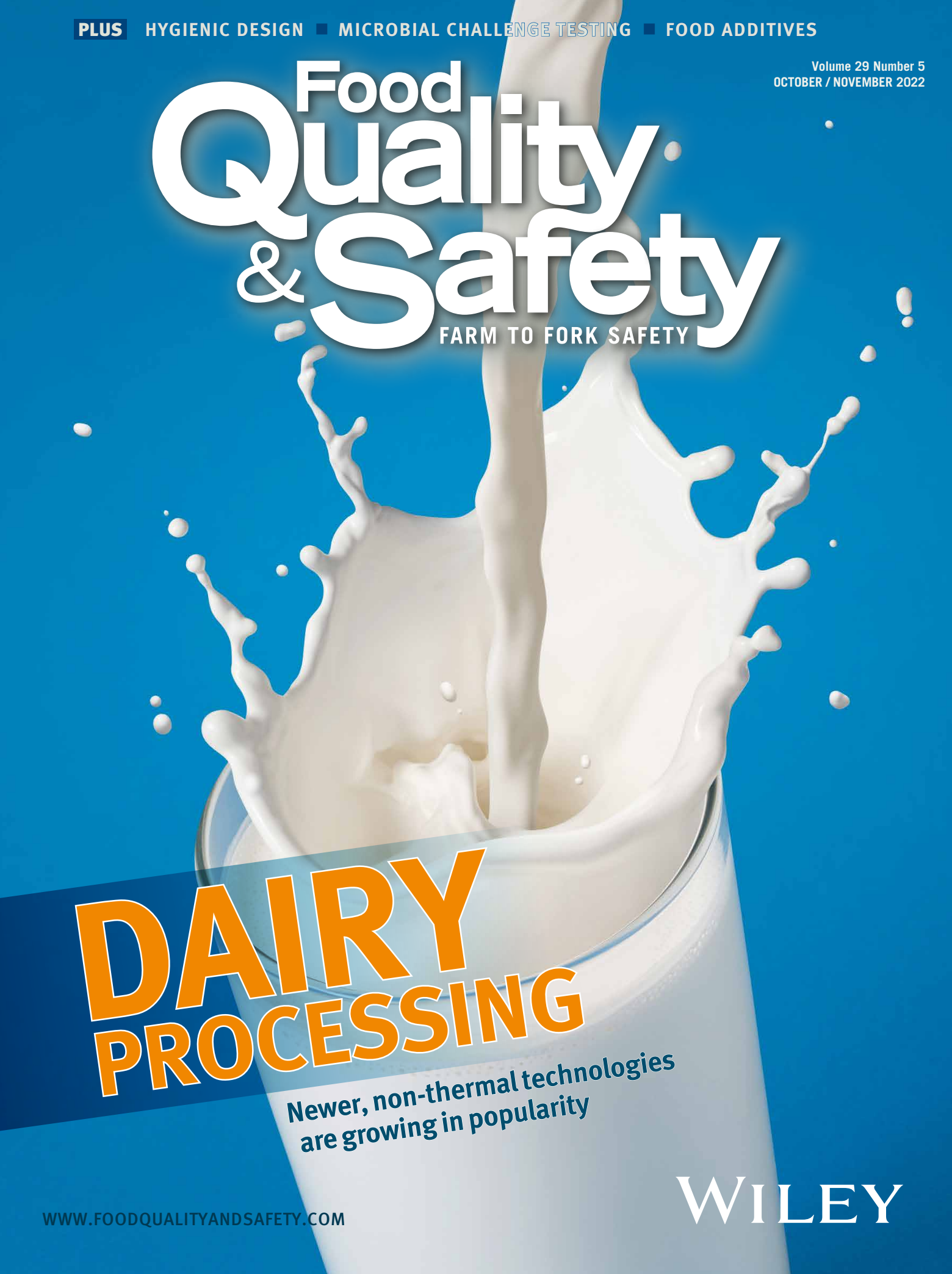
PLUS HYGIENIC DESIGN ■ MICROBIAL CHALLENGE TESTING ■ FOOD ADDITIVES

Volume 29 Number 5
OCTOBER / NOVEMBER 2022

Food Quality & Safety

FARM TO FORK SAFETY



DAIRY PROCESSING

Newer, non-thermal technologies are growing in popularity

WWW.FOODQUALITYANDSAFETY.COM

WILEY

Making Food Delicious Is An Art. Keeping Food Safe Is A Science.

Scientific studies have shown that hand-washing alone is not enough to ensure microbe-free food handling. For your customers' well-being, choose **Made in Malaysia** food handling gloves. Malaysian manufacturers make certain the products comply with stringent international standards, and are consistent in quality and competitively priced. Malaysian manufacturers are committed to social responsibility and sustainability initiatives to not only ensure human health is preserved, but to have an equally positive impact on communities and the environment. When it comes to rubber, **No One Knows Rubber Like Malaysia Does.**

Reach Malaysian manufacturers via **Marketplace** at **www.myrubbercouncil.com**

- Excellent Barrier Protection
- Conform to International Standards
- #1 World's No. 1 in Natural Rubber Gloves & Nitrile Gloves
- Made in Malaysia Quality Rubber Products

www.myrubbercouncil.com @MYrubbercouncil @MYrubbercouncil @MYrubbercouncil

MRC MALAYSIAN RUBBER COUNCIL

Contents

OCTOBER / NOVEMBER 2022 • VOLUME 29 NUMBER 5 • www.foodqualityandsafety.com

Features

Safety & Sanitation

Cannabis Corner

Food Quality & Safety (ISSN 2572-8644) is published 6 times a year in Feb/Mar, Apr/May, Jun/July, Aug/Sept, Oct/Nov, Dec/Jan by Wiley Subscription Services, Inc., a Wiley Company, 111 River St., Hoboken, NJ 07030-5774.
Print subscriptions are free for qualified recipients. Annual paid subscriptions are available to European readers at €164, U.K. readers at £133, and rest of the world readers at $248.
For subscription questions, email customer service at wileygit@vuservice.de.

Food Quality & Safety is a proud member of: United Fresh Produce Association
APEX, Folio Ozzie, and ASBPE award winner for editorial and graphics excellence.

POSTMASTER: Send all address changes to *Food Quality & Safety*, Wiley Periodicals LLC, c/o The Sheridan Press, P.O. Box 465, Hanover, PA 17331 USA

(Continued from p. 3)

Safety & Sanitation

Quality

In The Lab

Columns

Washington Report

Legal Update

Departments

***Food Quality & Safety* magazine welcomes letters to the editor on any relevant industry topic.**

Letters should be no longer than 350 words.

Submit letters to:
Samara E. Kuehne
Professional Editor
Email: skuehne@wiley.com

(Letters may be edited for space and style.)

Visit us online! Other articles available at www.FoodQualityandSafety.com include:

- Ground Beef in HelloFresh Meal Kits Linked to *E. Coli* Outbreak
- Oil-Based Systems May Eradicate *Salmonella* on Food Production Machinery
- FDA and CDC Partner to Reduce Foodborne Illness in Retail and Food-service Establishments
- Certain Brands of Brie and Camembert Cheeses Recalled Nationwide Due to Potential Contamination with *Listeria*

OUR WEBINARS SATISFY YOUR APPETITE TO LEARN.

Food Quality & Safety
FARM TO FORK SAFETY

A host of audio and video webinars are available on demand at **www.foodqualityandsafety.com/webcast/**

TAKE YOUR PICK!

From The Editor

Getting By, with a Little Help

Water, water everywhere, and not a drop to drink.

Somebody from Florida probably wrote that right after a hurricane. I'm a Florida native—there are a few of us actually from here—and while Hurricane Ian took a late turn that spared my area, there are millions who were impacted.

While I'm grateful that none of my family were in Ian's path, I'm sending all the hope and prayers I have to those who weren't so lucky. No water and no power in Florida, in September, cannot be described. One has to experience it for a week or two to truly understand what it means to be hot and miserable for days, with no end in sight. Simply put, there is a huge difference between living with hot air and cold water and having the luxury of cold air and hot water.

If only we could send all the flood waters to California, so much would be solved—lives restored, crops saved, and misery ended sooner rather than later.

For some, homes will be rebuilt, new jobs will be found to replace the ones lost, and life will seem normal again. But some homes will never be rebuilt, and some neighborhoods are gone forever, with nothing left but fading memories. And sadly, this time, lives were lost as well. You know who they were. The guy who always had a great laugh and a helping hand to offer, the woman who always had a casserole that could feed an army. The family who always had the time and the tools to help fix anything. Gone now, but never forgotten.

But this is Florida, and the sun is already shining again. Federal help was on its way before the rain stopped. An early cool front followed Ian, so nighttime temperatures are blissfully in the 60s where I am. Friends, old and new, show up with water and food. Debris is gradually being removed and power is coming back. Normal may still be a long way off, but we can see it coming, feel it in the cool night breeze, and know that here in Florida, it will come back again. There will be other hurricanes, other floods, other natural disasters. Each one different, yet always the same, because it's the people around you who get you through the tough times.

