to addressing systemic racism, to ensuring affordable housing, there must be a root cause approach and a paradigm shift to see real progress,” Springstead says. One measure some in the anti-hunger community are pushing for is to establish a Presidential commission on hunger and its root causes.

USDA

Tom Vilsack, former governor of Iowa, is serving as the head of USDA under President Biden. He had previously served as the U.S. Secretary of Agriculture from 2009 until 2017. There are mixed opinions on Vilsack in food safety circles. Some are optimistic about his experience and ability to manage such a diverse set of priorities, but some feel that it will be “business as usual.” Dr. Acheson, who says he doesn’t think Vilsack accomplished much concerning food safety when he was in office before, as it wasn’t a focus for him, doesn’t anticipate much happening at FSIS that

will be new and game changing involving food safety mandates.

The Trump Administration’s food and agriculture policy was led by USDA Secretary Sonny Perdue, who, although he received mixed reviews among agriculture and food safety experts, seemed to go out on a high note: One of the last things he did before leaving office was to sign an agreement that shifts oversight of gene-edited livestock to USDA, something many in the agricultural industry were in favor of. This agreement is expected to remain in place under President Biden.

Additional Issues

President Biden and his administration will devote a great deal of time early on to solving the COVID-19 epidemic, so it could be a while before anything concerning food safety becomes a larger area of focus.

Early on, Biden has released detailed proposals to set up small business support and outlined a “restart package” to help them reopen. He has also laid out numerous policies to help small businesses build back through greater access to capital, expanded procurement opportunities, and targeted resources for veteran-, women-, and minority-owned businesses, among others. This will be especially important for restaurants and small food manufacturers.

Dr. Acheson would eventually like to see more focus on product tracking and a greater use of technology involved to improve food safety. “I would like President Biden to encourage food companies to use technology such as whole-genome sequencing without the fear of regulatory action,” he said. “That would improve food safety for ready-to-eat foods.”

Additionally, transdisciplinary sciences and the application of advanced technologies such as artificial intelligence and blockchain are needed to transform the food systems so that they are more resilient and agile, and can meet the increasing food and nutrition demands of the growing global population. ■

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

Have something to say? *Food Quality & Safety* magazine welcomes letters to the editor on any relevant industry topic. Submit letters to skuehne@wiley.com.

Legal Update



COVID-19 and Employer Liability

Understanding the law and mitigating risk

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

Employer liability protections have been among the most controversial policy debates surrounding COVID-19. With a new administration in the White House and an ongoing debate about additional stimulus measures, the question of whether liability protections for businesses are a good idea has been front and center.

This article aims to provide a neutral overview of the state of the law, share the legal and social considerations associated with COVID-19 liability shields, and explain how companies can best protect themselves from lawsuits.

As of late January 2021, nearly 2,000 COVID-19-related lawsuits had been filed against employers. The subject matter and type of relief sought in these lawsuits vary significantly from case to case. Most cases fall within the following categories:

1. Alleged workplace safety violations and failures;
2. Employee compensation claims arising out of business closures and shutdowns;

3. Age and disability discrimination claims;
4. Family Medical Leave Act (FMLA) and similar state/federal law claims; and
5. Whistleblower and retaliation claims.

In some cases, employees (or the estates of employees who died of COVID-19) are seeking monetary damages based on their employers' alleged failures. These include, for instance, negligence lawsuits, in which plaintiffs contend that the defendants breached their legal duty of care through various acts and omissions, including failing to develop or implement appropriate safety measures.

Many other suits are seeking injunctive relief. These suits seek to compel a company to do something or to not do something. This would include, for example, lawsuits seeking to force a company to enact certain protective measures, such as providing PPE.

Rulings

The rulings to this point have been mostly favorable to employers. In *Rural Commu-*

nity Workers Alliance v. Smithfield Foods, Inc., employees sought a preliminary injunction that would compel the defendant meat company to enact employee safety measures, including mandating social distancing, providing personal protective equipment, and conducting testing and tracing. In denying the requested injunction, the court held that the risk of injury was too speculative and that the court lacked the authority to grant the requested relief.

In *Palmer et al. v. Amazon.com Inc. et al.*, a New York federal district court dismissed a lawsuit alleging that Amazon was in violation of New York laws that mandated implementation of various COVID-19 protections. Here too, the court demurred, holding that the Occupational Safety and Health Administration (OSHA) was responsible for overseeing workplace safety requirements.

In *New York State Nurses Association v. Montefiore Medical Center*, the court denied a request for a preliminary injunction that would have forced the medical center to implement additional safety measures for at-risk nurses. In denying the request, the court reasoned that interfering with the hospital's decision making during a dynamic and rapidly changing pandemic situation could be "particularly problematic."

It's important to recognize that these cases are not being decided on the merits. That is, the courts are not ruling that these companies are, or are not, complying with the law, nor are they commenting on whether the companies are acting responsibly. Rather, the courts are ruling either that they lack the authority to grant the relief sought by the plaintiffs or that granting the requested relief would potentially make matters worse in the future. This may seem indecisive or even callous to some, but it's fundamentally important for courts to exercise judicial restraint.

Judicial restraint is a principle of judicial interpretation pursuant to which judges refrain from rendering judgment except and unless it will resolve a concrete dispute between adverse parties. In short, judicial restraint encourages judges to limit the exercise of their own power. Court orders, such as those requiring a business to take certain actions, cannot be easily va-

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cated. Meanwhile, COVID-19 is an unprecedented pandemic involving a novel virus about which our understanding is evolving. Expert guidance continues to change as we learn more about the way the virus propagates. Thus, to issue an order mandating companies to implement certain measures—even as the guidance of health experts continues to change and evolve—could ultimately endanger public health rather than protect it. The decision in *New York State Nurses Association v. Montefiore Medical Center* acknowledges that during a pandemic, the hospital is better suited than the court to make day-to-day decisions and to decide which safety measures are feasible.

As for other types of cases, such as those alleging discrimination, negligence, and so on, we may have to wait some time for rulings. Whether or not there will be a flood of additional lawsuits will depend on how courts rule in the currently pending cases. This is because plaintiffs' attorneys are waiting to see whether a given claim or liability theory is likely to result in a recovery before they incur the effort and expense involved in bringing such cases. So, if courts collectively dismiss the negligence cases, but not the discrimination cases, plaintiff attorneys will bring the latter. As of early 2021, we have only seen the first salvo of cases seeking monetary damages for employer conduct.

Liability-Shielding Legislation

With a new administration in the White House, and Congress now controlled by Democrats, it's increasingly unlikely that Congress will enact a federal liability shield. Although Congress has not passed any liability-shielding legislation, some states have. Georgia passed a law that creates a rebuttable presumption that the employee assumed the risk of exposure, transmission, infection, or potential exposure to COVID-19. To overcome this, the plaintiff must prove the employer's conduct amounted to gross negligence, willful misconduct, or reckless behavior. Multiple other states, including Iowa, Kansas, Louisiana, Mississippi, North Carolina, Oklahoma, Utah, and Wyoming, have enacted similar COVID-19 liability laws. New Jersey enacted a narrower law, which grants liability protections to

health-care providers "to ensure that there are no impediments to providing medical treatment related to the COVID-19 emergency."

As a general matter, business interests and Republicans tend to favor the enactment of legislation shielding businesses from liability, while Democrats tend to oppose it. Senate Minority Leader Mitch McConnell (R-Ky) has advocated for a liability shield, stating, "We can't get the economy back to normal if we have an epidemic of lawsuits on the heels of the pandemic."

Conversely, those opposed to a liability shield contend that employees should have recourse against employers that recklessly endanger the health and safety of employees. They further contend that existing laws already provide appropriate protections for employers and against frivolous lawsuits. Workers' compensation laws, for instance, may bar most employee-asserted COVID-19 related lawsuits. Workers' compensation laws are intended to provide the exclusive remedy for all work-related injuries, illness, and disease. This legal framework grants injured workers partial wage-loss replacement and all medical costs but bars workers from suing employers for workplace injuries. Plaintiffs' attorneys are testing creative workarounds to skirt this prohibition, but even then, a showing of egregious conduct by the employers is still required.

There are strong arguments for and against a liability shield, and reasonable minds can reach different conclusions. The complex legal issues and verbose statutory regimes that often make the law seem opaque and inaccessible belie the elegant simplicity of civil liability, which can be distilled into the following axiom: Those who fail to exercise reasonable care should be accountable for any injuries that result.

Advice for Employers

At this point, though it is still early days, it appears that COVID-19-related lawsuits against employers are doomed to fail in most cases. The exception will arise in instances where companies engaged in intentional, reckless, or grossly negligent conduct. Thus, avoiding COVID-19-related lawsuits will require employers to demonstrate reasonable and good faith efforts to protect employees and comply

with any applicable governmental guidance, regulations, or rules pertaining to COVID-19.

The good news is that employers will be able to avoid most lawsuits by enacting commonsense measures to protect employees. The following recommendations will help companies to avoid future lawsuits:

- Most importantly, review and follow CDC guidance for businesses, including implementing and updating as necessary a workplace-specific plan that identifies all areas and job tasks with potential exposures to COVID-19, and adopts control measures to eliminate or reduce such exposures. See the CDC website for additional specific guidance.
- Assess and comply with OSHA guidelines and utilize OSHA resources in adopting policies and procedures for employee safety and return-to-work guidance.
- Focus on ensuring effective communication and compliance of all policies and procedures to employees.
- Assign a specific person or group of people to monitor any revisions or changes to CDC and OSHA guidance or regulations. This will be particularly important as the Biden administration implements new regulations and rules in the coming weeks and months.
- Maintain regular communications with state and local health authorities and follow guidance or regulations issued at the state and local level.

The fallout from the pandemic will continue to reverberate through our society for many years to come. In less than a year, the pandemic has fundamentally changed almost every aspect of our society and how we interact with one another. In turn, novel legal questions of law will continue to percolate through the courts and legislatures across the nation.

As always, we can reduce our exposure to legal risk (and contagion) by following the science and doing the right thing. Another effective approach, when faced with any difficult decision, is to ask what 12 jurors would think. ■

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Allergen Control



My Sample Tested Positive for Allergen Residues—What Next?

Part 2: Moving forward after confirming a positive result

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 2 of a two-part series on allergen residue results. Part 1, which published in the December 2020/January 2021 issue, focused on how to confirm a positive result. Part 2 focuses on steps to take once a result has been affirmed.

Recipients of positive allergen test reports often leap toward recalling the product if it is already in distribution. To some degree, the food industry commitment to recalling products with undeclared allergens is laudable. However, this situation can be viewed as a major decision point. If the positive result shows high levels of undeclared allergen in a consumer-ready food product, the decision is easy and a recall is appropriate.

Many in the food industry seem to believe that recalls are required when any undeclared food allergens are found, especially with confirmation by testing. However, FDA Reportable Food Registry

requirements indicate that an RFR notice should be filed with FDA “when there is reasonable probability that an article of food will cause serious health consequences or death to humans.”

In situations where very low levels of allergen residue are present, especially in ingredients and more especially in minor-use ingredients, the probability of serious health consequences may be low. We would recommend a quantitative risk assessment (QRA) in such situations. QRA takes into account the known level of sensitivity of the population allergic to a specific food, the analytical result(s), and knowledge of consumption of the particular food from surveys such as NHANES (National Health & Nutrition Examination Survey). Serving size can be used in QRA, but some consumers are likely to eat multiple servings, so use of NHANES data is preferred. FDA does not officially recognize QRAs but, in our experience, may consider QRA when risks are genuinely low. QRAs can also be

used as one of the supporting pieces of information needed during a thorough risk assessment and root cause investigation, which will aid in determining if it is even necessary to contact FDA about the need to file a RFR notice. This corporate decision should be made under advisement from internal and/or external legal counsel.

Special considerations arise when the allergen residue testing is initiated by a consumer complaint of an allergic reaction. In these situations, FDA, USDA FSIS, or other regulatory agencies may already be aware of the complaint. FDA may show up and take samples for their own analysis, because they strongly prefer FDA laboratory results over results that come from any other laboratory.

If FDA does take samples, you should take duplicate samples at the same time. If positive analytical results are obtained with samples related to a consumer complaint, then FDA may strongly suggest a recall even if the results are not strongly positive. Testing samples provided by consumers who have experienced allergic reactions is a process fraught with uncertainties but can also yield valuable information. Obviously, testing an opened sample of food can yield unreliable results because the consumer may have advertently or inadvertently contaminated the sample.

Years ago, we investigated a case where a very young, milk-allergic child experienced an allergic reaction to sorbet that should have been milk-free. Our analysis of the remaining sorbet provided by the consumer revealed a very low level of detectable milk, and the product was recalled from the market. However, a conversation with the mother revealed that her older child was served ice cream at the same time, and the two children were left alone in a room to eat their ice cream and sorbet. Many circumstances could have occurred in that room that contributed to the allergic reaction. In such situations, the Food Allergy Research and Resource Program (FARRP) Laboratory recommends

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Cannabis Corner



The Chocolate–Cannabis Dilemma

How fats may interfere with potency testing in cannabinoid-infused chocolate

BY JESSE STANIFORTH

For consumers, it seems like an easy question to answer: How much tetrahydrocannabinol (THC) is in that cannabis-infused chocolate bar? For analytical testers, however, the answers are anything but simple.