We'll get there. Until then, we'll get by—with a little help from our friends.

Patricia A. Wester
Executive Industry Editor

WILEY

Food Quality & Safety
FARM TO FORK SAFETY

PUBLISHING DIRECTOR Heiko Baumgartner, hbaumgar@wiley.com
SENIOR ACCOUNT MANAGER Vanessa Winde, vwinde@wiley.com
PROFESSIONAL EDITOR Samara E. Kuehne, skuehne@wiley.com
DESIGN Maria Ender, mender@wiley.com
PRODUCTION Claudia Vogel, cvogel@wiley.com
Jörg Stenger, jstenger@wiley.com
Elli Palzer, palzer@wiley.com

EXECUTIVE INDUSTRY EDITOR Patricia A. Wester, fqseditor@pawesta.com
INDUSTRY EDITOR, PROJECTS Purnendu C. Vasavada, PhD, purnendu.c.vasavada@uwrf.edu

Advertising Director
Dan Nicholas
111 River Street, Hoboken, NJ 07030
(716) 587-2181, dnicholas@wiley.com

Sales Office
U.S./Canada/International
Vanessa Winde
vwinde@wiley.com

Editorial Office
111 River Street, Hoboken, NJ 07030-5774, USA
Reprints: E-mail dsurdel@wiley.com

Printed in the United States by Dartmouth Printing, Hanover, NH.

NEWS & NOTES

©JACKF - STOCK.ADOBE.COM

FDA Proposes New Guidelines for "Healthy" Claim on Food Labeling

FDA has proposed updated criteria for when foods can be labeled with the nutrient content claim "healthy" on their packaging. This proposed rule would align the definition of the "healthy" claim with current nutrition science, the updated nutrition facts label, and the government's current Dietary Guidelines for Americans.

The proposed rule, which has been in development for several years, would update the definition of "healthy" to better account for how nutrients in various food groups may work together to create healthy dietary patterns and improve health. Under the proposed definition for the updated "healthy" claim, which is based on current nutrition science, more foods that are part of a healthy dietary pattern would be eligible to use the claim on their labeling, including nuts and seeds, higher fat fish (such as salmon), certain oils, and water.

Under the proposed definition, to be labeled with this claim on food packaging, products would need to:

- Contain a certain meaningful amount of food from at least one of the food groups or subgroups (e.g., fruit, vegetable, dairy) recommended by the Dietary Guidelines.
- Adhere to specific limits for certain nutrients, such as saturated fat, sodium, and added sugars. The threshold for the limits is based on a percent of the daily value (DV) for the nutrient and varies depending on the food and food group. The limit for sodium is 10% of the DV per serving (230 milligrams per serving).

FDA is also exploring the development of a symbol that manufacturers could use to show that their product meets the healthy claim criteria. ■

Biden Executive Order Endorses Biotechnology for Food and Agriculture

BY KEITH LORIA

President Biden unveiled a new executive order on September 12 designed to advance biotechnology and biomanufacturing innovation, which could have a big impact on the food industry.

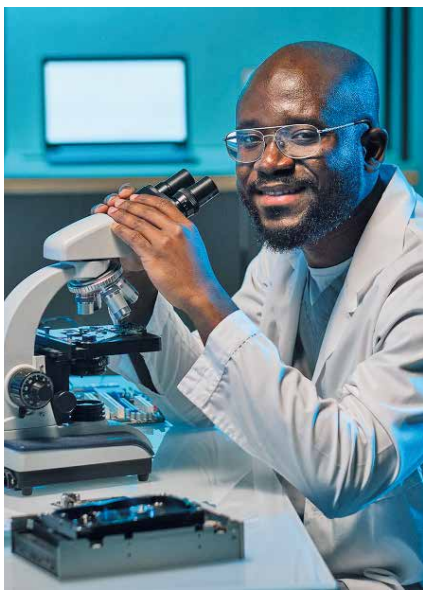
The order, the "National Biotechnology and Biomanufacturing Initiative," aims to provide innovative solutions in several sectors, including health, climate change, energy, food security, agriculture, supply chain resilience, and national and economic security.

Among its goals are to determine how biotechnology and biomanufacturing can help limit food waste, increase food quality, and identify ways to produce alternative food sources. Under the executive order, the Secretary of Agriculture has 180 days to submit a plan on ways these tasks can be accomplished.

Charles R. Santerre, PhD, professor and chair of food, nutrition, and packaging sciences at Clemson University in Clemson, S.C., who also previously served as a senior policy advisor for agriculture and health in the White House's Office of Science and Technology Policy, says that Biden's new executive order is a smattering of different pieces, but until a plan is activated and action is taken, it's hard to know what it will accomplish.

One thing Dr. Santerre does expect to happen is that GMOs will play a larger role in sustainability and in improving the food supply chain. "What we've seen in the environmental benefits are five things: less pesticide usage, less erosion in the fields, dramatically increased yields, products being developed with drought resistance, and extended shelf life of some of the products, which can lead to less food waste," he tells *Food Quality & Safety*. "Consumers get benefits also, such as better nutrient profiles, better flavor and texture appearance, and increased safety."

Another part of the executive order deals with humane production of animals through biotech. "Biotechnology has easily demonstrated how it can grow the economy and it is an important area that can make our foods become safer," Dr. Santerre says. ■



©PRESSMASTER - STOCK.ADOBE.COM

(Continued on p. 8)

©VERA - STOCK.ADOBE.COM

(Continued from p. 7)

Study: Lower Air Pollution Could Lead to Higher Crop Yields

BY JESSE STANIFORTH

In the near future, China could increase its winter crop yields by roughly 25% and its summer crops by 15%, while Western Europe could increase winter yields by roughly 9% and summer crops by about 11%. The catch? They'd have to cut the air pollutant class of nitrogen oxides—found in both vehicle exhaust and industrial emissions—by half of their current levels.

This is the takeaway from research recently published in the journal *Science Advances* by David Lobell, PhD, the Gloria and Richard Kushel Director of the Center on Food Security and the Environment at Stanford in Palo Alto, Calif., and his team (doi: 10.1126/sciadv.abm9909).

The main message of the paper is that nitrogen dioxide, a principal form of nitrogen oxides and key indicator of the presence of others, is consistently harming crop yields around the world, says Dr. Lobell. "Losses from nitrogen dioxide are often 10% or more, which is a big number in agriculture; 10% is roughly the yield loss that a significant drought would cause," he says. "This finding is significant because this study is the first time we have been able to measure the exposure of crops to nitrogen dioxide over large scales in many regions."

Dr. Lobell notes that, due to the U.S. Clean Air Act and other North American environmental protections, limits to nitrogen oxides have already brought crop yield gains to this continent. His team's findings centered on potential gains in crop yields in China, but also predicted significant yields in Western Europe, as well as India, which could see crop yield gains of 8% in summer and 6% in winter following a 50% reduction in nitrogen oxides.

Thomas Sharkey, PhD, a professor in plant biology at Michigan State University in East Lansing, says the research conducted by Dr. Lobell and his team connects a series of dots that have always been present. "But I would say they've never been connected so well," he says.

Dr. Sharkey says that this research begins with the need to reduce the production of ozone, which inhibits crop growth. "A lot of work has been done showing how ozone inhibits crop growth," he says, "but the people studying the ozone haven't gone that next step and said, 'Where did that ozone come from?' It comes from nitrogen oxides that are around."

The other half of the equation is hydrocarbon, which is produced by trees and other plant matter. "The hydrocarbons are unavoidable; that means that we need to address the nitrogen oxide pollution," Dr. Sharkey says. "That's how we can get rid of ozone. This paper now connects for us in a way that hadn't been explicit that, because you have nitrogen oxides you have ozone, and because you have ozone, you have crop damage."

Dr. Lobell's paper also contained a wholly unexpected finding: Nitrogen oxide has the capacity to reduce crop yields on its own, independently of its role in ozone production. "That was a surprise," says Dr. Sharkey. "I don't think anyone would've necessarily predicted that."

Dr. Lobell believes that the boosts to crop yields are achievable, noting that nitrogen oxides are the product of fossil fuel sources that are already the target of reductions from many sides; however, he says, "I don't think crop yield gains alone would have to justify the investment, since the benefits for local human health are often many times the cost of changes. The crop yield gains are more like icing on the cake." ■

FDA Report on Infant Formula Shortage Admits Agency Shortfalls

BY PATRICIA WESTER

While the infant formula recall ended in June 2022, supplies currently still remain below normal levels. Robert M. Califf, MD, FDA commissioner, requested that an internal agency review of the situation be conducted, and assigned the task to Steven M. Solomon, DVM, MPH, director of FDA's Center for Veterinary Medicine and a 32-year veteran of the agency, including 23 years in the agency's Office of Regulatory Affairs (ORA), which, among other functions, houses FDA's inspectional programs.

Dr. Solomon was charged with identifying the challenges encountered in addressing the circumstances that led to a nationwide shortage of infant formulas that serve as the sole source of nutrition for many infants and for people with certain metabolic conditions that require specialty formulas. He was also tasked with providing recommendations to prevent similar events in the future.

The evaluation team led by Dr. Solomon conducted 43 interviews with a total of 61 employees. The employees included many with a lengthy history with the agency. The findings of this internal evaluation, published on September 20, identified five major areas of need in the agency:

- Modern information technology that allows for the access and exchange of data in real time to all the people involved in a response;
- Sufficient staffing, training, equipment, and regulatory authorities to fulfill FDA's mission;
- Updated emergency response systems that are capable of handling multiple public health emergencies occurring simultaneously;
- Increased scientific understanding about *Cronobacter*, its prevalence and natural habitat, and how this translates into appropriate control measures and oversight; and
- Assessment of the infant formula industry, its preventive controls, food safety culture, and preparedness to respond to events.

Some of these findings will come as no surprise to most. FDA has been shorthanded and in need of additional resources for many years. There were 15 specific findings in the report that shed more light on these

concerns, with emphasis on findings 8 and 9 to address some of the resource shortages:

Finding 8: FDA's foods workforce maintains expertise across the 80% of the food supply regulated by FDA; however, funding limitations have stalled the growth of the foods program, hindering the agency's ability to keep pace with the growing workload, increased complexity of supply chains, and scientific and technological changes in food manufacturing. FDA's shortage of investigators, subject matter experts, and compliance personnel with infant formula expertise hinders the agency's ability to comprehensively inspect infant formula manufacturing facilities, review and evaluate new products, and respond to product concerns or complaints in a rapid manner.

Recommendation: FDA should evaluate its workforce needs related to infant formula regulation and oversight and utilize the appropriations process to help secure the resources needed.

Finding 9: The critical nature of infant formula products as a sole source of nutrition posed unique challenges to public health, complicating compliance actions compared to typical food compliance actions. This incident required an unusual level of agency leadership involvement to assess and weigh risks associated with potential product contamination against risks of essential products being unavailable due to a shortage. Typically, product safety is the primary driver during food safety incidents and product availability does not impact compliance actions.

©AIGUL - STOCK.ADOBE.COM

Recommendation: FDA should review its compliance procedures for critical food products and determine whether there is a need to clarify roles and responsibilities, consider the need for a decision matrix, and consider alternative activities to minimize product availability concerns when the product is a sole source of nutrition. ■

Court Orders Delay of Massachusetts Pork Production Law

BY KEITH LORIA

A United States federal court judge for the District of Massachusetts approved an agreement to delay enforcement of a state law that would ban pork production processes that used gestation crates.

Judge Mark Wolf signed the agreement on August 11, 2022, which halted the state law, known as Question 3 (Q3), a 2016 Massachusetts ballot initiative set to go into effect on August 15 of this year. The law was set to ban any uncooked whole pork meat sold in Massachusetts that did not meet specific sow housing requirements, regardless of where it was produced.

"The reaction to these proposed laws hearkens back to the early 1900s and the horrible conditions in meat packing facilities and the mishmash of inconsistent laws from state to state to state," notes Shawn K. Stevens, food industry attorney for the Food Industry Counsel and member of the *Food Quality & Safety* Editorial Advisory Board.

These conditions led to what is now the Federal Meat Inspection Act, which says that individual states are prohibited from enforcing any laws different from or in addition to the federal standards. That act has led to the courts being reluctant to enforce laws such as Q3. "The arguments to the court are, 'We can't have a free market where we can freely ship, sell, distribute, and consume these types of animal products if the individual states are requiring their own specific requirements; it's just not fair,'" Stevens says.

He also notes that the law, if enacted, wouldn't allow transshipment of whole pork through the state of Massachusetts, jeopardizing approximately $2 billion worth of pork that moves into neighboring New England states.

The National Pork Producers Council (NPPC) called the ruling a "significant outcome," noting the importance of allowing pig farmers to raise hogs in a way that is best for their animals while maintaining a reliable supply of pork for American consumers. "The impact of Question 3 would have been particularly harmful to those in surrounding New England states who did not have a vote in the 2016 Massachusetts referendum, nor any notice of the dramatic steps that activists had taken trying to force these harmful initiatives on voters in other states," says Terry Wolters, NPPC president.

©DIDESIGN - STOCK.ADOBE.COM

The Supreme Court is currently reviewing a similar law in California—Proposition 12—which was approved by voters in 2018 and makes it illegal to sell pork in the state unless the pig it comes from was born to a sow housed with at least 24 square feet of space and in conditions that allow the sow to turn around freely without touching her enclosure.

A lawsuit was brought by NPPC and the American Farm Bureau Federation against this legislation, arguing that the law is unjustified and counterproductive to advancing animal health and safety and, if enacted, would undermine the global competitiveness of the U.S. pork industry and increase food prices.

Maura Healey, the attorney general for Massachusetts, has gone on record stating that the Q3 rule should be put on hold at least until 30 days after the U.S. Supreme Court issues its ruling on Proposition 12.

The agreement is limited to the pork sales provision of Q3, so producers in Massachusetts are still required to comply with in-state housing standards for pork production. ■

Washington Report

USDA Declares *Salmonella* an Adulterant in Some Poultry Products

What the action means for food safety, and what comes next

BY **KEITH LORIA**

In the fall of 2021, USDA's Food Safety and Inspection Service (FSIS) unveiled its plan to initiate a stronger and more comprehensive effort to reduce *Salmonella* illnesses associated with poultry products. "Far too many consumers become ill every year from poultry contaminated by *Salmonella*," said Tom Vilsack, Agriculture Secretary, in a statement at the time. "We need to be constantly evolving in our efforts to prevent foodborne illness to stay one step ahead of the bad bugs."

The agency's goal, spelled out in the *Healthy People 2030* Food Safety Object 4, is to reduce *Salmonella* illnesses by 25% nationwide. "Reducing *Salmonella* infections attributable to poultry is one of the department's top priorities," said Sandra Eskin, USDA Deputy undersecretary, who is leading the initiative. "Time has shown that our current policies are not moving us closer to our public health goal. It's time to rethink our approach."

The plan encourages the use of pilots, data gap assessments, and a broad range of other stakeholder inputs to reduce *Salmonella* contamination across the poultry supply chain. The data generated will be used to determine whether a different approach could result in a reduction of *Salmonella* illness in consumers. One of the key ways USDA hopes to accomplish this is by declaring the pathogen an adulterant in breaded and stuffed raw chicken products, an action that FSIS set into motion on August 1 of this year. Products containing an adulterant must be destroyed or reprocessed to ensure the adulterant is destroyed.

Examples of the raw, breaded poultry products in this newly regulated segment include chicken Kiev and cordon bleu entrees found in the freezer section with products that may appear to show a fully cooked entree. These prodcuts, however, are only heat-treated to brown and set the batter or breading, so the product itself may appear cooked when it actually still contains raw poultry. To date, efforts to shore up product labeling by adding large statements that the product must be cooked have not been effective at reducing related consumer illnesses.

As of August 1, 2022, *Salmonella* is an adulterant in these breaded and stuffed raw chicken products. FSIS plans to publish notice and rulemaking on will be considered adulterated if they exceed a very low level of *Salmonella* contamination and would be subject to regulatory action. The agency will be proposing to set the limit at 1 colony forming unit (CFU) of *Salmonella* per gram for these products, a level that the agency believes will significantly reduce the risk of illness from consuming these products. The agency will also seek comment on whether a different standard for adulteration—such as zero tolerance or one based on specific serotypes—would be more appropriate.

The notice is expected to publish in the Federal Register in the fall and FSIS will be seeking public comments that address what the standard should be as well as to inform a final implementation plan, including a verification testing program. Once published, the notice will be posted in the FSIS Federal Register and Rulemaking page for review and comment. When the proposal is finalized, the agency will announce its final implementation plans and the date it will begin routine testing for the pathogen in these products.

In 2020, William D. Marler, an attorney with food safety law firm Marler Clark in Seattle, filed a petition with FSIS asking the agency to declare 31 strains of *Salmonella* adulterants that would, in turn, also be banned in pork, beef, and chicken. Based on differing levels of virulence, his reasoning was that several other toxic *E. coli* strains in addition to O157:H7 that are currently banned from meat and poul-

try, and the same level of regulatory limitation was needed for products that could lead to severe *Salmonella* outbreaks.

Although USDA did not grant his petition because it was too broad, his persistence did result in this latest action regarding certain poultry products. "They picked these products because there have been multiple outbreaks," Marler tells *Food Quality & Safety*. Over the past 24 years, breaded and stuffed raw chicken products have been associated with as many as 14 separate *Salmonella* outbreaks, resulting in nearly 200 illnesses, according to USDA.

A Look Back

Mitzi Baum, CEO of STOP Foodborne Illness, a nonprofit organization focused on preventing illness caused by foodborne pathogens, says that in 1987, FSIS declared *Listeria monocytogenes* an adulterant in cooked and ready-to-eat meat due in part to its high mortality rates and to the danger it posed to unborn babies if the mother became infected. Additionally, the agency declared *E. coli* O157:H7 an adulterant in 1994 after a large, deadly outbreak originating at Jack in the Box restaurants that killed at least four children who ate hamburgers contaminated with the pathogen.