According to research published last year by David Dawson, PhD, a researcher with Vertosa, a cannabis technology company based in Oakland, Calif., chocolate contains compounds that interfere with labs' abilities to determine the dose of cannabinoids infused into the product. Dr. Dawson and his team developed precise solutions of cannabinoids—the active ingredients in cannabis—added these to chocolate, and then attempted testing to prove the chocolate contained the exact volume of cannabinoids they had added. Over and over, they were only able to prove that some of the cannabinoids were present, but not all of them.

“Any time we get less [cannabinoids] than we expected, that’s a sign they’re

having interactions with the chocolate,” Dr. Dawson says. “The only thing we changed was the identity of the chocolate, and the quantity.” He and his team found a straightforward trend that correlated with a few factors, one of which was that the more chocolate product in the vial, the lower the recovery of cannabinoids. “Chocolate was absorbing, interacting with, and trapping the cannabinoids, reducing the amount in the actual solution,” he adds.

In his research, Dr. Dawson looked at the four most commercially available cannabinoids: THC, known for the “high” associated with cannabis; cannabidiol (CBD), known for a variety of medical effects but also popularly embraced as a relaxation and wellness tool; and two lesser known cannabinoids, cannabinol (CBN) and cannabigerol (CBG), which have only started to appear in commercial cannabis products, in comparatively small doses. Dr. Dawson tested the four cannabinoids in three types of chocolate: dark, milk, and

cocoa powder. Each interfered in some way with cannabinoid measurements.

Dr. Dawson is quick to stress that chocolate only poses a problem for analytical testers wishing to get an exact read on cannabinoid contents. “This doesn’t affect the product as it exists in real life,” he says. “The [same] amount of cannabinoids is there, regardless. It doesn’t affect how high you’ll get from eating the chocolate; it doesn’t affect the amount of cannabis in the chocolate. It’s just how we measure it that gets miscalibrated. This is an issue for analytical testing labs, not chocolate producers, and not consumers.”

That may be encouraging news for consumers and producers, but it does little to solve the mystery of how to accurately measure the dose of cannabinoids in infused chocolates.

Testing Specifics

Interestingly, Dr. Dawson notes that the four cannabinoids he tested behaved differently from each other: Roughly 10% of THC and CBN remained trapped in chocolate products, while CBD and CBG “had a slight downward trajectory, but recovery was fine by any analytical lab standard.”

He realized that THC and CBN molecules have a single phenolic hydroxyl (OH) group, while CBD and CBG have two. After synthesizing a cannabinoid with no OH groups, Dr. Dawson was able to prove that the more OH groups a product has, the more likely it is to create “signal suppression,” preventing analytical testers from getting a clear measurement. “If you have two OH groups, there’s basically no signal suppression; interaction with chocolate is minimal,” he says. “If you have one OH group, there’s a mild or moderate effect. If you have no OH group, there’s a strong effect.”

Amber Wise, PhD, scientific director for Seattle testing lab Medicine Creek Analytics, notes that the 10% difference Dr. Dawson and his team found is not uncommon. “To put analytical test results in this field into perspective, people need to be able to

expect at least a 10% difference in the signal [indicating cannabinoids] between any two labs, or any two experiments in a given lab,” Dr. Wise says. “If the signal is 5, 10% of that is 0.5—it’s not the difference between 5% and 15%. This is not a place where we’re unable to test chocolate for cannabinoids or get the right answer. If you had a bad experience with an edible, it’s probably not because of this issue.”

Cannabinoid Solubility in Fats

Dr. Wise joins Dr. Dawson in lamenting how new the field of cannabis testing actually is, and how this isn’t just about chocolate, but about cannabinoids’ incredible solubility in fats, from which it is very difficult to get the dissolved molecules back out to measure their combined dose.

In addition to dried cannabis flower and infused foods and beverages, clients of Dr. Wise’s lab have also brought her topical products for testing. Sometimes, the contents may be very simple, such as only coconut oil and added cannabinoids.

Legal Obligations for Manufacturers

Helene Hopfer, PhD, the Rasmussen Career Development Professor in Food Science at Penn State’s Department of Food Science, talks about the issue of cannabinoid levels in terms of legal protection for consumers—and legal obligation for producers. “To the FDA and USDA, if you add something to a product, and consumers will pay more for that reason, you have to demonstrate that the added content is actually in there,” she says. “This is especially an issue because you’re adding something with a certain claim. If you want to add something to chocolate—to spike it or enrich it, like vitamin D added to milk, you have to actually be able to accurately determine how much vitamin D is in that product.” She says that ingredients in chocolate vary from manufacturer to manufacturer, but there’s little consumer interest in whether one brand contains more vanillin or sugar than another; however, “from a consumer protection point of view, if I claim there’s 10 mg THC or CBD in my product, I need to demonstrate or measure that,” she adds. “Then you encounter this problem that you can’t get that cannabinoid out of there.”—JS

Clients, accordingly, often figure that if the mixture is simple, the science behind it must be as well.

Not so, says Dr. Wise. “It’s actually really hard to get a number out of [cannabinoids dissolved in fats],” she adds. “People don’t understand the fundamental solubility issues occurring here. Most everyday people are only familiar with water-based chemistry.”

Dr. Dawson is familiar with fat solubility, so the outcomes he discovered weren’t a total surprise. After all, he says, “chocolate is a very, very complex food matrix.” Considering cocoa solids alone, milk chocolate contains roughly 50 different types, while dark chocolate contains roughly 70. “Those cocoa solids are 50 or 70 unique, identified organic molecules that contribute to the nuanced chocolate flavor,” he says. “On top of that, there are the fats—cocoa butter, say, or milk fats added to milk chocolate. Fats are chemically distinct from the organic flavor molecules. Additionally, we have the sugars added to chocolate. The organic flavors, the sugar, and the fat are three very broad, wide-ranging chemical classes. It is a very complex matrix.”

Helene Hopfer, PhD, the Rasmussen Career Development Professor in Food Science at Penn State’s Department of Food Science in University Park, concurs. “Chocolate, if you look at it, about 50% is fat—cocoa butter—[and] the other 50% is cocoa solid: starch, polyphenols, proteins. That changes during processing, during roasting. In order to get chocolate, you need to go through that roasting step to create those flavor compounds. It’s a complex food like a lot of other complex foods: Think of wine, distilled spirits, or tea.”

The chocolate products Dr. Dawson tested were 42% fat by weight, and cannabinoids are fervently lipophilic. “Obviously, the cannabinoids are going to have some kind of desire to remain in the matrix,” he says. “They’re having positive chemical reactions with the fats in the chocolate matrix. That’s something that needs to be overcome [in order to get a clear read on cannabinoid contents].”

Some clients have been adamant with Dr. Wise that if they added 10 mg THC per serving of their product and don’t see test results showing 10 mg, it’s a lab error. She disagrees: “It’s not my math that’s wrong.

It could be your mixing, or a thousand other molecules in this mixture that are interfering with our signal as a lab. I’m happy to explore it more deeply, but that costs time and money.”

The bad news is that this issue isn’t just about chocolate but impacts any infused product with a high fat content. Dr. Dawson warns that this reaction could occur easily in any baked good, such as brownies. “Anything that’s thick and rich and creamy could very well display an analogous phenomenon,” he adds.

Dr. Hopfer agrees. “This is not a problem unique to chocolate. It will be similar with butter, probably.”

Where to Go from Here

Dr. Wise says that the issue of fats in foods causing diminishing test numbers isn’t impossible to resolve—the products just require a little more work. She suggests that formulators send their labs a “blank” solution of the same food product without cannabinoids. “We can run the blank mixture on its own to see if there are any interfering peaks that might look like cannabinoids,” she says. “We can also add a known amount of cannabinoids and do our extraction to see if we can get back all the cannabinoids we put in. That’s not perfect. David Dawson has been working on his research for a couple of years now; this isn’t something you can figure out overnight. But, we have ways of helping clients make sure there aren’t compounds interfering directly with their signal, and to be sure we can extract cannabinoids out of that matrix.”

Solvent extractions can work as well, Dr. Wise says, as long as labs are willing to be adventurous and try multiple solvents beyond the standard formulations. She suggests trying five or six different solvent systems to determine which one recovers the most cannabinoids.

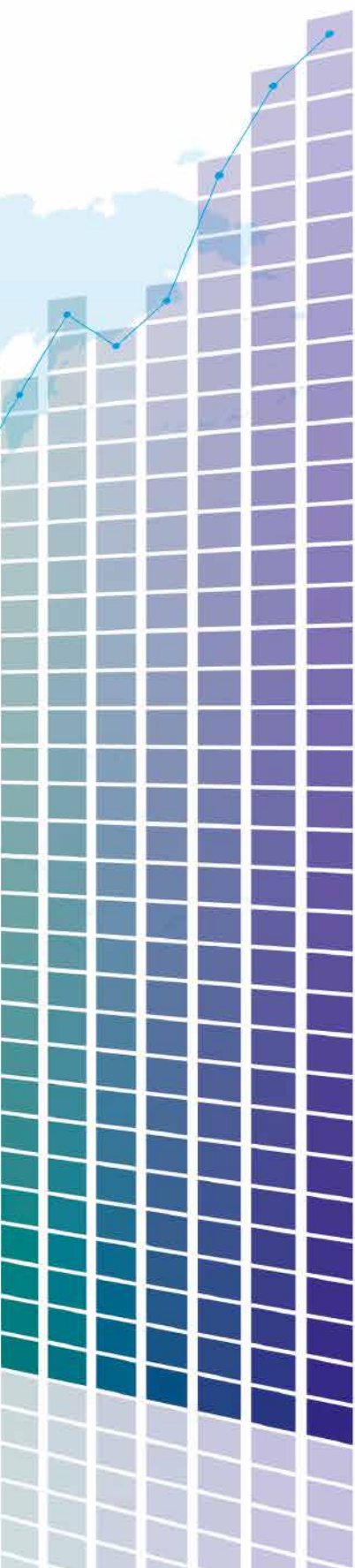
But above all, Dr. Wise stresses, this problem isn’t the end of the road for infused-chocolate producers, or producers of infused products with high fat content. The challenges in testing chocolate, she says, are complex but, nonetheless, manageable. “As a producer–processor, there are a few things you can do in working with your lab.” ■

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Sustainability and Food Safety

Innovative technologies, including traceability, blockchain, and agricultural initiatives, are part of an effort to ensure that a safe food supply can feed a growing global population

BY KAREN APPOLD



The world's population is expected to increase by two billion people in the next 30 years, from 7.7 billion currently to 9.7 billion in 2050, according to a United Nations report. The World Economic Forum estimates that demand for food in 2050 will be 56% greater than it was in 2010.

With world hunger slowly on the rise since 2015, concerns are mounting about how to feed a growing population. "We are not on track to reach the United Nations' goals of eliminating global hunger by 2030," says Rich Kroes, senior director of global sustainability at Oracle, a global information technology company in Lake Placid, NY. In fact, an estimated 821 million people worldwide suffered from hunger in 2018, according to the U.N.

In achieving a sustainable food supply, many factors play a role. For example, climate change and population growth can negatively impact the amount of available food. On the positive side, initiatives in technology, food packaging, and waste reduction can lengthen food's shelf life and increase its supply. We asked food industry experts to weigh in on how these factors may impact food sustainability, and offer suggestions for overcoming challenges.

Food sustainability throughout the supply chain requires a commitment from all players to create a system that can deliver food to consumers without excess waste or shortages. "The food industry is complex, and aligning supply with demand is challenging," says Will Daniels, president of the produce division at IEH Laboratories and Consulting Group, Inc., a laboratory analytics and consulting firm for the food industry in Lake Forest Park, Wash. "There must be outlets for food when supply exceeds demand and a surplus when the opposite occurs."

Another factor that heavily impacts food sustainability is food safety, because sustainability isn't possible without the safe production and distribution of food products. "One of the challenges in achieving sustainability is helping ensure that food safety practices and procedures are properly executed across the supply chain," Kroes says. "A chain is only as strong as its weakest link, so any instance of unsafe activity, such as a food product being stored at temperatures outside of its recommended range, can render that product's entire supply chain unsustainable."

Global Forces

One of the biggest challenges to the world's food supply over the next 10 to 30 years will be climate change, Kroes says. Increased occurrences of floods and droughts will continue to threaten a wide range of staple foods, such as wheat and corn, making crop yields increasingly unpredictable. Rising global temperatures will also affect the frequency and persistence of bacteria, viruses, parasites, and foodborne diseases.

While there's no silver bullet to overcoming the challenges created by climate change, the World Health Organization recommends that governments focus on bolstering their emergency preparedness and response programs in order to better prevent and manage the threat of increased foodborne risks associated with climate change. In addition, "both corporate and government institutions will need to make a collective effort to slow down and reverse the trends in the earth's climate resulting from human activities," Kroes says. "Plans will need to be implemented to both adapt and mitigate to changing climatic conditions."

Due to atypical rainfall patterns that may cause floods or droughts that increase crop spoilage, Deane L. Falcone, PhD, chief scientific officer of Crop One Holdings, a technology-driven indoor vertical farming company in Millis, Mass., says it's critical to increase reliance on plant-based foods. "Greater use of plants as major sources of dietary protein will help shift the food supply from unsustainable animal protein production," he says. "This could substantially impact sustainability, particularly in water use, to enhance global food security, while providing healthy sources of dietary protein to greater numbers of people."