Janilyn Hutchings, a food scientist with StateFoodSafety, a food safety education company, notes that there are some legal precedents for the recent proposal to treat pathogens as adulterants in certain products. Historically, naturally occurring pathogens such as *L. monocytogenes*, *E. coli*, and *Salmonella* were not previously treated as adulterants because they were not added substances in raw meat and poultry. "That started to change in 1987 when FSIS labeled *Listeria* as an adulterant in cooked, ready-to-eat meat products," Hutchings says. "Presumably, its reasoning for doing so was [that] meat that has been cooked should not contain enough pathogens to make a consumer sick, and so the presence of *Listeria* in any amount in a ready-to-eat meat product could be considered an adulterant."

In 1994, after the *E. coli* outbreak linked to Jack in the Box restaurants, FSIS began a sampling program that treated that pathogen as an adulterant. "Supermarkets and meat industry organizations brought legal action against FSIS over the sampling program, arguing that *E. coli* could not be treated as an adulterant because it wasn't dangerous if ground beef was properly cooked," Hutchings says. "The court ultimately denied the plaintiffs' case, stating that 'in light of common cooking practices of most Americans, there is at least a rational basis for treating *E. coli* differently than other pathogens' and that 'many Americans consider ground beef to be properly cooked rare, medium rare, or medium, which isn't enough to reduce *E. coli* to safe levels.'"

> This is a baby step, but it's a step in the right direction.
>
> —William D. Marler

Most consumers won't eat undercooked chicken, but FSIS is using similar reasoning to justify its proposal to treat *Salmonella* as an adulterant in breaded and stuffed raw poultry products.

Impact on Industry

While some are happy with the stricter controls on breaded or stuffed chicken products that the new action would mean, not everyone is pleased.

For instance, the National Chicken Council (NCC), a trade organization that includes multiple companies that produce breaded or stuffed raw chicken products, says its member companies have worked for more than 10 years and spent millions of dollars to reduce *Salmonella*, and the organization says that those efforts have paid off in the form of a decline in illness over the past seven years.

"NCC is concerned about the precedent set by this abrupt shift in longstanding policy, made without supporting data, for a product category that has only been associated with one outbreak since 2015," a spokesperson with the NCC tells *Food Quality & Safety*. "It has the potential to shutter processing plants, cost jobs, and take safe food and convenient products off shelves. We're equally concerned that this announcement was not science based or data driven."

NCC cited the passage of the Poultry Products Inspection Act in 1957, in which the mere presence of *Salmonella* has not rendered raw poultry adulterated. "There is no silver bullet or one-size-fits all approach to food safety, which is why we employ a multi-stage strategy," the NCC says. "The only way to ensure our food is safe 100% of the time is by following science-based procedures when raising and processing chicken, and by handling and cooking it properly at home."

Next Steps

The FSIS plan will next go to a comment period as experts in the industry discuss how the rule-making process would work best. At press time, the adulterant language is slated to be released in October 2022, with comments on the proposal coming from those in the industry in November or December of this year.

Additionally, since this announcement is part of a larger USDA initiative to reduce *Salmonella* illnesses linked to poultry, it seems reasonable to expect more proposals to test other poultry products, Hutchings says.

James E. Rogers, PhD, director of food safety research and testing at *Consumer Reports*, notes that with a new administration and Eskin's extensive history in food safety, this issue has been pushed more than ever and he hopes that it is only the beginning. "The bottom line is a lot of people get sick from *Salmonella* and poultry contributes to that foodborne illness burden, so something had to be done. This is an important first step." He also hopes the agency will have enough data and information to declare the pathogen an adulterant in all poultry products.

Marler expects that there will be zero tolerance for the pathogen in the chicken products, given that they reside in a product category that consumers are confused about, although he wouldn't be surprised if USDA tries to create some wiggle room. "This is a baby step, but it's a step in the right direction," he says. "It proves my point that *Salmonella* should be considered an adulterant. It will take time, but you will wind up having the same success you will have with *E. coli* in ground beef; also, I don't think it will be the death knell of chicken, but it could be for the product that looks like it's already cooked." ■

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

Legal Update

Food Freedom or Regulatory Disaster?

Regulation of the sale of of homemade foods varies dramatically by state

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

The "food freedom" movement is intended to expand the rights of individual consumers to produce and consume their own homemade foods with no regulation. The idea is to enable consumers to achieve better overall health by controlling the quality and safety of the food they eat.

In turn, over the last several years, this movement has inspired new laws in all 50 states and Washington, D.C., that embrace this concept, while also permitting the sale of homemade foods to other consumers in certain circumstances. These state laws vary dramatically in the scope of permitted products, limitations on sales, and required oversight by state or local public health agencies. Often, states have implemented either a "cottage food law" or a "food freedom law." Cottage food laws are typically limited to the sale of baked goods and other shelf-stable, not potentially hazardous foods, while food freedom laws generally significantly expand the ability of home producers to process and sell food products.

Model Food Freedom Laws

Model food freedom laws have been issued by the American Legislative Exchange Council and the Institute for Justice. These model laws have served as the framework for advocates who work to create or expand food freedom laws at the state level.

These model laws typically allow for the sale of any homemade foods, regardless of the product type or total amount of sales made. Sales can be made directly to the consumer or through an agent of the home producer (such as a retailer). Products that contain meat or poultry or that would be classified as dairy products, however, can only be sold by the home producer directly to consumers and must be personally delivered by the home producer. The actual transaction (sale) in all cases can be in person or remote, through internet or phone sales. Additionally, homemade foods must be labeled with a statement indicating that the food was produced in a residential kitchen that is exempt from licensing and inspection.

Overview of Implemented State Cottage Food and Food Freedom Laws

Although model food freedom laws have been made available for the states generally, many states have opted to implement their own laws that vary from the model acts in many ways.

For example, many states have implemented maximum annual sales levels for homemade foods. Maryland recently raised the annual revenue cap for cottage food producers to $50,000, while Connecticut has an annual gross sales limit of $25,000 for cottage food products. In other states, such as Colorado, restrictions are enforced as an annual limit per "product," which has an annual net revenue limit of $10,000.

Other laws implemented by the states limit the types of foods that can be sold. For example, some states restrict the sale of homemade foods to non-perishable items,

while others exclude the sale of acidified foods. Florida and Georgia, for example, permit non-potentially hazardous foods, including bakery items (without temperature-controlled ingredients), jams and jellies, and candy products, while excluding canned acidified foods and other products that are potentially hazardous. In addition to the products permitted by Florida and Georgia, Kansas also permits certain cut produce items, eggs and poultry from small producers, juice, and fish and seafood products. Maine permits shelf-stable foods, including acidified foods, bakery items, and candies. However, Maine's food sovereignty law allows local governments within the state (such as cities or counties) to expand the types of food that can be sold beyond those items permitted by the state cottage food law.

In some states, in addition to limiting the types of homemade products that can be sold, the states limit the specific locations where the homemade products can be sold. For example, Washington, D.C., limits sales of cottage foods to direct-to-consumer sales that occur at farmers markets, public events, or online sales within the District. Idaho, on the other hand, permits any direct-to-consumer sales, regardless of where and how the sale occurs. As noted, some states permit, in addition to direct-to-consumer sales, sales to retailers. Maryland, for example, allows cottage food producers to sell their products to a retail food store. When Maryland home producers sell to a retail store, basic information about the food and producer must be filed with the overseeing department of health, and the department must determine that requirements for retail sale are fulfilled; however, these requirements are much less stringent than those imposed on food manufacturers.

In some states, home kitchens are required to register with the local public health authority and may be subject to inspections prior to the commencement of homemade food sales from the kitchen. Other states require the completion of a food safety course by the person selling the homemade food. For example, Alabama requires completion of a food safety course approved by the department of public health, and the certification must be renewed every five years. Arizona requires both completion of a food safety course and registration with the Department of Health Services. Massachusetts requires that cottage food producers, including those selling only direct-to-consumer, register and obtain a permit from the local board of health; this will typically include an inspection of the residential kitchen prior to issuance of the permit.

Though most states also require specific labeling components, the required elements and defined language vary state to state. Typically, labels must include the name and contact information of the producer, a list of ingredients and allergens in the food, and a statement that the food was produced in a home kitchen not subject to licensing or inspection by the public health agency.

It's apparent that the ability of homemade food producers to sell their products, and the process required to do so, are broadening significantly.

Although this provides just a sampling of state laws permitting the sale of homemade foods, it's apparent that the ability of homemade food producers to sell their products, and the process required to do so, are broadening significantly. As these trends continue to expand, it will be interesting to see, in the absence of strict regulation, whether significant concerns arise with respect to the overall safety of these products. Additionally, due to the substantial variation among state laws permitting sales of homemade foods, there is a potential for conflict among the individual states as well as the federal food safety regulations governing the interstate manufacture, distribution, and sale of foods.