Over the next 30 years, Mick Rickerd, corporate executive chef of nutrition services at Spectrum Health, a healthcare system in Grand Rapids, Mich., says it will be necessary to shift from conventional methods of farming to alternative models, growing food in safe, controlled environments, due to the expanding urban environment. This might include an urban container-controlled micro farm, an aquaculture facility, or a hydroponics farm. These environments can provide pathogen-free conditions and grow more with less land. For example, 10 urban container-controlled micro farms the

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size of a city lot (about 1/5 acre) can produce as much fresh produce as a 20-acre field.

Effects of Population Growth

Over the next 10 to 30 years, population growth will continue to challenge the agriculture industry to grow more using less land, as well as less water and energy, says Nikki Cossio, founder and CEO of Measure to Improve, LLC, a produce sustainability consulting firm in Salinas, Calif. More attention will need to be given to nurturing healthy soils to cultivate plants that are more resistant to diseases and pathogens.

As the population grows, agriculture will compete with development for land. “If farmers can’t make a decent living, they will be more likely to sell out to development, reducing the capacity to grow food,” Cossio says.

Ultimately, population growth is on a collision course with climate change. “While growth increases the demand for food, climate change decreases the ability to meet the demand due to extreme weather events, changing growing regions, and shortening growing seasons, not to mention reduced resources,” Cossio says.

To meet these challenges, a better understanding of today’s resource usage is needed. “We can only improve what we measure; we need to get serious about collecting and understanding data about how we use resources,” Cossio says. “This will help us to

One of the challenges in achieving sustainability is helping ensure that food safety practices and procedures are properly executed across the supply chain.

—Rich Kroes

be proactive and build resiliency, rather than wait for government mandates. This will also help anticipate and mitigate risks.”

The World Economic Forum states that the solution to ensuring food security and sustainability amid rapid population growth needs to be multi-faceted and focus on reducing global warming, developing skills, and making agriculture more productive and sustainable, among other factors. In addition, plant science, automation, and technologies employing artificial intelligence can also play a critical role in feeding future generations, Kroes says.

Initiatives to Improve Sustainability

While some forces work against food sustainability, steps can be taken to improve it. Innovative technology is increasingly helping ensure food safety and sustainability, most notably in the form



The team at Crop One work in a vertical farm in Millis, Mass., pre-COVID-19.

of tracking and tracing food across the supply chain using blockchains and Internet of Things (IoT)-connected sensors, Kroes says.

Technology can also help organizations better forecast and manage supply and demand across their food chains. Real-time condition monitoring and precise recall abilities will prevent unsafe food from getting onto grocery store shelves and will make it easier to pull unsafe food off shelves if needed, Kroes says.

Food packaging is another area of focus. “The ability to extend the life of fresh food has allowed for distributing food further away from its source,” says Daniels. “However, packaging can also increase risk by pushing the life of a product and providing an atmosphere that’s conducive to pathogen growth.”

Sarah Chartier, MBA, senior sustainability project manager of supply chain services at Spectrum Health, says the packaging industry can support sustainable food efforts through more intentional design efforts to limit packaging waste. Plastic waste has global implications from production to disposal, including microplastics that pollute the natural environment. “Creating solutions to dispose of packaging as part of the product design process is critical to reducing waste,” she says. “Limiting materials to those that are easy to recycle with conventional recyclers is a helpful short-term solution.”

Along these lines, Paula Pendley, JD, a partner at the Environmental & Tort Practice Group, Lathrop GPM LLP, a law firm in Dallas, Texas, says that food producers should strive to use recycled materials in portions of their packaging when possible, while also maintaining freshness and protecting food from food-borne diseases or chemical contamination during transportation. “By using recycled materials, producers can support food sustainability by minimizing the environmental footprint of packaged food and reducing food waste accumulation, which can reduce costs over time,” Pendley says. “Consumer demand for companies to show how they’re being green can also increase market pressure to use recycled goods.”

Pendley provides a word of caution, though—any packaging that directly touches food must meet federal regulatory requirements, and packages must meet certain specifications to allow for temperature fluctuations and high humidity. “Some companies are working on that, as well as innovating packaging that will extend food shelf life, thereby reducing food waste,” she adds.

Another food packaging initiative that supports sustainability is for producers to consider printing information directly on packaging, rather than applying an additional label to it, Pendley says. This would enable food producers to save on packaging costs, reduce paper waste disposal, and reduce their carbon footprint.

According to Kroes, other food packaging initiatives making headway include switching to reusable or compostable packaging, offering recyclable packaging that can withstand heat and hold liquids, and experimenting with new approaches to packaging. For example, USDA researchers have developed an edible, biodegradable packaging film made of casein, a milk protein, that can be wrapped around food to prevent spoilage. And, Apeel Sciences has developed a natural coating that adds a layer of tasteless, odorless, plant-based protection onto the surface of fruits and vegetables, which helps produce last twice as long.

Reducing Food Waste

An estimated 40% of grown foods in the U.S. are wasted, which occurs throughout every step of the value chain. “Finding creative solutions and secondary markets is key,” says Chartier. This waste consumes more than \$218 billion, or 1.3% of the gross domestic product, in growing, processing, transportation, and disposal costs. Internationally, approximately one-third of all global food production is either lost or wasted annually, at an estimated price tag of \$940 billion, according to the Food and Agriculture Organization of the United Nations (FAO).

A PFAS Phase Out

FDA is phasing out certain short-chain per- and polyfluoroalkyl substances (PFAS) from the market, which could directly impact the sustainability of the food supply chain, says Paula Pendley, JD, a partner with the Environmental & Tort Practice Group, Lathrop GPM LLP, a law firm in Dallas, Texas.

PFAS create a water, grease, and stain-repellent coating in packaging, preventing food from adhering or sticking to packaging and the food’s grease or oil from leaking through packaging. However, some scientists think that there might be a link between long-term exposure to PFAS and adverse health effects in humans, Pendley says. In May 2019, U.S. Rep. Debbie Dingell of Michigan introduced a bill, “Keep Food Containers Safe from PFAS Act of 2019.” The bill would enable FDA to deem unsafe the PFAS substances in any food containers or cookware, giving FDA until 2022 to enforce a ban on using PFAS in all food packaging, Pendley says.

Although the bill hasn’t moved forward, the pressure of that bill and others like it led FDA to strike a deal with manufacturers of certain PFAS substances to agree to a three-year phase-out of short-chain PFAS in food packaging, beginning in January 2021. “The phase-out plan will occur in stages to minimize potential market disruptions to food packaging supply chains during the pandemic,” Pendley says.

Food sustainability throughout the supply chain requires a commitment from all players to create a system that can deliver food to consumers without excess waste or shortages.

However, the food industry can play a leading role in addressing the problem throughout the food distribution chain, from growing and production, to processing, and to retail and food services, according to a recent report from the U.S. Government Accountability Office.

Many proposed solutions for the problem of food waste involve the application of new technologies. Some involve creation of digital apps using blockchain or IoT so food manufacturers and consumers can trace products throughout the distribution chain.

Agriculture’s Role

Farmers can increasingly use innovative technologies to reduce waste and increase sustainability at the beginning of the food chain. This is a significant development, since the FAO has reported that farmers lose 20% to 40% of their crops to pests and diseases. For example, some farmers are now using autonomous scouting drone technology to spot pests and diseases sooner and apply pesticides only where and when they’re needed. This technique benefits both the farmer’s bottom line and the environment, Kroes says.

In another effort, greenhouse production is emerging as a proposed solution to deliver fresh food in urban areas without the challenges of distribution or extended shelf lives. “We can now grow crops in areas and times of year that would otherwise be impossible,” Daniels says. “These systems also tout the ability to be safer because of the closed system and lack of exposure to vectors of contamination. However, this is only true as long as there isn’t a breach in the system which could lead to widespread contamination of the entire system.”

A Time to Act

Knowing that demands on the world’s food supply will continue to grow, industry players should focus their efforts on meeting these needs with strategies to increase food sustainability and safety. Notable initiatives are already underway but, according to experts, more needs to be done to stop hunger rates from rising. ■

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Opinion



Whole-Genome Sequencing

A double-edged sword for the food industry

BY **BOB LIJANA**

Whole-genome sequencing (WGS) has proven to be very effective at identifying where resident *Listeria* strains may be found in a food facility. To date, however, it has also been proven to be equally effective at ensuring that only a few food companies want to use the technology.

WGS as a Technology

For the most part, scientists, such as molecular biologists, and regulators, such as FDA, view WGS as an evolving state of the art. Using these methods has repeatedly helped regulators identify resident strains in a food facility before the strains can cause significant public health issues. If the strains end up on manufacturing equipment and/or in food, WGS is very useful at identifying the association between the original source, retail distribution, and public consumption of that food.

WGS is, in essence, an upgrade from its precursor technologies such as pulse-field gel electrophoresis (PFGE), multilocus sequence typing (MLST), and multiple-locus VNTR analysis (MLVA).

As has been demonstrated in recent years, the science of identifying genes, bacteria, and food-related organisms keeps progressing, and always will. As many people have stated in published articles and speeches, WGS technology has probably outpaced the food industry's ability to keep up with it at the moment. But surprisingly, industry has been reluctant to embrace the technology, in large part because of fear that their products will be linked to human illness and the potential resulting regulatory enforcement actions.

Keeping Up with the Technology

Grabbing any new technology and putting it to work in a manufacturing plant is rarely straightforward, is difficult to mandate, and must be done with careful consideration. This is because new technologies come with baggage, some of which include significantly higher costs

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initially (compared with past/current technologies), longer lead times initially, and higher alpha- and beta-risks (i.e., chances of false results).

These are all good reasons why the food industry in general has not embraced WGS as a routine tool. And this is in spite of the fact that FDA will sequence any positive it finds during a “swab-a-thon.” In fact, the food industry has barely even embraced WGS as a problem-solving tool.

WGS as a Problem-Solving Tool

One of the best uses of WGS in a food production plant is increasing the odds of finding the root source of a strain of *Listeria* that is resident. For example, positive WGS findings (i.e., matching gene sequences with an extremely high probability) can help a company identify a regularly incoming raw material as the source of a Zone 3 recurring contamination (e.g., on pallets).

FDA takes this same approach in attempting to link a specific *Listeria* strain sequence found in a clinical isolate or food product with an identical strain found in a food plant.

Using WGS in this manner takes a lot of time (and money), and it is at the moment a best practice for identifying *Listeria* strains that have resided in given locations over time. This allows discovery of “hot spots” and certainly helps in identifying external sources (e.g., a supplier issue). Hence, a regular use of WGS testing of strategic samples around a food facility can pay huge dividends in identifying, and then eradicating, resident *Listeria* strains.

By contrast, WGS is a poor tool to use to identify transient strains of *Listeria* and/or when results are needed quickly to be able to respond to an issue or corrective action. This is primarily because of the fact that by the time the WGS results come back, the transient organism is long gone. And although the cost of WGS testing has dropped by orders of magnitude over the years (as happens with new technologies that become mainstream—look at wide-screen TVs), simply churning out WGS samples to try to locate *Listeria* in a food facility can become extraordinarily expensive.

Other techniques are far quicker and can be equally effective at the end game. For example, there is still value in using some of the older techniques such as

PFGE and MLVA. Even easier and cheaper, although less informative, is using well-proven standard microbiological techniques to assay for *Listeria* (e.g., FDA BAM Chap 10). These standard micro tests have widespread proven use in environmental monitoring programs to “seek out and destroy” pathogens in a food facility, regardless of whether those organisms are transient or resident. WGS can then be used sparingly as a means of continued

FDA wants to encourage use of WGS to help minimize food safety risks to the public, but by its policy execution, it may be driving the industry away from a proven scientific tool that could achieve that very end.

surveillance, ensuring that strains are or are not taking up residency.

The “time and cost” value equation of WGS, however, is still a reason why food companies do not routinely use WGS. Do note that over the past two years, turnaround time and costs have been significantly reduced (e.g., a five-business day turn for *Listeria* WGS is about \$500). However, this value equation is either still not good enough, and/or companies are still saying that the tests are “too long and too costly” as a shield for not wanting to enter FDA’s territory.

FDA and WGS

Clearly FDA sees WGS as a savior; euphemistically speaking, if use of the technology prevents even one illness, then its use is warranted. And, since the technology is available, an informed public would most likely want FDA to use it. So, it may be that as time progresses, public and political pressure may push WGS forward independent of food safety professionals wanting to do so or not.

Having WGS in its toolkit also allows FDA to trumpet what it is doing: WGS is a well-defined technology, and the public

can understand it (especially when the public watches crime shows that use DNA testing, or consumers use DNA sequencing for ancestry determination purposes). FDA will continue to use these tools to find organisms, such as *Listeria monocytogenes*, which can cause significant adverse health consequences or death to the small populations that are highly susceptible to the organism’s effects.

This is also why FDA continues to maintain a “zero tolerance” policy for *Listeria monocytogenes*. This is not the case worldwide (e.g., Canada and Australia), but it is the position FDA has taken. Granted, the rationale for this is to protect the public health, but it also allows FDA to conduct deeper investigations into a food company’s practices and, when resident pathogens are detected and linked to human illness, initiate the enforcement actions the public would expect them to take.