Potential Conflict with Federal Food Safety Regulations

The jurisdiction of federal food safety agencies is typically limited to the oversight of food products manufactured, distributed, or sold in interstate commerce, and will therefore typically not impact the cottage food industry. With that said, where a home producer sells his or her products to retailers over state lines, federal jurisdiction (and, by extension, regulation) may be triggered. Though both FDA and USDA exclude retail establishments from the scope of their regulations, when states permit wholesale distribution of homemade foods to retailers, producers may be subject to federal regulation. Indeed, USDA previously announced its objections to Maine's food freedom law unless the state modified the law to ensure that all meat and poultry products complied with USDA requirements and exemptions. USDA indicated that, without this modification, Maine's state inspection program for meat and poultry would no longer be recognized by USDA, subjecting the producers within the state to federal inspection in place of the state program.

Additionally, the FDA Food Code states that food prepared in a private home cannot be used or offered for sale in a food establishment, such as a restaurant. Though the Food Code is not binding on states, many states have enacted a version of the Food Code as the regulatory framework for retail establishments. Contrary to the Food Code, however, several states now permit food producers operating under cottage food laws to sell foods to retail food establishments.

Cottage food and food freedom laws allow more people to begin producing and selling homemade foods, while also expanding the number of local, handmade foods available to consumers; however, given the substantial variation in state laws, those looking to produce and sell through a cottage food law must carefully consider the applicable state law, as well as any country or local requirements, to ensure that their business plan is feasible under the particular state's regulatory scheme.

Further, to avoid federal regulation, sales should be made directly to consumers through face-to-face distribution, or only to retailers within the actual state where the food is produced. Doing so will help home processors avoid unanticipated regulatory scrutiny. ■

Stevens is a food industry attorney and founder of Food Industry Counsel, LLC, and a member of the *Food Quality & Safety* Editorial Advisory Panel. Reach him at stevens@foodindustrycounsel.com. **Presnell**, a food industry consultant and lawyer who is also with Food Industry Counsel, has worked in the food industry for nearly a decade. Reach her at presnell@foodindustrycounsel.com.

Cannabis Corner

The Cannabis Administration and Opportunity Act

This bill could end cannabis prohibition at the federal level, but some are skeptical it will pass

BY **JESSE STANIFORTH**

A potential route to the end of U.S. federal prohibition on cannabis products was introduced in July 2022 in the form of the Cannabis Administration and Opportunity Act (CAOA), authored by Senate Majority Leader Chuck Schumer (D-N.Y.), Sen. Cory Booker (D-N.J.), and Sen. Ron Wyden (D-Ore.). The CAOA is the first-ever bill by major party senators to propose decriminalization of cannabis; the bill also would expunge federal cannabis-related criminal records while also providing funding for law enforcement to shut down illicit cannabis growers and sellers.

However, the CAOA is a hail-Mary bill that few believe will pass.

"We take CAOA very seriously because it's the first piece of truly comprehensive legislation to legalize, tax, and regulate cannabis at the federal level and has the support of the Senate Majority Leader," says Aaron Smith, co-founder and CEO of the National Cannabis Industry Association. "That said, we're still a way off from seeing this bill or any other comprehensive reform proposal pass the Senate, given the filibuster's 60-vote threshold."

Jennifer Briggs Fisher is a partner at law firm Goodwin Procter, and co-chair of the firm's cannabis practice. She's equally skeptical that the legislation will make it through the Senate. "I don't think we're going to see much movement," she says. "Many in the industry, myself included, were very hopeful, following the 2020 election, that we would be able to achieve comprehensive cannabis reform at the federal level in President Biden's first term. It has become abundantly clear that that's not going to happen, and [it] may have even less of a shot following the election in November."

Fisher notes the inconsistency at work in the politics of federal legalization: At this point, 37 states have voted to legalize either medical cannabis or medical and adult use products, and there are ballot initiatives that will likely expand this number in November 2022. "If we use the last couple of election cycles as examples," she says, "the initiatives will pass, with sometimes overwhelming public support—even in surprising states. We will likely see that trend continue. It's matched by public opinion and the evolution of how people think about legalization in the United States."

Yet broad popular support for legalization hasn't translated into legislative support for the project. In theory, Fisher says, senators from every one of the 37 states where there is some legalization should be supporting the industry, which she says drives revenue, employment opportunities, and access to medicine for constituents. In practice, that hasn't happened.

Meanwhile, Fisher notes, there remains a strong anti-legalization posture among some politicians, perhaps due to continued stigma against an industry the federal government considers criminal. In many cases, these politicians' opinions are contrary to their constituents' feelings about legalization.

Those clinging to prohibition will hold their positions, Fisher says, "until they start to feel that kind of pressure, either from their constituents—so voters—or industries, [meaning] the job creators in their states who happen to be cannabis companies or the other ancillary companies that benefit from providing products and services to the legal cannabis market. There are a lot of people who have a stake in seeing federal legalization happen, but you haven't seen them mobilize in the way that's probably necessary to really move the needle on broad scale legalization and reform."

Challenges Ahead

The stakes of federal legalization are high, says Smith. "I'm under no illusion that moving from federal prohibition to a system of federal regulation will be easy for the industry, at first; however, federal legalization would bring banking access, fair taxation, and interstate commerce—three issues the industry desperately needs to see resolved in order to thrive."

Fisher concurs, noting that, above all, an end to federal prohibition would finally allow cannabis companies to engage in interstate commerce, while banking access would allow cannabis producers to use banks like any other business. The third massive challenge for state-legal cannabis producers operating under federal prohibition is Section 280E of the Internal Revenue Code, adopted in 1982, which prevents businesses that traffic in controlled substances—including cannabis—from deducting business expenses. Fisher says that this code is "very debilitating," and adds that it cuts deeply into a company's ability to be profitable. "For these companies, you see a lot of coverage around revenue numbers, but profit is a different story," she says.

While the refusal of the federal government to end nationwide prohibition is a source of frustration, few in the cannabis industry believe the process of adapting to a federally legal system would be easy. In particular, Fisher notes, states such as California that have taken initiatives to regulate cannabis-infused food products that FDA would not touch will face the challenge of harmonizing their regulations with whatever occurs at the federal level.

"There are still many details that have yet to be determined, but federal regulations should not entirely replace state systems, especially for in-state operators," says Smith. "Edibles producers would still be licensed and primarily regulated by states with an additional layer of regulation by the [Alcohol and Tobacco Tax and Trade Bureau] (TTB) and/or FDA, depending upon the products."

This places California—and many other states—in the position of having fostered consumer trust in edible cannabis products through regulation that will have to be balanced against any future federal legalization initiative.

Fisher anticipates an additional federal level of regulation could be complicated unless, she says, the federal government takes the approach of looking at the legal states that have already been in the business and have "very sophisticated" regulators looking at how to regulate these markets and how to provide oversight on these types of products. "Hopefully, they would take a best-practices approach and not create extra layers of of regulation, but really look at what the states ... who are so much farther ahead than the federal government [have done]."

Few in the cannabis industry believe the process of adapting to a federally legal system would be easy.

All that is possible, Fisher says, but it's not guaranteed. She points to the passage of the Farm Bill in 2018, which federally legalized hemp and hemp-derived cannabidiol (CBD) and granted FDA authority over products containing CBD. "Congress very specifically made sure that the FDA would still have jurisdiction over food and drugs, income cosmetics, containing hemp-derived cannabinoids.," she says. "They kicked it to the FDA to regulate—and we're now almost four years post passage and the FDA hasn't done so." To date, CBD-infused food, beverage, and cosmetic products remain prohibited from products overseen by FDA.

Fisher believes that the harmonization of state laws and an eventual federal law will be possible, but that the process will be time consuming and face the challenge of merging one federal law with dozens of state laws in different degrees of development. Some states have complex cannabis regulations, while other states where legalization is legal are still in the process of figuring out how to manage their regulatory schemes. Other states, meanwhile, may differ in their desire for regulation.

There may also be issues with states who don't want more robust food safety protocols or manufacturing regulations, adds Fisher, because they haven't had them before. "It's hard to get people to go backward in a way, because they've been operating under a regime and they've been making investments in manufacturing equipment and plants to comply with the only rules that they need to comply with at the moment, which are state rules that vary widely in terms of how stringent they are," Fisher adds.

Gateway to Other Initiatives

Despite the inevitability of that conflict, Fisher and Smith both see the CAOA as an essential move toward an end to federal cannabis prohibition. "We are just at the beginning of a process to determine what a post-prohibition future will look like for this country, and CAOA is a big step forward in that process," Smith says. However, he adds, "legislation will need support from both sides of the aisle in order to have a chance at passing out of the Senate, and the current CAOA seems to be mainly a Democratic effort."