Why FDA Is the Biggest Reason for Industry Not Using WGS

Setting aside consideration of whether or not FDA should be spending so much time enforcing a zero-tolerance principle, one would surmise that if FDA allowed for some tolerance of *Listeria*, the food companies might begin using the technology much more widely. But, as everyone knows, they are not.

Why?

FDA has issued a Draft Guidance for Industry: Control of *Listeria monocytogenes* in Ready-To-Eat Foods. Although still in draft form, the document essentially offers a “three strikes and you’re out” approach for detection of *Listeria* species in a food production plant. In other words, if there is a new identification of *Listeria* on a non-food contact surface (for example), this is not the end of the world. Intensified sampling and/or cleaning might be mandated, but production does not necessarily need to halt.

Many people have praised this approach, and for good reason: The odds that an environmental sample is positive for *Listeria monocytogenes* are generally low, as are the odds of a consumer being exposed to a sufficient number of organisms to become compromised (since the vast majority of people eating the food are

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healthy). Moreover, many products require further preparation and heating by consumers prior to consumption. Thus, even when *Listeria* may be present, the risk to consumers is often generally low.

If FDA finds *Listeria* in a food facility or in its review of a company's environmental monitoring records, then FDA often times responds aggressively. Sometimes, some would argue, too aggressively. It's likely that all food companies would test more frequently for *Listeria* in food facilities and work harder to find *Listeria* if FDA did not take such a critical view of zero-tolerance positive testing results.

This is a major reason why the approach of other countries might be better in the long run. Canada, Australia, and the European Union (via its laboratory Guidance Document), all use an allowable limit of <100 CFU/gm for *Listeria monocytogenes*.

While the focus of this article is FDA, it is important to note that for dual-jurisdiction plants, USDA quietly watches, and sometimes follows the lead of, FDA. USDA conducts its own environmental sampling for enforcement purposes, but for the most part the agency seems to keep an eye out for what action FDA is pursuing. USDA often asks companies for their FDA data with regard to *Listeria*, even if the company is not legally obliged to share the data with them.

Why Having *Listeria* Data Is Good—and Bad

It is also important to note that this article is not advocating a cavalier attitude toward *Listeria*. A company cannot get a "hit" or "two" and then think they can take some action to avoid the "third strike." This is indeed a road to perdition, not only for the company but for public health. Rather, the company needs to have a scientifically justified corrective action plan in place, and a very active environmental monitoring program for the organism.

That said, FDA risk becomes even worse if a company has WGS data, and doubly worse should the company know that the sequence of their *Listeria* sample matches a sequence in FDA's Genome-Trakr database. This would mean that the company knows of a linkage, and one which may or may not implicate the com-



pany. Should FDA be told, or should the company solve the problem and move on?

Let's say that the company generated its data (and linked an environmental sample to a retail food or, worse, a clinical sample from a patient hospitalized in their immediate vicinity) under a protected status, e.g., attorney-client privilege. The company would seem justified in not sharing the data with FDA. But what if there is a public health problem down the road, and FDA uncovered that same data after the fact?

Almost no company wants to be in either pressure-cooker, i.e., having data that could escape into the public domain, or having data which could be discovered later. What is the result? The result is that few companies want to use WGS under these circumstances, no matter how helpful the data might be to public health protection.

Of course, this is the same reason food companies have their microbiology labs test only for *Listeria* spp. and not directly for *Listeria monocytogenes* (Lm). Again, as soon as the Lm notation appears, "zero tolerance" comes to mind. And, once that Lm designation is in the corporate files, it could be devastating for the company even if the company is taking all appropriate efforts to eradicate the bacteria from the premises.

The Sword: Double-Edged, or Damocles?

This clash of paradigms is clearly a double-edged sword. FDA wants to encourage use of WGS to help minimize food safety risks to the public, but by its policy execution, it may be driving the industry away from a proven scientific tool that could achieve that very end.

My call to action, then, is for FDA to allow a better path for companies to use WGS testing, without having to face the consequences of an initial positive result. Perhaps, human isolates could be stripped from a custom public database that could be accessed by food companies. If this were made available, it seems likely that a significant number of additional companies would begin using WGS to solve contamination challenges in their facilities.

If nothing changes in the near term, then the use of WGS will likely remain low. That would be a shame, not just from the perspective of trying to banish *Listeria* from food facilities, but also due to the opportunity cost of spending so much time being outmaneuvered by these elusive bacteria. ■

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Environmental Monitoring and Sanitation

Part 3: When conducting a system analysis on a CIP system, go with the flow

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

Editors' note: This is part 3 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 2, which reviewed sanitation recommendations after receiving an out-of-specification microbiological result, was published in the December 2020/January 2021 issue.

This is part 3 of a three-part series discussing the link between environmental monitoring and sanitation. In part 2, we provided root cause investigation's information on equipment and, in this part, we'll continue to discuss root cause investigations, turning our attention to clean-in-place (CIP) systems.

CIP System Types

There are two basic types of CIP systems:

1. Single-use systems: Typically, this is one tank where the CIP solution is used and then replaced with a fresh solution. An example of a single-use system is a pasteurizer wherein solutions are used a single time to reduce the contamination risk.

2. Re-use systems: In this system, multiple tanks use the wash solution repeatedly to clean multiple circuits. Re-use systems have a higher initial capital cost but may allow for shorter CIP run times or they can be set up to wash two different circuits at the same time, using two supply pumps. Multiple tank re-use systems can

lower water and energy cost by having the cleaning chemicals stored in one or two tanks and fresh water for final rinsing in another. A final tank, the reclaim tank, stores the spent post-rinse water after the alkaline wash and may be used as the pre-rinse water for the next CIP circuit.

CIP systems can be time-based or conductivity-based, which measures chemical concentrations. Time-based controls are simplified in that they receive a signal from the CIP controller and the pumps run for a specified time. The pumps deliver the same volume every cycle regardless of demand.

CIP: Less Is More. The objective of a CIP system is to clean the interior of an enclosed stand-alone vessel and its fittings (tanks, spiral freezers, mixers, blenders) or multiple closed-system vessels within processing line(s) and their connecting pipe-work. The substantive goal being, counter-intuitively, less—less workforce, less water, less disassembly, less downtime, fewer chemical accidents, less chemical waste, and lower operating costs.

Mechanical Action (or, in the CIP World, "Flow"). In part 1 of this series, a "Sinner's circle" was described that identified the four factors needed for cleaning/sanitation: mechanical action, temperature, time, and chemical concentration. As one factor is altered (decreased or increased), the others are adjusted to compensate. In manual cleaning, mechanical action is created through scrubbing, water sprays, and foaming. In CIP, mechanical action is produced by flowing liquids

(flow) to create turbulence, which, in turn, generates convection (energy transfer by mass motion of molecules). Convective energy is more efficient at removing soils because the surface soil's adhesive force is often less than the force of convective energy (flow plus temperature), leading to the soils being released from the surface more quickly and with a lower temperature and fewer chemicals than when exposed to conductive energy (energy transfer by direct exposure) or temperature and chemicals exposure via soaking. Or, said another way, the amount of time, temperature, and chemicals can be reduced (or their effect is amplified) when flow is present.

How is flow rate calculated? Flow rates are calculated by two factors:

- Pipe diameter and configuration: This is the largest pipe size diameter in the circuit and flow requirements for all spray devices in the line. Pipe diameters are a critical consideration because they must be completely filled and the solution velocity high enough to produce turbulent flow during both cleaning and sanitizing. While this may sound easy, piping can be a dizzying maze, causing missed diameter size changes.
- Spray balls: Each spray ball will have a gallon/minute rating. If there are four in a line each rated 40 gal/min, the pump for that line will need to deliver 160 gal/min.

What are minimum flow rates? The minimum flow rate necessary for effective

Table 1. Water hardness classification measured as parts-per-million (ppm) or grains-per-gallon calcium carbonate.

Water Hardness*		
Hardness (ppm* or mg/L)	Hardness (grains per gallon)	Classification
<17	<1	Very soft
17–60	1.0–3.5	Soft
60–120	3.5–7.0	Moderately hard
120–180	7.0–10.5	Hard
>180	>10.5	Very hard

*One grain = 17.1 part-per-million as calcium carbonate

turbulent flow is 5 feet/second. To put this into perspective, it is similar to wiping down a counter with a cloth, therefore highlighting the synergistic attributes when convective flow is applied. Nevertheless, even under the best circumstances, there are areas these flow rates are unlikely to reach—notably at dead ends, 90 degree corners, fissures, and cracks.

How is flow generated? Pumps, valves, spray devices, and pipe diameter work together to create a flow rate.

- Valves create flow by pulsing (opening and closing). Flow is created when the pressure behind a closed valve is released. Often, valves are used to direct supply and clean the O-rings of the valves, which rotate when pulsed. Valve placement and pulse timing are also factors in restricting or routing flow.

- CIP systems must be designed with enough pump capacity to exceed soil build-up resistance, allow for valve back-flow pressure, meet spray ball capacity, completely fill pipe diameters, and maintain liquid velocity.

System Analysis and Root Cause Analysis. Poor cleaning is the No. 1 symptom of CIP failures. Other indicators include the creeping up of finished product indicator results (aerobic plate count, coliforms, *E. coli*, yeast/mold), pre-op allergen findings, a color bleed-through, or cleaning rinse water pH abnormalities. The CIP failures allow for incomplete soil or chemical removal. The longer that soils remain on the surface, the stronger they attach (think of dishes left in the sink overnight versus dishes cleaned shortly after use). Compounding the effect, sanitizers may be less effective because they do not have direct contact with microbial cell walls/membranes, which is needed for microbial reduction/elimination.

On some CIP systems, software packages can be added that report system functionality, including flow rates, conductivity, temperatures, preventive maintenance prompts, or other sanitation verifications. These reports are valuable to detect system drift, unintended consequences of program changes, or equipment damage. Additionally, since day-to-day interior equipment/circuit inspection after cleaning and before sanitation is difficult or not conducted until preventive maintenance results in disassembling pipes or tanks, these metrics are tools to maintain system effectiveness.

(Continued on p. 40)



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The Seven Principles of HACCP

Create and implement your HACCP plan for long-term success

BY ERIC HANSEN

Hazard analysis and critical control point (HACCP) guidelines are the primary preventive approach applied in the United States to keep food safe from biological, chemical, and physical hazards at every stage of the production process or food chain. HACCP guidelines were revised extensively in 1997 and promulgated. Much more recently, HACCP has added radioactivity to its list of hazards.

If your company is required to comply with HACCP guidelines—and they are applicable in food manufacturing to preparation processes such as packaging and distribution, as well as to retail sales and food serving—your steps are laid out in the seven principles of HACCP. The overriding goal of these principles is to prevent harm to customers (and also to mitigate damage to the reputation of your brand and customer loyalty). The plan's methodology emphasizes a systematic approach to the entire process, and the result is a HACCP plan and food safety system for your busi-

ness. The fundamentals of HACCP have been applied successfully to growing, harvesting, processing, manufacturing, distributing, merchandising, and preparing food for consumption. The details for each stage, industry, and business will be different, of course. (Prerequisite quality assurance, such as good manufacturing practices, is viewed as a foundation for HACCP success.)

Systematic Planning, Implementation, and Monitoring

Because the essence of HACCP guidelines is systematic planning and vigilance, their implementation at a company requires an across-the-board effort. This means that the plan must have complete buy-in from top management and the company must adopt a commitment to making food safety and quality an enduring priority. It means the kind of leadership that catalyzes the interest and commitment of employees at all levels. One tool of management is regular training in key con-

cepts, control points, standards, and best practices in monitoring different kinds of processes and stages in production (see “Employee Roles in a HACCP Program,” below).

The HACCP Team

All of these and other roles are defined by the HACCP team you form to create and launch the plan. Special knowledge and expertise, representation from various departments, and other considerations go into choosing your team. Depending on your industry, size, and any special issues, your plan might include production, sanitation, quality assurance, food safety, manufacturing, and operations. In addition, you probably will need to involve consultants with specific technical expertise. When creating your team, you'll want to think about the following elements.

Products and processes to cover: Get clear about your final food product—ingredients, recipes, and final product standards, for example—and how it is prepared, including materials, equipment, and processes.

Food product use and users: This element could be considered the public at large, but also, more specifically, babies and children, hospital patients, or members of the armed services.

Distribution and storage methods: A key variable, for instance, will be at what temperature the food is distributed (room temperature, chilled, frozen).

Employee Roles in a HACCP Program

- Sanitation standard operating procedures (SSOPs);
- Cleaning standards and schedules;
- Pest prevention;
- Individual cleanliness;
- Best practices for handling materials and ingredients;
- Proper storage methods;
- Management of manufacturing, storage, and cooking equipment (as applicable);
- Product tracing and recovery;
- Proper transportation methods;
- Supervising chemicals to prevent contamination; and
- Verification of qualified suppliers.

The procedure: How does the food move through the parts of the system that your firm controls? What are the stages where the HACCP process is vital, and what are the checkpoints?

Check your flow diagram on site: Whether your core team or an outside inspector handles this component, you must check the accuracy of the flow diagram “on the ground” and modify it as needed to both perfect and, if possible, streamline it. Usually, the more attention you bring to these “setup” steps, the better you will be prepared to apply the seven principles of HACCP.

Implementing HACCP Principles

FDA guidelines offer comprehensive guidance for the entire HACCP process, including instructions for each guideline, a glossary of key terms, diagrams, tables, and appendices. It is not the goal of this article to repeat that information, but to offer an overview of the seven principles—the essentials—and how they progress.

1. Conduct a Hazard Analysis

The HACCP system is built on the identification of hazards. In this context, a “hazard” is a “biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.” The standard is “reasonably likely,” and the preventive measures (control responses) are required to reasonably control the hazards. In other words, no complex, continuous process is perfect. The focus is on hazards that are reasonably likely to occur. Although your company is focused on quality, and safety is an aspect of quality, the HACCP process should focus resolutely on hazards and not quality.

An effective, comprehensive hazard analysis that follows the guidelines but zeroes in on your facility or retail location is of the essence, because each facility is different. If potential hazards are overlooked, no amount of adherence to a food safety system will protect you. In the same vein, the severity of the hazard, not in general but in your particular case, should correlate with the amount of effort devoted to it.

2. Determine Critical Control Points (CCPs)

A CCP is a step in your process—whether it is manufacturing or food preparation—

where the right procedure makes the difference between controlling a potential health hazard or failing to do so. Attention to CCPs in conducting your business reduces the risk of harm to the public. FDA guidelines illustrate a CCP decision tree useful in diagramming each CCP.

3. Establish Critical Limits

No operating conditions at every point are immutable. When your planning team has identified CCPs, the next step is to establish the range within which your process can vary at a given CCP without tipping over from a safe to an unsafe operation. These limits must be referable to scientific factors, guidelines, regulatory standards, experts, or experimental results. When challenged, the range you have set must refer to one of these justifications. A few examples might help you to concretize the kinds of factors to consider as you establish the range of allowable variation: humidity, pH, physical dimensions, salt concentration, sensory information (visual appearance, smell), temperature, time, viscosity, or water activity.

4. Establish CCP Monitoring Procedures

Once you’ve identified the CCPs that are relevant to your business and established safe ranges within which the process may vary, the challenge become monitoring them. Continuous monitoring that is accomplished electronically is ideal. The alternative is periodic or intermittent monitoring, which is often performed manually. When you automate, you increase the accuracy, control, and visibility of the process. By monitoring a specific point in the process, you will know if the trend is toward loss of control, and you can act to remedy the problem. You also record when a deviation occurs. Employees trained to conduct monitoring have to have accountability and, for this reason, must schedule their work and documentation outcomes.

5. Establish Corrective Actions

Deviations can occur in any process, so your corrective actions must be available to implement immediately. Determine the cause of noncompliance and correct the situation so that the CCP is back under your control. At the same time, you must decide on the appropriate way to dispose

of the non-compliant product, and document what you discovered and how you have managed the process. Your HACCP planning will identify the people responsible for these steps and where you will store the documentation of the steps taken.

Because the essence of HACCP is systematic planning and vigilance, its implementation requires an across-the-board effort.

6. Establish Verification Procedures

The HACCP process must not only perform its protective function; its performance at any given moment must be verifiable. You may verify your monitoring, but, more broadly, you will need to verify the successful operation of the HACCP system as a whole at your specific location and facility. This is not only product testing, as important as that may be. It is a direct, regular review of the HACCP plan itself. Initially, the goals will be to validate the plan’s technical and scientific aspects, which can be done through scientific studies, observations on location, measurements on location, or evaluations on location.

7. Establish Record-Keeping and Documentation Procedures

The systematic approach of HACCP requires objectivity, which makes it crucial to maintain records for all aspects of the HACCP and be prepared to be audited. The FDA guidelines give this enumeration of aspects of the system to be documented: core team, assigned roles and responsibilities, description of the product, intended use and consumer, flow diagram, CCPs, hazards likely to occur, critical limits, monitoring, corrective actions, verification procedure, verification schedule, and documentation procedures.

Applying an effective HACCP plan will ensure the safety and loyalty of your customers, your brand’s reputation, and the long-term success of your business. ■

Hansen is the VP of Technical Solutions at SafetyChain Software.

A Psocid-Free Facility

How to identify, prevent, and remove psocids from food processing facilities

BY SHARON DOBESH



When it comes to food processing pest management, some threats are more obvious than others. Signs of common pests—such as rodents, flies, and cockroaches—are usually hard to miss. Pests unique to the food processing and distribution industry, known as stored product pests, pose their own distinct challenges. One of these pests, the psocid, is particularly difficult to manage.

Food processing facilities can experience psocids as contaminants in or on ingredients and packaging, and these pests can quickly eat through your profits if left unmanaged. In large numbers, psocids can contaminate sizable amounts of product, especially when that product is left in storage, tainting ingredients and potentially altering the taste of products.

Part of what makes psocids so difficult to identify and manage is their nearly microscopic size. Psocids typically measure only one millimeter in length, appearing as tiny dots to the naked, untrained eye. Inspectors, however, know where to find them, and frequently do. While you might not recognize a psocid problem, your auditor surely will. To avoid learning about psocid activity in your facility from your auditor, you first need to know how to identify these minute pests.

Identifying Psocids

Psocids, also known as booklice or barklice, range in color from white to brown or grey. While only one millimeter in length, their bodies measure three times longer than they are wide, giving them an elongated, flattened appearance. Atop

their heads, psocids have long, thread-like antennae. The psocid head oftentimes looks too large for its body, with its widest point just before the start of the abdomen. Some species of psocids have wings that cover their abdomen at an angle, forming a roof.

Sightings of psocids can range from a few isolated individuals to millions coating surfaces. Once they are sighted, psocid treatment for a facility begins with iden-

Packing supplies stored in poorly ventilated, humid areas are especially vulnerable to psocid activity.

tifying what psocids are present. Psocids have different life stage characteristics that can require knowledge of what life stages are present and if there is a mixture of winged and non-winged individuals. Food processing facilities encounter eight common species, and food processing infestations can involve more than one species.

The reproductive habits of psocids further add to the challenge. Psocids develop from egg to adult in as few as 18 days. And, because adults can live up to three months, psocids can reproduce often, quickly, and for a significant period of time, allowing their populations to multiply rapidly. Certain species of psocids have an additional advantage. At least two species, *Liposcelis bostrychophila* and *Lepinotus reticulatus*, can reproduce parthenogenetically, meaning without the presence of a male, which further increases birth rates. The presence of a few psocids can rapidly increase to an infestation, unless they are dealt with efficiently and immediately.

Preventing Psocids

Fortunately, preventive measures for psocids can begin in house, once you know what to look for. Effective prevention methods help reduce or even eliminate conducive conditions. Conducive conditions are elements of the facility's environment that attract pests, and for psocids these include high humidity and sanitation issues.

Psocids thrive in humid environments, because one of their preferred foods is mold spores. Facilities located in climates with routine or occasional humid weather should inspect for psocids during the humid stretches of time. Packing supplies stored in poorly ventilated, humid areas are especially vulnerable to psocid activity. To help alleviate high humidity, facilities should consider adding environmental controls and preventing moisture when possible. The classic recommendations to correct higher moisture levels include portable heaters, fans, dehumidifiers, and other means to move air and promote reduction of humidity or dampness. Prevent added humidity further by avoiding wood pallets, which tend to hold moisture.

Psocids feed primarily on organic matter such as molds, fungi, and algae, but will also feed on starch-based materials such as grains and glues. Dust is another known harborage for psocids because molds and other food sources can occur with it. Psocid activity behind storage

racks can occur, since air movement is limited, allowing higher humidity, dust, and molds to accumulate. Facilities should store products to avoid dust buildup, placing the most susceptible supplies or products above floor level on racks where air circulation will be best. Regularly inspecting bags and packages containing starchy products can also be helpful in preventing psocid activity.

Involving Your Provider

While in-house efforts can help keep additional pests from entering, it's best to involve your pest management professional to address both conducive conditions and any existing infestations.

Though there's limited knowledge on the effectiveness of certain psocid treatments, some options are more likely to succeed than others. Temperature control, humidity control, organophosphates, and some grain protectants are some of the more effective psocid management strategies.

While optimum temperatures for psocid development range in the 80s and 90s (degrees Fahrenheit), their susceptibility to heat mortality increases in the 100°F to 140°F range, depending on the species, making heat control a potential treatment tool. Applying temperatures higher than 104°F can stunt the development of psocids, helping put an end to population expansion.

Based on the psocids species at hand and the location and extent of the infestation, your pest management provider will consider the specific needs of your facility and develop an effective strategy for control.

Psocids offer a unique challenge in pest management, so don't hesitate to call on a provider you can trust. With the help of your pest management provider, your facility can be psocid free. ■

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COVID-19 and Intentional Adulteration

How the pandemic may necessitate changes to your IA rule preparedness | BY CRISTINA BERNAL

Nearly two decades ago, before the Food Safety Modernization Act (FSMA) was enacted, food manufacturing facilities prepared themselves to protect the food supply from a threatened or actual terrorist attack by following the requirements of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, also known as the Bioterrorism Act. As a result, manufacturers were asked to consider the possibility of intentional adulteration for widescale public harm and took precautions to avoid it.

Under the law, manufacturers outside of the U.S. registered with the FDA and provided advance notice of their food shipments entering the country, among other requirements. Initial precautions were also intended to guard against intruders enter-

ing manufacturing facilities. For some, this included installing reinforcement gates, posting guards at facility entrances who were trained with protocols to ensure that only approved people entered the facility, investing in CCTV to monitor the exterior of the facility, and implementing additional security procedures. These efforts have helped keep strangers from entering manufacturing facilities and harming the public through food adulteration.

Then, in January 2011, FSMA was signed into law and, on May 27, 2016, FDA issued the Intentional Adulteration (IA) final rule (21 CFR 121: Mitigation Strategies To Protect Food Against Intentional Adulteration). This rule, also referred to as “the Food Defense rule” or “the IA rule,” was initially scheduled for implementation in May 2019, three years after the final rule

was issued. However, FDA modified the implementation dates to start in July 2019, with three different compliance dates, depending on FDA’s description of business size.

One of most significant differences between the Bioterrorism Act and the IA rule is that the latter requires food facilities to implement mitigation strategies not only for keeping external intruders from entering the food facility, but also to prevent a person or people already inside the facility from intentionally contaminating food with the goal of extensive public harm. In reviewing your food defense plan, it’s worth considering how to best respond if an employee or contractor is persistently non-compliant with the rules of the facility or exhibits other behavior that can negatively affect the operation. This is particularly important if the behavior can impact the implementation of one or more mitigation strategies, which would necessitate corrective actions and sometimes a modification of the impacted mitigation strategies or even a change of the person or people responsible for monitoring them.

Another significant difference between the Bioterrorism Act and the IA rule is the involvement of the human resources (HR) department. Because the focus of the Bioterrorism Act was to prohibit external people from entering the facility, and internal personnel behaviors were not necessarily considered, the role of HR was not fundamentally as significant as it is now. Complying with the current IA rule necessitates looking at both external and internal threats, so it’s important that the HR department be involved as part of the food defense team.

Since the introduction of the IA rule, manufacturers have prepared by implementing their food defense plan per rule requirements, finalizing their written vulnerability assessment, implementing the mitigation strategies chosen by the facility to minimize or reduce the risk in the corresponding step of the process where a significant vulnerability is identified, and ensuring their personnel are trained as qualified individuals to comply with the law. While each manufacturer has been challenged in modifying their programs to attain compliance with the IA rule, most have found a way to fulfill the

(Continued on p. 32)



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(Continued from p. 30)

requirements and are confident in their preparedness.

However, COVID-19 has introduced some complexities.

Impact of COVID-19 on IA Compliance

Just as FDA inspections for the IA rule were scheduled to begin in March 2020 for certain businesses, domestic and foreign inspections were postponed due to the emerging global pandemic. Although the coronavirus (SARS-CoV-2) that causes COVID-19 is not a food safety issue, as it is understood that it is not transmitted by food or food packaging, its impacts on the food industry have been unprecedented.

While consumer demand for food at retail rose, due to more people eating at home, and retailers expectations increased to promptly meet that demand, food manufacturers encountered an array of obstacles to support increased production. Impacted by ingredient and supplies shortages, including a shortage of personal protective equipment and sanitizing solutions, some manufacturers even turned to their crisis management plans to help mitigate the initial impacts. Personnel then began falling ill with the virus, and additional measures and restrictions were enacted around the world to help control the spread of the disease. Suddenly, the pandemic had upended the food industry’s “normal.” For many, it’s also added new complexities to complying with the IA rule.

Revisiting Your Food Defense Plan

In 21 CFR 121.157, the IA rule states that a re-analysis of your food defense plan should be conducted every three years but should be done earlier (the complete food defense plan or sections of the food defense plan) “whenever there is a significant change made in the activities conducted at the facility, whenever new information becomes available about potential vulnerabilities associated with the food operation or facility, whenever the mitigation strategies are not properly implemented, and whenever the FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, and development in scientific understanding.”