Fisher sees the CAOA as the beginning of a more piecemeal approach that encourages the adoption of other bills such as "SAFE Banking Plus," a bipartisan bill built on previously failed legislation and designed to allow banks to work with cannabis companies, which also features equity measures (to provide those convicted of cannabis offenses easier access to the market). There's also the "Capital Lending and Investment for Marijuana Businesses (CLIMB) Act," introduced in June 2022, which would allow capital investment in cannabis. "SAFE Banking Plus" is approaching a deal, and Fisher suspects it may be voted on during the lame-duck session following the election.

One constant for Fisher is the idea that legal states, producers, and consumers have no appetite for a return to prohibition. The United States is an enormous country, whose size and diversity have been reflected in the varying approaches states have taken to legalization, but Fisher says that one thing that an increasingly vocal majority of Americans have made clear is that cannabis markets are going to expand. "I don't think we could be surprised by anything at this point," she adds, "but the only thing that is for certain is that we are not going backward." ■

Staniforth is a freelance writer based in Montreal, Quebec. Reach. Him at jbstaniforth@gmail.com.

Emerging Dairy Processing Technologies

Newer, non-thermal technologies for dairy product processing are growing in popularity

BY **KAREN APPOLD**

©BREBCA - STOCK.ADOBE.COM

Changing consumer trends have fueled the increasing interest of dairy product manufacturers in developing "non-thermal" processing technologies. Specifically, customers want products that are safe, minimally processed, fresh-like, nutritious, and devoid of synthetic food additives, says Aubrey Mendonça, PhD, an associate professor in the department of food science and human nutrition at Iowa State University in Ames.

"Demand increased since the COVID-19 pandemic began, as consumers moved toward foods and beverages that help to strengthen immunity and improve overall health," says Errol V. Raghubeer, PhD, senior vice president of microbiology and food technology at JBT Corporation's Avure Technologies, which manufactures high pressure food processing equipment in Middletown, Ohio.

Although traditional "thermal" milk processing technologies such as heat pasteurization, ultra-high temperature (UHT) treatment, canning, and dehydration have been used for several decades to ensure microbial safety and extend dairy products' shelf life, these processes can cause degradation of heat sensitive bioactive and nutritional components, and undesirable changes in the properties of treated dairy products that detract from "fresh-like" characteristics. "More health-conscious consumers prefer to consume dairy products made from raw milk," Dr. Mendonça says.

Thermal technologies use heat treatments to achieve fluid milk safety by killing any microbial contaminants present; however, the temperatures used can also cause changes in protein structure and functionality as well as the activity of bioactive compounds, including vitamins and minerals in dairy products, says Maneesha S. Mohan, PhD, associate professor and endowed chair in dairy manufacturing in the dairy and food science department at South Dakota State University in Brookings. For example, whey proteins in milk start to denature above 150°F and form covalent bonds with sugars and other proteins, which affects the flavor, color, bioactivity, and functionality, causing changes such as gelling, enzyme coagulation, and sedimentation of individual components and the overall product.

Some non-thermal technologies for dairy processing include high-pressure processing (HPP), pulsed electric fields (PEF), and ultraviolet (UV) light processing. "These technologies do not rely on high temperatures (i.e., temperatures greater than 50°C) to achieve the ultimate goal in food processing—which is to maintain food safety and quality during shelf life," says Federico Harte, PhD, a professor of food science at Pennsylvania State University in University Park.

Many of the non-thermal technologies have either been commercialized in the past decade or are in the research phase prior to commercialization, Dr. Mohan says. Many are effective in inactivating microorganisms and pathogens in dairy and other food products.

Here's a look at some of the newer, non-thermal technologies, how they work, and their advantages and disadvantages.

High-Pressure Processing

HPP involves placing packaged foods in a pressure vessel and filling it with water as the pressurizing fluid. High pressure, typically 600 MPa, is generated by a pair of intensifiers by pumping more water into the closed pressure vessel. Foods are held at the targeted pressure for a specified time before releasing pressure, says Alvin Lee, PhD, associate professor in the department of food science and nutrition at the Illinois Institute of Technology in Chicago and director of the Center for Processing Innovation at the Institute for Food Safety and Health in Bedford Park.

During compression, physiological and biochemical processes within microorganisms are affected, resulting in their inactivation, Dr. Raghubeer says. However, product nutrients and bioavailable compounds are largely unaffected because covalent bonds aren't affected at these pressures. This results in fresh-tasting, nutrient-rich products.

Zifan Wan, PhD, an assistant professor in the School of Agriculture at the University of Wisconsin in Platteville, concurs, and adds that HPP treatment leads to enhanced quality because the process doesn't affect heat-sensitive compounds (e.g., vitamins, simple sugars, and volatile flavor

(Continued on p. 18)

(Continued from p. 17)

compounds). Therefore, it doesn't result in non-enzymatic browning and loss of flavor and nutrients.

Other Benefits of HPP

When using HPP, foods with different-sized packages can be processed in the same batch, says Yiming Feng, PhD, assistant professor of food science and nutrition at California Polytechnic State University in San Luis Obispo. Because foods are processed in packages, they don't directly contact processing devices, which prevents secondary contamination and reduces sanitation costs. By having processes performed at room temperature, HPP reduces the energy consumption associated with heating and subsequent cooling.

The quality of dairy products made from HPP-treated milk can actually improve, Dr. Wan says. For example, one study published in 2007 in the *International Dairy Journal* showed that yogurt made from HPP-treated milk had a firmer gel structure and greater resistance to syneresis (doi: 10.1016/j.idairyj.2006.10.001). In addition, HPP-treated milk leads to enhanced lipolysis in cheese during ripening compared to cheese made from heat-pasteurized milk, in which lipase is mostly inactivated during heat treatment.

With enhanced lipolysis, a higher score of overall aroma for cheese made from HPP-treated milk was observed compared to cheese made from thermal pasteurized milk, because the breakdown of lipids into free fatty acids by lipase contributes to cheese's unique flavor and smell, Dr. Wan says, citing an article published in 2001 in the *International Dairy Journal* (doi: 10.1016/S0958-6946(01)00044-9). HPP is not ideal for fluid milk production due to the insufficient inactivation of lipase, however, as lipolysis of milk fat contributes to rancid off-flavors.

Although the initial capital investment for HPP treatment is high, the technology has gained widespread acceptance commercially in the manufacturing of different thermally sensitive food products such as guacamole, sauces, jams, and jellies, Dr. Mohan says. The dairy industry has commercialized high pressure-treated fluid milk, colostrum, cheeses, and yogurt fruit smoothies.

Some Downsides of HPP

Some disadvantages and challenges in applying HPP to dairy products exist, Dr. Mendonça says. For example, bacterial endospores are extremely resistant to inactivation by high pressure. In fact, the highest pressure levels typically used in commercial pressure treatment won't completely destroy bacterial endospores unless repeated cycles of HPP are applied. In this scenario, HPP is time consuming and increases energy usage, making it economically unfeasible. Figure 1 shows the components of a typical HPP system (see p. 19).

Another downside is that appropriate packaging is required. As a batch product, there are limitations regarding how much product can be processed at a time. HPP is also not a one-size-fits-all "safe harbor" process. "This technology is young enough that each situation needs to be evaluated to ensure it's effective against the potential hazards for that product," says Tim Stubbs, senior VP of the Product Research and Food Safety Innovation Center for US Dairy in Rosemont, Ill. "It can be misapplied."

Pulsed Electric Fields

In PEF processing, high-voltage electrical pulses are applied to food products to destroy microorganisms. The treatment of food products occurs between two high electric field electrodes in a treatment chamber. The electrodes are connected by a non-conductive material, which prevents electrical current flow among electrodes, Dr. Mendonça explains. For effective microbial inactivation, the PEF process involves applying about 10 to 80 kilovolts for a very short time, usually microseconds to milliseconds. The components of a PEF processing system are shown in Figure 2 (see p. 20).

The electrical pulses are transferred to food products and disrupt microbial cell membranes, destroying microorganisms. Various temperatures in sub-ambient, ambient, or higher than ambient ranges are used during PEF processing, Dr. Mendonça says. Treated food products are aseptically packaged and refrigerated during storage and distribution.

Advantages of PEF

Both PEF and conventional thermal treatments can enhance the microbial safety and shelf life of raw milk and other dairy products. Compared to thermal treatments, however, PEF can preserve heat-sensitive bioactive and nutritional components while reducing undesirable sensory changes in those products. "This aspect of PEF processing is important considering the rapidly growing

interest in the health properties of bioactive functional food ingredients derived from dairy products," Dr. Mendonça says.

The major advantage of using PEF to treat raw milk and dairy products is the potential for providing safe, high-quality finished products for consumers. "PEF processing is superior to conventional heat processing technologies because it reduces degradative changes in food quality and nutritional components and maintains sensory properties of foods while ensuring microbial safety," Dr. Mendonça says. PEF processing improves energy usage efficiently and economically, resulting in greater cost savings compared to applying thermal treatments such as pasteurization and UHT.

Moreover, applying PEF in addition to mild heating can reduce microbial populations of dairy products at levels comparable to heat pasteurization but without significant changes in sensory and nutritional quality, Dr. Mendonça says. Therefore, PEF technology has the potential to replace conventional thermal processing of raw milk and other dairy products.