While the IA rule is very clear in its statements regarding the reanalysis of

your food defense plan and when it’s necessary to do so, there continue to be questions about how these plans should be updated and where to start. Two of the key reasons for reanalyzing your food defense plan and a good place to start with that review are based on those “significant changes” (21 CFR 121.157 (b)(1)) and “potential vulnerabilities” (21 CFR 121.157 (b)(2)) as defined in the rule. In

The pandemic has upended the food industry’s “normal.” For many, it’s also added new complexities to complying with the IA rule.

response to the pandemic and the associated operational disruption, there have been “significant changes made in the activities conducted at the facility” by most manufacturers, as specified in the IA rule. As the impacts associated with the pandemic have been so fluid, it is also likely that “new information becomes available about potential vulnerabilities associated with the food operation or facility,” again as noted in the rule. Each of these scenarios should be analyzed to determine how they impact your food defense plan.

These operational disruptions may have occurred for any number of reasons, including increasing the focus on employee health and safety through the use of face masks and face shields; entering the facility only after a temperature check and sometimes even after participating in a health check assessment; adjusting infrastructure to comply with required social distancing or the addition of physical barriers on production lines, in breakrooms, locker rooms, and meeting rooms; rearranging personnel schedules to avoid large gatherings; and reallocating or hiring staff to meet increased production demand. Each of these changes and many others made in response to the pandemic are worth analyzing as part of the implementation of your food defense plan.

For instance, as an example of a change made during the pandemic, employees may not be appropriately donning and doffing their face masks. This may result in an environment where the coronavirus is actively being spread to others by an asymptomatic employee in the immediate area. It then becomes worth considering whether a non-compliant employee is doing this on purpose and, if so, determining whether the employee is intentionally contaminating their surroundings and the manufacturing area they work in. Another example could be the reduction of all-staff meetings to avoid contact in large groups. This may create an environment where communication breaks down and employees are not receiving complete directions about updated processes or procedures they should comply with, such as the behaviors expected in the facility and the correct ways to monitor the mitigation strategies.

The Path Forward

If it is found that these or other changes to the operation develop into a significant vulnerability that needs a mitigation strategy, or these changes are keeping mitigation strategies from being properly implemented, then additional strategies will need to be implemented. Further training and supervision may also be necessary and warrant increased involvement of HR. This will help ensure that all of your personnel receive the necessary support and direction in this new normal, while limiting the number of disgruntled employees in the facility. Situations that create new significant vulnerabilities without corresponding mitigation strategies could be considered potential violations and non-compliant, as the FDA inspects the facility as part of the IA rule.

As you continue to navigate through the pandemic and make further changes to accommodate evolving circumstances, analyze the impacts of these changes to determine whether they should be considered potential vulnerabilities as part of your food defense plan. Taking such an approach will help ensure compliance with FSMA’s IA rule, even during these difficult circumstances. ■

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My Sample Tested Positive ... (Continued from p. 13)

that affected companies prepare to conduct a very thorough analytical investigation involving testing of the consumer's product sample, retain samples from the same and other manufacturing runs, and perhaps gather additional retail samples of the product. If companies believe that the complaint has absolutely no basis (e.g., no peanuts in that product or the manufacturing plant), they might wait for analysis of the consumer's sample before conducting additional analyses. Certainly, if you test a sample obtained from a consumer, a non-detect result will ease your anxiety and likely preclude any further testing.

Testing Can Provide Clues to Root Cause

If you have received a positive allergen test result and perhaps have recalled a product, you should try to determine the root cause of the situation. Sometimes the cause may be clearly identifiable, but not always. The chance of subsequent episodes will be substantially lessened if you can identify this root cause and take corrective action.

Test results can help to identify the root cause of the undeclared allergen. If multiple samples of a product are tested from one, or preferably, several manufacturing runs, and all of these test samples are positive with reasonably consistent levels, the root cause is probably an ingre-

dient. Ingredients are added to every batch of a product at consistent levels, and a contaminated ingredient will lead to consistent levels of allergen in multiple samples of the final product. Rework can also lead

Saving retain samples from each manufacturing run of each product can be a lifesaver in situations where unexpected analytical results appear.

to multiple positive samples, but rework is not often consistently used at the same levels from one run to another, so analysis across several manufacturing runs will reveal differences. Sporadic but higher-level positives throughout one or more manufacturing runs can point to a contaminated particulate ingredient. The particles of the allergen may not show up in every sample. If inadequate cleaning is the basis for the undeclared allergen, then samples from the beginning of the run after changeover will be more positive than samples taken later in the run. Furthermore, unless the cleaning is uniformly inadequate, samples from a separate manufacturing run will not be positive.

Saving retain samples from each manufacturing run of each product can be a lifesaver in situations where unexpected analytical results appear. Then, it is possible to trace allergen levels through multiple manufacturing runs and dates. Additionally, saving retain samples of each lot of each ingredient can be very helpful in root cause investigations. Ideally, retain samples are collected from several points throughout the lot of production such as the beginning, middle, and end of the product run.

Hopefully, you will now be well prepared for the occasional unexpected positive test result obtained from your selected external laboratory. Ask the right questions. Gather all of the appropriate information. If you want to call FARRP experts, we are available at any stage of the investigational process. Following the strategy outlined in this article can save you from anxiety and headaches.

Knowledge is power! ■

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Testing



Cereal Grains Testing

While traditional testing methods continue to be the gold standard, newer methods for rapid detection have emerged

BY MARY BETH NIERENGARTEN

A successful business relies on developing and maintaining consumer trust and confidence in the products they buy. For food manufacturers, building this trusting relationship is even more essential, given the primary importance of food to health and well-being. A product contaminated with microorganisms or toxins that may cause foodborne illness can taint consumer confidence far beyond the product recall.

As a staple ingredient in many food products, cereal grains play a prominent role in the food supply chain. Corn, wheat, barley, rice, oats, rye, millet, and sorghum are the main cereal grains used worldwide as the raw materials for many

food products, such as flours, cornmeal, breads, pasta, breakfast cereal, cakes, and tortillas, and for beverages such as beer. Over the past 50 years, worldwide production and yield of these grains has increased to meet the needs of a growing population.

Given the critical and growing reliance on these grains worldwide, ensuring their quality and safety is vital for a strong and reliable food supply chain. The safety of these grains has come under particular scrutiny over the past years due to outbreaks of foodborne illness and recalls attributed to contaminated wheat flour. A 2019 study, published in the *Journal of Food Protection*, was conducted to assess a baseline level of contamination of patho-

gens in more than 5,000 raw wheat samples prior to milling and found the prevalence of *Salmonella* (1.23% of the samples), *Escherichia coli* (0.44%), and *Listeria* spp. (0.08%) was sufficiently high to indicate a risk for foodborne illness. Along with the health risk, the investigators underscored the potential subsequent loss of revenue for food manufacturers, and a subsequent dent in consumer confidence (*J Food Protection*. 2019;82:1022–1027).

Understanding the ways in which cereal grains can be contaminated, the types of tests used to mitigate that risk, and gaps and vulnerabilities that persist in ensuring the safety and quality of cereal grains is important for food manufacturers, who must know their food supply chain. “Knowing the origin of the bulk commodity and understanding the processing interventions used by the supply chain to ensure food safety is important, as you can predict some of the quality and safety defects that might occur,” says Douglas L. Marshall, PhD, CFS, the chief scientific officer for Eurofins Microbiology Laboratories in Fort Collins, Colo. “Testing for both desirable quality attributes and for detrimental food safety hazards improves trust in the supply chain and keeps everyone honest.”

Newer Tests for Safety and Quality

Infectious microorganisms such as *Salmonella* and *E. coli* are considered major types of biological hazards to food safety associated with grains. Mycotoxins are another type of biological hazard. Along with these, cereals can also be contaminated by chemical and physical hazards (See “Table 1. Potential Contaminants of Cereal Grains,” p. 35).

Much of the testing for safety of cereal grain is focused on biological contaminants, as these can occur throughout the grain supply chain—from crop growth through harvesting and post-harvesting drying and storage—and may directly affect the quality and safety of the grains used for milling and food production.

“[Cereal grains] are biological materials, living and breathing materials that continue to respire after harvest,” says Gerardo Morantes, PhD, director of food safety at Plymouth, Minn.-based Bühler, a food processing and manufacturing technology group. “Best agricultural practices,

Table 1. Potential Contaminants of Cereal Grains

Biological	<ul style="list-style-type: none"> • Mycotoxins, which are fungal toxins such as aflatoxin, ochratoxin, and tricothecenes that may be produced naturally during production in the field or during grain storage; elimination once present is difficult. Physical separation (i.e., during grain cleaning, selection, and milling) is the most effective mitigation measure • Pathogenic bacteria such as <i>Salmonella</i> and <i>E. coli</i>. Risk mitigation, for example in wheat, includes using organic acids and salts during the tempering step of milling or thermal treatment of the final flour
Chemical	<ul style="list-style-type: none"> • Harmful substances such as heavy metals in soils or irrigation water in agricultural environments, or agricultural chemical residues (i.e., pesticides).
Physical	<ul style="list-style-type: none"> • Foreign objects that may be harmful if ingested, such as sticks and stones

Table 2. Rapid Detection Tests for Microbiological Hazards

Hazard	Tests
Microbial (pathogenic bacteria)	<ul style="list-style-type: none"> • Polymerase chain reaction (PCR)-based methods • Targeted or whole genome sequencing • Matrix-assisted laser desorption/ionization–time of flight (MALDI-TOF)
Mycotoxins	<ul style="list-style-type: none"> • Enzyme-linked immunosorbent assay (ELISA) • Multi-contaminant screens using liquid or gas chromatography with mass spectrometry (also used to measure pesticide residues)

weather events, and supply–demand cycles will have an effect on every single crop produced.” Food processors, he adds, should keep this in mind when sourcing these grains, as the quality and food safety challenges faced throughout the food supply chain are directly related to these factors.

Dr. Morantes describes mycotoxins as a universal hazard addressed by all supply chains worldwide. More recent attention and allocation of resources, he says, are focused on infectious microorganisms, such as *Salmonella*, to better understand alternatives in risk mitigation to prevent foodborne outbreaks such as those recently caused by contaminated raw flour.

Andrea Bianchini, PhD, an associate professor in the department of food science and technology at the University of Nebraska in Lincoln, highlights how important it is for food processors to recognize the emerging hazard posed by pathogenic bacteria. “Until 10 or 15 years ago, microbiological concerns related to grains perhaps were more directed to molds and their potential to produce mycotoxins,” she says. Today, she adds, food scientists understand that pathogenic bacteria can also be associated with these products.

According to Dr. Bianchini, traditional methods continue to be the gold standard for reference testing for both mycotoxins and bacterial contaminants, but newer methods for rapid detection have emerged.

Dr. Morantes says that, unlike traditional culture-based methods that can take up to five days for preliminary results, rapid testing can significantly reduce the time needed to make an informed decision about the release of a product. This in turn, he says, can have significant implications for preventing foodborne outbreaks and reducing food losses.

Table 2 (below) lists a number of these newer rapid detection tests. Of these, Dr. Bianchini says that ELISA and PCR-based methods are the most commonly used. “No matter what testing platform is used, it is important that it be validated for the matrix (e.g., flour) in which it is to be used so [that] results obtained with the rapid methods are equivalent to those obtained using standard methods,” she says.

To ensure quality in cereal grains, Dr. Marshall underscores that the quality determines whether the grain is fit for use in a certain application. “The proximate composition of the grain determines its functional properties, such as amount of starch, protein, lipid, fiber, and moisture,” he says. “For example, the protein content of wheat dictates its performance as flour for pastas, breads, or cakes.”

Devin Rose, PhD, an associate professor of food science and technology and agronomy/horticulture at the University of Nebraska in Lincoln, says that the definition of quality in cereal grains means different things, depending on the industry. “Among others, wheat growers are concerned with disease resistance, drought tolerance, protein concentration, and yield; millers are concerned with wheat kernel size, shape, weight, hardness, and protein concentration; and bakers are concerned with such things as protein quality and sprout damage,” he adds.

Although many tests for cereal grains analysis are not new, Dr. Rose says that new applications are being discovered daily. He and Dr. Marshall highlight a number of new tests currently in use (see Table 3, below).

Table 3. Newer Ways to Test the Quality of Cereal Grains

Single kernel characterization system	Measures dimensions and hardness of kernels
Farinograph, extensograph, alveograph, mixograph	Instruments that measure the rheology of wheat flour doughs
Optic sensors	Automatically cull defects and sort by size, shape, and color
Near infrared spectroscopy	Rapidly measure proximate composition of grains

Dr. Morantes highlights the new possibilities with near infra-red spectroscopy for measuring gluten, water absorption, and starch damage in wheat flour milling. “By using this type of analysis, it’s possible to assure constant product quality, which makes a consistent contribution to the profitability of mills,” he says.

(Continued on p. 40)

The Effect of Microplastics on Oysters

Microplastics can have a negative impact on our food chain, both by contaminating the seafood we eat and by harming seafood populations

BY JAMES CIZDZIEL, PHD



Plastics continue to be produced at an unprecedented rate. While they may be cheap and convenient, plastics can also take hundreds of years to decompose, and are accumulating at an increasing speed in our environment.