PEF has been proposed as an alternative to the non-thermal pasteurization of milk used in cheese making. "It can be used when aiming to keep enzymes active while removing native microbial populations," Dr. Harte says. "However, for cheeses that rely on milk's native microorganisms for appropriate flavor and texture profiles, PEF may be as detrimental as traditional thermal processing."

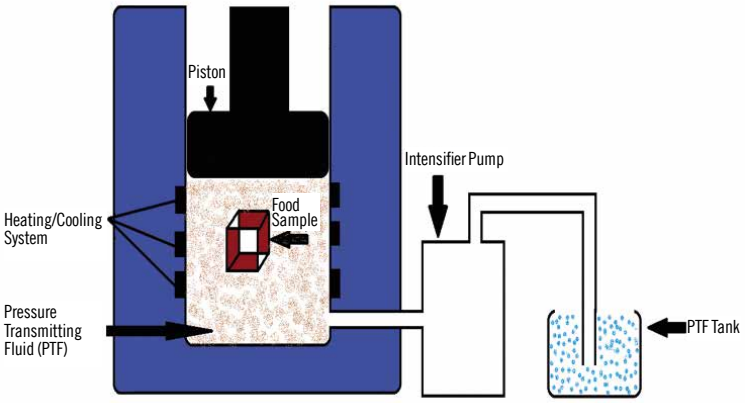


Figure 1. Schematic showing components of a high-pressure processing system.

Disadvantages of PEF

PEF is still in its early developmental stages. Currently, PEF processing costs more per unit volume/weight compared with other techniques (e.g., membrane filtration, UV radiation, and conventional heat processing). "More work is needed in order for PEF to lower its energy demand and scale up to the industrial level," Dr. Feng says.

Another disadvantage of PEF processing, like HPP, is that it's ineffective in destroying bacterial endospores, which are extremely resistant to many physical and chemical antimicrobial processes. "However, most of PEF's limitations are technical and associated with occurrences of electrochemical reactions," Dr. Mendonça says. These reactions can cause corrosion and fouling of electrodes, migration of electrode material into treated food products, electrolysis of water, and chemical changes in foods.

Ultraviolet Light Processing Techniques

UV light processing involves exposing food products to artificially produced UV radiation for set exposure times. Solid foods on a conveyor belt are exposed while passing under a UV light source, whereas liquid foods are passed through a UV reactor Dr. Mendonça says (see Figure 3, p. 21).

Sources of UV radiation include mercury vapor lamps, black light, fluorescent and incandescent light, and certain types of lasers. UV radiation can be categorized, depending on its wavelength, as UV-A (320–400 nm), UV-B (280–320 nm), and UV-C (200–280 nm).

The UV-C with shorter wavelengths is more energetic and can kill microorganisms. The genetic material of foodborne microorganisms is damaged when it absorbs short wavelengths, causing microorganisms to be unable to multiply due to irreparable damage, Dr. Mendonça says.

Pros and Cons

Food processing via UV radiation is a promising technology mainly because of its good commercialization potential, Dr. Mendonça says. Moreover, of the food products treated by innovative food processing technologies,

(Continued on p. 20)

©PORMEZZ - STOCK.ADOBE.COM

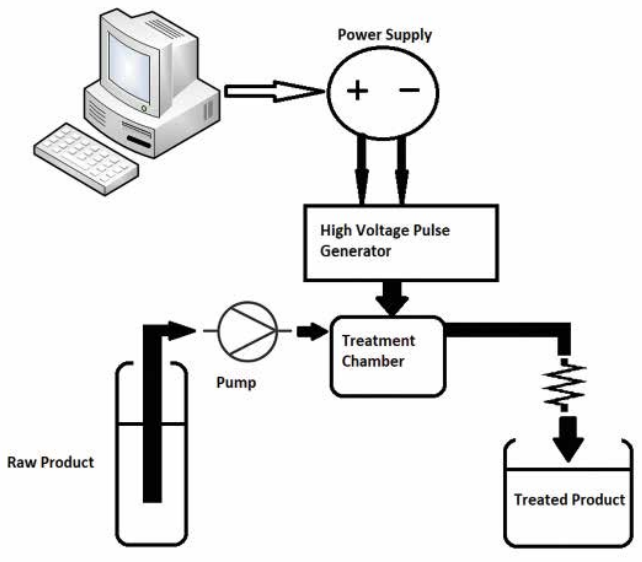
(Continued from p. 19)

those treated by UV were described as high quality (94%), safe (92%), and having improved shelf life (91%), according to a 2015 study published in *Innovative Food Science & Emerging Technologies* (doi: 10.1016/j.ifset.2015.06.007).

From an economics perspective, applying this technology involves relatively low installation, maintenance, and operational costs. Additionally, it's environmentally friendly because it requires relatively low energy usage for operation and no waste is generated, Dr. Mendonça says. Like other non-thermal processing technologies, UV radiation treatment can provide consumers with microbiologically safe, minimally processed food products with fresh-like characteristics.

Other benefits include retaining food texture and nutritional aspects without undesirable sensory and nutritional changes, no detrimental effects on the environment (no chemical residue or toxins), and no heat generation, Dr. Feng says.

Despite the attractiveness of UV light as a food processing technology, it has a few limitations. For one, it has intrinsically low penetration power. This reduces its antimicrobial effectiveness in foods with high concentrations of suspended solids and in opaque liquids such as milk, Dr. Mendonça says. Therefore, UV light application is restricted to treating clear liquids, surfaces of foods, and food packaging films such those used to wrap cheese. Workers should use caution by wearing personal protective equipment such as eye goggles, shields, and gloves, because prolonged exposure to UV light can damage their eyes and skin.



CREDIT: COURTESY OF AUBREY TREVOR MENDONÇA.

Figure 2. Schematic showing components of a PEF generating system.

Thermal Processes Will Still Play Main Roles in Dairy

Despite the benefits of using non-thermal technologies in dairy processing, thermal processing will continue to be the major processing method for dairy products, says James Gratzek, PhD, director of the Food Product Innovation and Commercialization Center at the University of Georgia in Athens.

"Thermal processing is low cost, highly reliable, well understood, and easy to validate," says Manpreet Singh, PhD, department head and professor of food science and technology at the University of Georgia and member of the *FQ&S* Editorial Advisory Board. Additionally, equipment operators only require minimal training.

"Unless there's a unique and marketable advantage resulting from a new process, it's unlikely that thermal processing will be replaced," Dr. Singh says. "And although there are certain niche processing areas with great benefits, thermal processing will maintain its dominance in dairy for decades to come."

According to Maneesha S. Mohan, PhD, associate professor and endowed chair in dairy manufacturing in the Dairy and Food Science Department at South Dakota State University in Brookings, "Emerging novel processing technologies offer huge possibilities, but require many more studies to better understand their effects on nutritional, biochemical, functional, and food safety properties of different food components and resultant products."

Additionally, new technologies need to be optimized for commercial application. Over time, many non-thermal technologies will evolve and be used in combination with each other or with thermal treatment for more effective outcomes in terms of food safety and quality, Dr. Mohan says.—*KA*

Adds Dr. Mohan, "While the microbial inactivation of UV light is encouraging, it has been associated with flavor changes in some cheeses and milks over their shelf life." UV light processing also has lower efficiency in foods with suspended solids and opaque or cloudy liquids such as milk.

Other Novel Non-Thermal Technologies

More non-thermal technologies are in the pipeline. Non-thermal (cold) plasma, an ionized gas and the fourth state of matter, has been proven to eliminate pathogenic and spoilage microorganisms with minimal changes in nutritional, functional, and sensory quality of food products, Dr. Wan says. The antimicrobial capability of cold plasma mainly results from three major components: reactive gas molecules, charged particles, and UV radiation. Advantages include being economical, adaptable, and environmentally friendly.

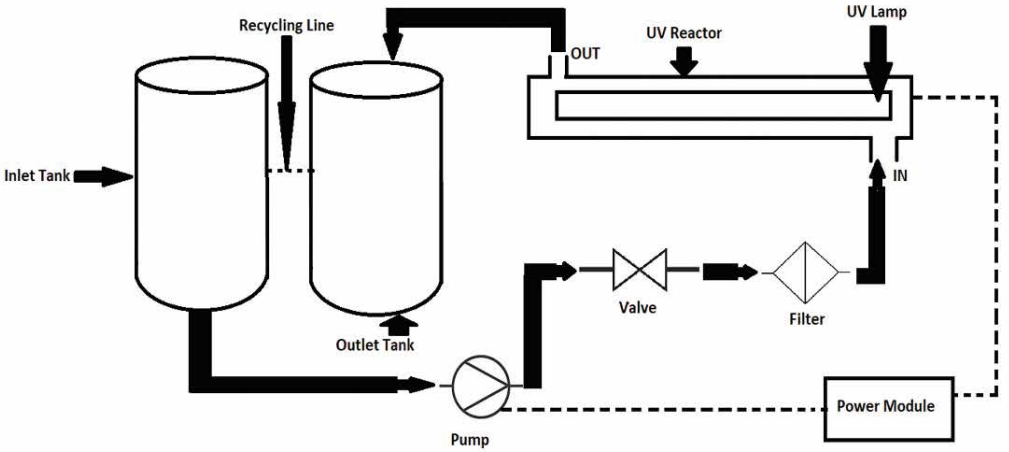
Filtration is another newer technology used commonly in dairy processing, says James Gratzek, PhD, director of the Food Product Innovation and Commercialization Center at the University of Georgia in Athens. Filters eliminate bacteria by size exclusion. For example, filtration makes it possible to exclude bacterial spores but not certain smaller vegetative types. In this scenario, filtration can be used in combination with gentle pasteurization to deliver extremely high-quality, long-life skim milk. Filtration can be used for a variety of dairy food types, including higher protein milks and Greek yogurt.