Microplastics, composed of plastics that are 100 nm to 5 mm in size, are a classification of plastic that has either been deliberately manufactured at that size or has degraded from larger pieces of plastic. Plastics have been found almost everywhere in the environment, from the tops of remote mountains to the depths of oceans, with samples even collected from snow in the Arctic. In addition to polluting our air, water, and soil, recent studies have confirmed the presence of unwanted microplastics in common consumer products such as salt and bottled water.

At the University of Mississippi, we are conducting research to help us better characterize and understand the prevalence of microplastic pollution in oyster reefs and other coastal sites in the Mississippi Sound along the Gulf Coast. Through this research, it's our aim to better understand the prevalence and threat of microplastics in order to better inform our ability to regulate and prevent this emerging containment from further entering our environment and our food chain.

Understanding Microplastics as an Emerging Environmental Contaminant

Microplastics have polluted our environment and are now pervasive in our oceans, lakes, rivers, air, and soil. Our oceans face an acute threat, with an estimated four to 12 million tons of plastic waste entering the oceans every year, posing a serious environmental threat to aquatic species.

Microplastics are damaging our ecosystem and negatively impacting our ocean life, threatening disruption and damage to the digestive tract if ingested. They also raise the risk of entanglement and a host of other negative consequences for aquatic species.

This interaction between microplastics and seafood can also have a negative impact on our food chain, both by contaminating the seafood we eat and by harming seafood populations. The majority of our seafood comes from estuaries and coastal areas, such as oyster reefs. It is in these estuaries and coastal areas that microplastics accumulate, due to the continual input and degradation of plastic litter from rivers and runoff.

Filter feeders like mollusks and oysters (*Crassostrea virginica*) are particularly vulnerable to microplastic pollution. However, few research papers have investigated the exposure of microplastics in oysters or by oyster reefs.

A Closer Look at Oyster Populations in the Mississippi Sound

Microplastics pose a significant threat to oyster populations, which have already decreased in recent years due to a combination of pollution (e.g., oil spills) and weather events, such as hurricanes and flooding.

To better understand this issue of microplastic prevalence in oyster habitats, we recently conducted a study examining the concentration of microplastic pollution in oyster reefs and other coastal sites in the Mississippi Sound, as well as the impact of freshwater inflows from flooding to these sites. We collected water samples from 10 sites, of which four were directly above oyster reefs.

Recent studies show that oysters nearer urban centers often contain higher concentrations of microplastics, which, given the prevalence of commercial fishing, oil drilling, and shipping ports in the area, implies that the Gulf Coast could be accumulating a considerable number of microplastics.

This was consistent with our findings, which estimated that oysters may be exposed to nearly 24,000 microplastics daily (range ~5600 to ~36,000), understanding that concentration and filtering rates vary depending on other factors such as site-specific conditions and oyster species. To put this into perspective, humans are

estimated to consume anywhere between 39,000 to 52,000 microplastic particles a year, meaning oysters are potentially exposed to half of our annual exposure every day. Overall, the study concluded that seawater along the Mississippi Gulf Coast had higher abundances of microplastics than what was observed in the Mississippi River and its tributaries to coastal areas.

The study also confirmed that estuaries have higher concentrations of microplastics than their riverine inputs, a finding uncovered in other studies as well. Given that the river is continually flushed of plastics, this is not surprising, because the estuary acts as a sink for these plastics, which, over time, degrade to form microplastics.

Research Methods

The microplastics particles that we are analyzing are often so small that they are invisible to the human eye. The number of microplastics actually increases with decreasing size, which calls for sophisticated analytical instrumentation and a robust research approach.

To analyze the abundance of microplastics in these oyster reefs and understand their potential threat, we used three key research methods: “the single one-pot” method for sample preparation, Nile red fluorescence to quantify the collected microplastics samples, and LDIR analysis to identify the major types of plastics in the collected samples. The “single one-pot method” is a novel approach developed by our lab that involves utilizing inexpensive jars, such as mason jars, to collect and prepare water samples for analyses. The advantage of this method is that it minimizes contamination and sample loss, because the sample is processed in the same jar in which it is collected, and the process successfully isolates microplastics needed for analyses.

These microplastic samples were then quantified using Nile red fluorescence detection. Adding a few drops of Nile red dye onto filters with microplastics reveals the exact quantity of microplastics within the samples. To identify the key types and size fractions of plastics in the collected samples, Agilent’s 8700 system was used. This instrument is the first major application of LDIR analyses to determine, characterize, and identify microplastics in natural waters.

A combination of the instrument’s proprietary quantum cascade laser (QCL) with a single-point mercury cadmium telluride (MCT) detector and rapid scanning optics allowed for two effective modes of action. By actioning these techniques, particles are located in the first step, and then information on the size and shape of particles can be obtained. In the second

Existing research already supports the fact that plastic contaminants pose a threat to aquatic organisms, and it’s very possible that these plastic particles also pose a threat to our own health, given the rate that they are entering our environment and our food chain.

step, a full spectrum is acquired for each particle, while the surrounding areas are ignored. This information is then compared to a spectral database built into the software in a fraction of the time needed with a traditional FTIR system.

The Critical Nature of This Research

Due to mass plastic production, there is now an extensive and increasing amount of microplastics in our environment, and scientific research has not yet uncovered an effective method to entirely remove these particles. Because this is a relatively new threat to the environment, further research needs to take place to understand the true impact of these pollutants, but one thing we do know is that these contaminants do not belong in our environment at all, and certainly not on such a large scale.

Existing research already supports the fact that plastic contaminants pose a threat to aquatic organisms, and it’s very possible that these plastic particles also pose a threat to our own health given the rate that they are entering our environment and our food chain. The research we are conducting at the University of Mississippi is

essential to filling in blanks on a known threat to our ecosystem. There is hope that this research could go on to inspire further needed research on the topic and inform our understanding of the exact nature of this threat to human and animal health.

Such research has the potential to guide policymakers in developing needed strategies to control and mitigate this environmental threat and provide evidence to regulate the use of our plastic.

One caveat, however, is that different labs around the world performing microplastics research adopt different testing approaches. These variations may hinder the accurate determination of the fate of microplastics and its global distribution across our oceans. Therefore, global harmonization and standardization of monitored microplastics testing methods is essential if we are to transform this investigative research into routine environmental screening procedures.

Our research has provided evidence of the abundance of microplastics in an area of critical ecological and commercial importance in our region. It’s important that we continue investing in new ways to research and understand contaminants like microplastics if we are going to make progress in the fight against them.

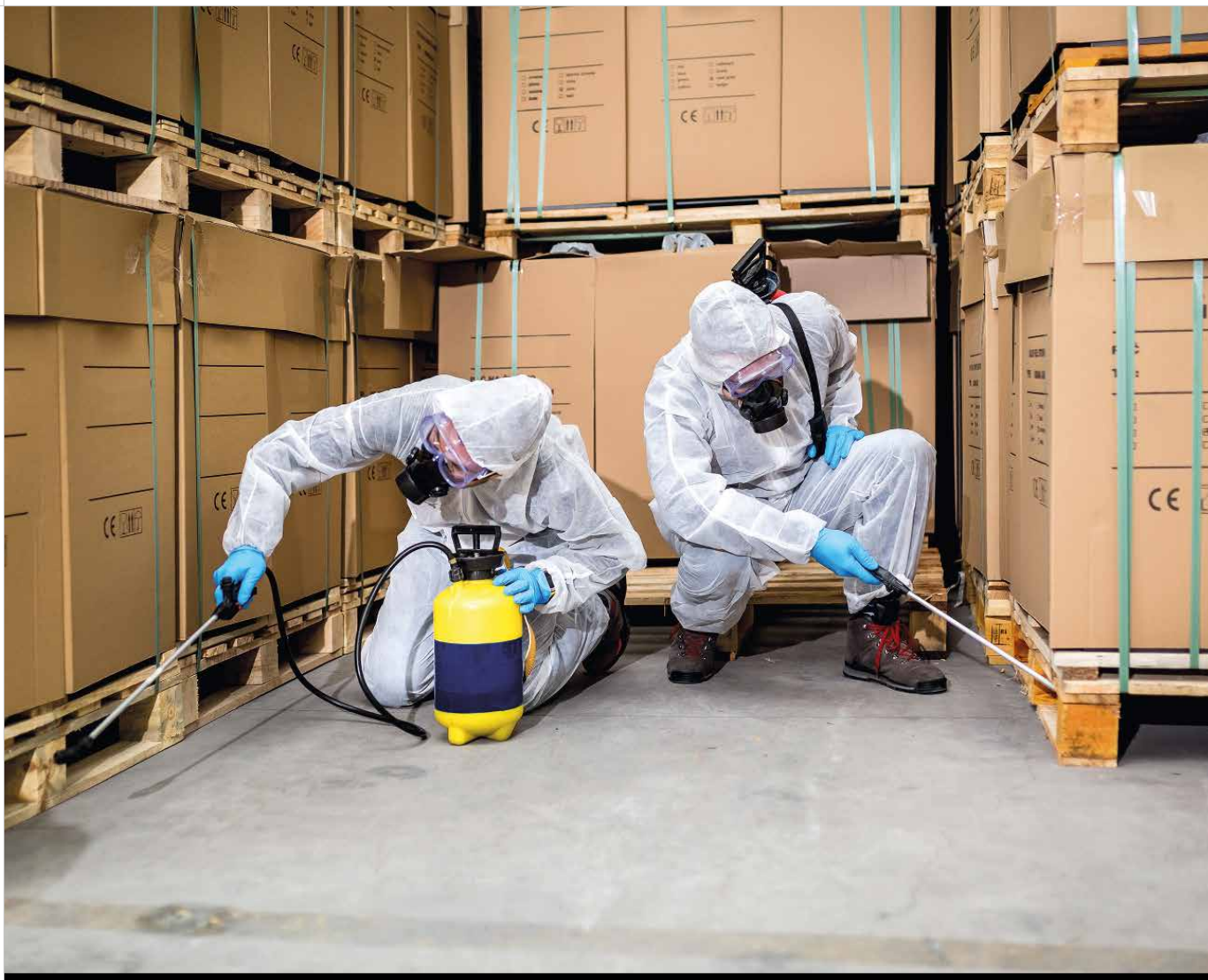
The future of microplastics testing needs widely accepted reference materials so that researchers can use them to assess methods and harmonize plastic pollution research. Also, additional scrutiny needs to be placed on analyses of fibers, which are often excluded from studies or not integrated within a broader context. Lastly, work needs to continue on the complex interactions between microplastics and other marine pollutants to address ongoing questions regarding the potential health risk associated with microplastics.

Academia, along with the life sciences industry, policy makers, and the public must all work together to reduce this type of pollution in our environment and to find new and innovative ways to remove that which is already there. It’s in our interest and that of future generations that we act now. ■

References for this article are available upon request.

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Manufacturing & Distribution



Pest Traceability and Your Business

How to monitor and track pests in your facility | BY GLEN RAMSEY

It's no surprise that one small pest issue in a food processing facility can quickly become a major issue for an entire supply chain. Not only can pests threaten your bottom line and employee well-being, but they can also tarnish your reputation and delay operations. All of this can become costly, which

is why it's important to follow industry regulations and prioritize food safety.

Pests can hitchhike across borders in transportation vehicles and travel in and out of your facility unnoticed via packaging. These critters need food, water, and shelter to survive and, unfortunately, food processing facilities provide ample

amounts of these attractants. Unlike some other industries, food processing plants have continued to operate during the coronavirus pandemic, making them a prime target for pests.

And while you may be taking all the right steps to ensure that a safe, quality product reaches consumers, you can't al-

ways guarantee that your suppliers' pest management programs are as effective as yours.

An integrated pest management (IPM) plan takes a proactive approach to pest control by implementing preventive measures, rather than reactive actions, to help keep pests away. Infestations can be costly and wreak havoc on your facility operations, bottom line, and reputation. Being proactive about pest management will help ensure that all food products leaving your facility make it to their next stop in the best condition.

Traceability is a key part of an effective IPM program; it can help keep pests out of your facility and, should they enter, help ensure they are taken care of promptly. As food supply chains become more connected, traceability and monitoring become more important.

Common Pests

To trace and monitor pests, you need to know what you're up against. Here are some of the most common pests:

- **Rodents.** One of the filthiest pests that can crawl through your facility is a rodent. Mice and rats can squeeze through small spaces and gnaw through tough materials. In addition to causing structural damage, rodents can contaminate your food products and spread diseases via their urine and droppings, making it essential to always maintain a sanitary facility.
- **Cockroaches.** Cockroaches carry more than 45 pathogens on their bodies, including *E. coli* and *Salmonella*, and can spread these across your facility by simply crawling around in search of food. Because they feed on almost anything, they can easily escape notice as they contaminate your food supply. They can also cause discomfort for your employees and trigger allergy issues.
- **Ants.** These critters are so tiny that they can migrate in and out of your facility almost completely undetected. Don't be fooled by their size though; ants leave an invisible pheromone trail to notify other ants once they've found a food source.

Be sure to discuss hot spots so your employees know where to focus their efforts. From triple checking deliveries and

shipments at the loading dock to disinfecting production floor equipment after each shift, little actions will go a long way in helping to prevent an introduction.

Tracking and Traceability Plans

Documentation is an important part of a food processing facility's audit preparation and, if you have a reliable pest management partner, it's likely that they have

Traceability is a key part of an effective IPM program; it can help keep pests out of your facility and, should they enter, help ensure they are taken care of promptly.

extensive pest tracking and trending information. This information can help you and your pest management partner find the source of pest issues.

Let's discuss the documents you should have on hand.

Food safety plan. Your food safety plan is the most important part of your documentation. Included in your pest management section should be details about all proactive measures taken to ensure that your food products are safe from pests. All corrective actions, potential hazards, and other steps to reduce risk should also be included in this document. If you use monitoring and verification procedures and have information on your suppliers' pest programs, you should include that as well. This shows you are monitoring incoming and outgoing shipments for pest activity and taking actions where necessary to prevent pests from infiltrating the supply chain.

Monitoring devices and traps. These are often used for tracking pests and minimizing their populations. Your pest control provider should have data for each device that details their location and pest activity levels. Some pest control providers even gather this information remotely and store it digitally for easy data visualization and record management. Make sure you work with your pest control provider to obtain the trend reports from these devices so you

can use the insights to revise your current pest management plan, as needed, and prove to your auditors that you're being proactive in your pest control efforts.

Annual assessments. Review your IPM plan with your provider annually, at a minimum. Make a note of pest problems that occurred and discuss resolutions for them accordingly. By performing these annual assessments, you'll be able to spot recurring problems quickly and develop more targeted solutions.

Sighting reports. Your facility should have a logbook for recording pest sightings and, if your staff doesn't already have access to it, they should. These will help your pest control provider perform thorough investigations of pest activity and make more accurate recommendations.

List of service changes. Your IPM program should change as your pest pressures do. No two food processing facilities are the same, and a variety of external factors can cause pest pressures to shift periodically. Whenever you make a change to your pest management program, be sure to note how you changed your program and why you implemented those changes.

Tracing and monitoring pests requires a team effort. In addition to staff training from your pest control provider, communicating with your supplier and distributors is important. It might seem as if it will damage your reputation to share news about documented pest issues with your supply chain, but it's quite the opposite. Keeping your suppliers and distributors informed of pest issues within your facility can help protect the rest of the supply chain from pests.

Pests will go to any lengths to get food, water, and shelter—especially during a pandemic. If you aren't already implementing traceable policies in your facility, now is the best time to start. In addition to a strong IPM program, finding and removing pests will be easier for you and your pest control provider with these traceability policies.

While pest pressures won't stop immediately, these tactics will help uphold food safety regulations and protect your business in the long run. ■

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Environmental Monitoring and Sanitation *(Continued from p. 25)*

Programming errors or changes can cause incorrect valve pulsing and sequencing, which may send cleaning solution down the wrong flow paths or release excessive amounts of heated solution to the drain. Additionally, incorrect valve pulsing may lead to decreased flow rates. Installation errors, such as incorrectly installed valves, process dead legs, and non-uniform pipe sizes, may result in unsanitary lines and bacterial contamination risk.

Temperatures of liquids that are above parameters for the soil can cause proteins to denature (unfold), exposing bonds that strongly adhere to surfaces. Liquids that don't meet temperature requirements may not dissolve soils, as in the case of sugar removal. Thermocouples and resistance temperature detectors (RTD) can be used to measure the temperature in the system. As with any temperature measuring device, calibration must be conducted for accuracy.

Conductivity measurements indicate interfaces between ionic cleaning solu-

tions and non-conductive water. Conductivity can be an indication of chemical concentrations and its removal from the system. The meter calibration must be maintained on a routine basis or drift can occur. If chemical concentration is in doubt, test kits provided by the chemical supplier can be used. Ensure that the reagents in the kit are not expired and that kit instructions are followed accurately. As a fast test, pH paper can be used to confirm acid or alkali presence, but should be followed up with a test kit for confirmation. Further, water hardness (calcium carbonate) and any mineral deposit build up will impact the effectiveness of the sanitizers used. Testing the parts-per-million (ppm), mg/L, or grains per gallon of calcium carbonate in the facility water will point chemical suppliers to the needed chemicals and temperatures for maintaining effective and efficient CIP functions (See Table 1, p. 25).

In conclusion, a CIP system can deliver cleaning and sanitizing functionality with

reduced operating costs. When issues arise, it is often due to system drift, minor operator adjustments that compound over time, not setting up, or trending metrics. While cleaning performance is a main CIP issue, the root causes are most often caused by reduced flow rate, a main component of temperature and chemical synergistic effect, followed by disparate temperature or conductivity values. Conducting consistent system analysis by measuring key metrics will drive CIP efficiencies and effectiveness. ■

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Cereal Grains Testing *(Continued from p. 35)*

Gaps and Vulnerabilities in Testing

Dr. Bianchini notes that, although the potential for contamination of cereal grains from mycotoxins and bacterial pathogens always exists, ensuring food safety will require more than relying on sample testing alone because of the low incidence and low levels of toxins and bacterial pathogens that will be found.

Instead, testing needs to be a part of a preventive approach to food safety that may include screening methods, she says. For example, testing for indicator organisms can help reduce the amount of inferior or low-quality products from reaching the market. "We still have knowledge gaps

that must be addressed, like a better understanding of routes and sources of these contaminations, natural frequency of occurrence and incidence levels, and the effect of emerging or innovative processing technologies on these contaminants," she adds.

Dr. Morantes highlights the prohibitive cost of cereal grains testing that restricts testing protocols based on a reliable, statistically sound sampling of the grains and reduces such testing to "finding a needle in a haystack," as he puts it. "As rapid-testing technology further develops, the potential to decrease cost without sacrificing accuracy opens

up opportunities for improvement," he says.

The need for rapid testing is also a priority for quality testing, according to Dr. Rose, who underscores the challenge of how long it takes to evaluate the end-use quality of cereals. "Baking bread, for instance, takes several days to prepare and analyze flour and then several hours to make the bread," he says. "Efforts are always underway to establish rapid methods to assess the quality of cereal without having to go through the long processes of making food products." ■

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NEW PRODUCTS



HTS Total Aflatoxins and DON ELISA Kits

PerkinElmer has released the MaxSignal HTS Total Aflatoxins and DON ELISA Kits, which feature automated mycotoxin testing workflows. Using the new assays and automation, food safety QA managers and lab teams at grain processors, feed mills, pet food companies, and contract labs can process up to 192 samples in less than 90 minutes. In addition to the significant improvement in productivity (or sample throughput), the new solutions handle complex matrices with high sensitivity and accuracy. The workflow is designed to “set it and forget it,” which minimizes the need for manual intervention, reducing the risk of manual error and helping the customer meet their regulatory standards. Particularly designed for complex matrices such as finished feed, grains, and oil seed by-products and pet food ingredients, the new automation solution enables aflatoxin and DON analytes to be extracted from a single sample. ELISA assays can also run in parallel. To further deliver ease of use and efficiency, ready-to-use reagents and standard operating procedures are included. Assays are highly sensitive, with detection levels of less than 2.6 ppb for total aflatoxins and 1.6 ppm for DON. Providing hands-free sample dilution and distribution, the automated system reduces cross-contamination and features an integrated barcode scanner for sample traceability. It can also integrate with LIMS systems for optimized and convenient result recording and analysis. **PerkinElmer, perkinelmer.com/category/food-safety-quality.**

Peroxide-Based Foaming Detergent

Madison Chemical introduces Pure-OX FOAM, a peroxide-based foaming detergent specifically formulated for tough organic soils on equipment or floors, walls, ceilings, shelves, and other surfaces within food processing environments. With the self-foaming characteristics of peroxide, the detergent provides cleaning power and convenience in a single package. Once the powerful oxidation reaction is complete, the degradation products are oxygen and water, so Pure-OX FOAM will not add salt, or conductivity to water discharge, nor will it impact wastewater pretreatment operations. Ideal for foam cleaning, it readily breaks down proteins, fats, greases, oils and other organic soils found in food and beverage processing facilities, especially dairy, poultry, wine, meat processing, and more. **Madison Chemical, madchem.com or solutions@madchem.com.**



Container Food Dryer

The Nyle Container Food Dryer features a dehumidification unit, air handling equipment, and touchscreen controls that create a fully controlled climate within the re-engineered shipping container. The customer can choose and customize racks, shelves, trays and/or carts that the product will be dried on within the container chamber. The dryer is pre-fabricated, can be moved, and



Plate Reader

3M Food Safety has released the Petrifilm Plate Reader Advanced, a new automation technology that gives food safety professionals new options to rapidly image, count, and document microbiological colonies on 3M Petrifilm Plates indicator tests. The plate reader is a small, peripheral device containing a five-megapixel camera and versatile bar code reader. The device uses fixed artificial intelligence networks to enumerate 3M Petrifilm Plates, which are inserted into the device. Imaging and information automatically display on a USB-connected computer in fewer than six seconds, and the reader can process up to 900 plates per hour. The device can enumerate 10 3M Petrifilm Plates and the Staph Express Disk and includes software that allows technicians to edit results and add other relevant sample information. **3M Food Safety, 3M.com/petrifilmproductivity.**

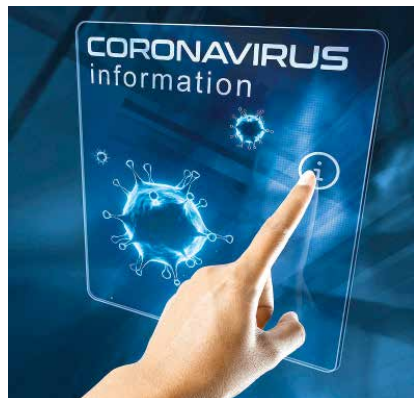
can accommodate facility expansion for customers who don't have the footprint to install a drying system within the walls of their facility. Heat pump dehumidification systems facilitate reduction of product moisture content while maintaining quality characteristics such as color, texture, nutrients, and essential ingredients. **Nyle, nyle.com.**

SCIENTIFIC FINDINGS

For access to complete journal articles mentioned below, go to “Food Science Research” in the February/March 2021 issue at foodqualityandsafety.com, or type the headline of the requested article in the website’s search box.

Food Safety Lessons Learned from COVID-19

The COVID-19 pandemic has ushered in a new era of food safety. To date, there is no evidence to suggest that consuming food is associated with contracting COVID-19. Nevertheless, the virus’s impact on food safety and security has been grave. The world is currently experiencing several supply chain issues as a direct result of extensive lockdowns and impacts on essential worker safety. However, disruption in the food supply, while catastrophic in nature, has created op-



portunities for the advancement of medical science, data processing, security monitoring, foodborne pathogen detection, and food safety technology. This article discusses the key components for food safety during the COVID-19 pandemic. The discussion draws from lessons learned early in the outbreak and analyzes the etiology of the disease from a food safety perspective. From there, we discuss personal protective equipment, detection of SARS-CoV-2, useful surrogates to study SARS-CoV-2, and the expanding field of data science, from the food safety point of view. In the future, scientists can apply this knowledge to the containment of COVID-19 and, eventually, to future pandemics. *Journal of Food Safety*. Published December 18, 2020. DOI: 10.1111/jfs.12878.

Fatty Acids and Volatile Flavor Compounds in Plant-Based Burgers

In recent years, interest in plant-based meat alternatives (PBMA) has been rapidly growing in both the food research community and the food industry due to higher consumer demands; however, scientific data regarding the health and aroma aspects of PBMA are rare. In this study, the fatty acids (FAs) and volatile flavor compounds (VFCs) were profiled in four types of plant-based burgers (PBs) and compared with beef burgers (BBs). More than 40 FAs and 64 VFCs were detected and quantified in the samples. Nonsignificant differences were observed in the percentages of most FAs between uncooked and cooked PBs. PBs contained lower percentages of saturated FAs and trans-FAs, higher percentages of unsaturated FAs, and a lower ratio of n-6 to n-3 FAs compared to the BBs. The FA profiles in PBs are mainly determined by their ingredients. The VFC profile of cooked PBs was different from that of the uncooked ones. The ingredients, thermally induced Maillard reaction, and lipid oxidation had contributed to the formation of the flavor. For uncooked samples, the VFC profiles of PB 3 and PB 4 were similar to that of BBs. For cooked samples, PB 1 had a similar VFC profile as BBs. This illustrated the importance of the cooking process for aroma formation; however, ingredients such as spices remain an important source of VFCs in these burger samples. Ingredient optimization could be an effective strategy to enhance the flavor of PBs so that they resemble BBs. *Journal of Food Science*. Published January 20, 2021. DOI: 10.1111/1750-3841.15594.



Rapid Testing Methods for Meat Species Identification

The authentication of animal species is an important issue due to an increasing trend of adulteration and mislabeling of animal species in processed meat products. Polymerase chain reaction is the most sensitive and specific technique for nucleic acid-based animal species detection; however, it is a time-consuming technique that requires costly thermocyclers and sophisticated labs. Recently, there has been a need for on-site detection by point-of-care (POC) testing methods and devices under low-resource settings. These devices must be affordable, sensitive, specific, user-friendly, rapid and robust, equipment free, and delivered to the end users. POC devices should also confirm the concept of micro total analysis system. This review discusses POC testing methods and devices that have been developed for meat species identification. Recent developments in lateral flow assay-based devices for the identification of animal species in meat products are also reviewed. Advancements in increasing the efficiency of lateral flow detection are also discussed. *Comprehensive Reviews in Food Science and Food Safety*. 2021;20(1):900–923.



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