Another method, nanobubble technology, can improve the functionality of different products, including protein concentrates and other high-viscosity products, Dr. Mohan says. These invisible nano-sized bubbles can consist of different gases such as nitrogen, carbon dioxide, oxygen, or air.

Due to their tiny size and charge, nanobubbles are stable in liquid systems up to a few days. In addition to possibly using the technology in different dairy processes for product manufacture, the technology may potentially be applied in effluent treatment plants in the dairy industry to reduce the suspended solids and organic matter load in the effluents discharged into water bodies, Dr. Mohan says.

There is a huge potential for using nanobubble technology in the dairy industry to improve the functionality of high protein products and sustainability of dairy processing by reducing effluent discharge loads, Dr. Mohan adds. ■

Appold is a freelance science writer based in California. Reach her at kappold@msn.com.



CREDIT: COURTESY OF AUBREY TREVOR MENDONÇA.

Figure 3. Schematic showing components of a UV treatment system for liquid foods.

Safety & Sanitation

HYGIENIC DESIGN

Designing for Food Safety

The design and manufacturing standards of food processing equipment are of vital importance in a food plant

BY **MATT HALE**

The modern food production industry has reduced the cost of food and drink products, making them more available, but the overall trend toward the centralization of the food supply also increases the potential for food safety issues, such as contamination with pathogens or toxins, to affect a larger number of people.

To prevent this problem, food producers implement strict systems such as hazard analysis critical control points (HACCP), but the design and manufacturing standards of food processing equipment are also of vital importance and are not always considered or understood.

Types of Contamination

Contamination of food and drink products can cause anything from minor quality issues to severe health outcomes and, at the most extreme level, death. The main types of contamination that can affect food and drink products are microbial, chemical (including allergens) and physical.

Microbial contamination is caused by microorganisms including pathogenic bacteria, viruses, mold, fungi, and toxin-producing organisms such as *Campylobacter*, *Salmonella*, and *E. coli*. Microbial contamination is the most common source of food poisoning globally. Control measures to prevent microbial contamination include the implementation of strict hygiene measures, ensuring separation between raw and cooked ingredients, and the use of techniques to reduce the microbial load in the product, such as pasteurization, sterilization, or irradiation.

Chemical contamination can arise from the poor control of products used to clean and disinfect equipment and surfaces. If chemical residues remain on food preparation or contact surfaces, or if chemicals are used in the vicinity of food and drink products, then contamination can occur. Another source of chemical contamination may be the production of primary food ingredients, such as the incorrect use of pesticides and medicines on farms. Poor design of equipment may also allow for chemicals such as lubrication grease from moving parts to come into contact with ingredients or finished products.

Physical contamination is caused by the presence of foreign bodies and can include anything from stones and pests to items made of plastic or metal. Within food processing facilities, poorly maintained or badly designed equipment can itself become a source of physical contamination in the form of items such as flaking paint or loose screws. Physical contaminants may also carry harmful bacteria, increasing the overall contamination risk presented in the final product.

The last source of contamination on the list is allergenic contamination, which can occur when a food that causes an allergic reaction comes into contact with another food that does not include the allergen on the label. There are 14 recognized allergens, including gluten, peanuts, eggs, mustard, soy, and fish, and the reactions caused can range from mild discomfort to fatal anaphylactic shock.

Start with Design

Food processing businesses adopt a range of processes and procedures to prevent these forms of contamination from occurring. These measures may include cleaning and maintenance procedures, pest control, personal hygiene, protective clothing, and dress codes, among others. Many of these procedures will have been implemented as a result of a HACCP assessment of the facility and the production methods employed, but there is another equally important aspect of avoiding contamination which is not always given such a high profile: the design and construction of food processing equipment.

(Continued on p. 35)

Hygiene Inspections

Create a healthy sanitation culture in your food plant

BY **PIERRE DI GIROLAMO**

Without effective cleaning and hygiene systems in place in food plants, equipment can become sources of contamination. Chemicals used for cleaning can also contaminate food if not effectively flushed through.

Adhering to best hygiene practices is one process that food plants cannot cut corners on. Across North America, standards were already very high pre-pandemic; however, the pressure of the global pandemic has changed the landscape for a number of food processors, with localized lockdowns and supply chain disruptions further complicating mandatory audits. Additionally, the pandemic has reinforced the importance of producers conveying confidence and having robust and proactive HACCP and hygiene protocols in place.

Health, safety, and well-being expectations have increased. During the pandemic, food consumption patterns and grocery shopping behaviors shifted. Although price remains king when it comes to what drives food purchasing, safety is an equally critical consideration. A 2020 report by Deloitte, called "The Future of Fresh," summarizes this well; it describes food safety as multidimensional, including safety for self, for others, and for the workers who produce food, as well as safety in terms of packaging to prevent contamination.

Sesame Makes Allergen List

Producers have continued to demonstrate their resilience. Now, new regulations, including the recently passed U.S. bill, the "Food Allergen Safety Treatment Education and Research Act," are placing production sanitation programs under renewed pressure.

For the global food allergen community, sesame has long been a concern. It is a common ingredient in many food types, especially Asian cuisine, dips, vegetable burgers, breadsticks, and burger buns, as well as a popular seasoning and flavoring in snacks, cereals, and chips. Affecting more than one million people in the United States according to Asthma and Allergy Foundation of America, sesame must be clearly listed on food labels by January 1, 2023. Currently, labeling practices often involves listing sesame under generic labels such as "natural flavor" or "natural spices."

> Hygiene protocols should be formalized and included in staff training, and every cleaning process should be verified and documented.

All food and beverage manufacturers have a responsibility to identify allergens that are contained in their products. This responsibility extends to isolating them from other non-allergen products processed in the same facility. If a dedicated line for foods containing sesame cannot be allocated, for example on bakery lines, a common tactic might be to create planning production schedules to isolate products containing sesame. Ingredients should also be stored separately. Additionally, cleaning must go well beyond normal hygienic requirements, even where heat processing is involved, because allergens of any type can survive high temperatures.

Habit Forming

It's human nature: We like things to be streamlined, efficient, faster, and better. Yet, taking hasty shortcuts is a risky strategy. Being careless with compliance can lead to more shortcuts, and that's not a cycle any food business would or should encourage.

In the hospitality sectors, the pandemic journey has focused where possible on removing human touchpoints. Yet, cleaning food manufacturing and processing machinery is not a contactless task. Instead, smarter equipment design can enhance hygiene and safety measures.

(Continued on p. 36)

©SEVENTYFOUR - STOCK.ADOBE.COM

A Global Perspective on Food Fraud

Understanding the risks

BY **AMANDA MCCARTHY**

Food fraud is nothing new. It has been a problem for many years and remains essentially unsolved. It is recognized as one of four different challenges to food integrity and is almost always motivated by economic gain. The European Commission defines food fraud as "any suspected intentional action by businesses or individuals for the purpose of deceiving purchasers and gaining undue advantage therefrom."

The other three challenges are:

- Food defense, which is primarily aimed at preventing intentional harm and may even occur when disgruntled employees sabotage food products;
- Food quality, which usually results from unintentional actions but may involve food fraud; and
- Food safety, which is mostly unintentional, with causes such as contamination and failure to control critical processes, but can also be malicious or fraudulent.

The phrase "food fraud" covers a variety of different types of fraud, among which are dilution, substitution, unapproved enhancement, concealment, counterfeit, mislabeling, and gray market. It is continually an issue because of the increasing length and complexity of supply chains. Moreover, supplier vulnerabilities are driven by the need to shift from one supply chain to another. Aside from the economic impacts of food fraud, there is always an inherent safety risk when ingredients are substituted, whether intentional or not. Traceability is lost, increasing the chanses of additional undetected substitutions.

An example of an unintentional action with a big impact is the melamine scandal in China in 2008. This started as a food fraud case when someone used melamine, a non-food nitrogen source that was misidentified as "protein" by substituting routine total nitrogen testing methods for testing that would have indicated digestible nitrogen in baby and pet foods. This resulted in fatalities and hospitalizations, followed by the establishment of new regulations to address the potential for economically motivated fraud that results in a food safety hazard. There have been other cases over the years of fake ingredients being used in many products driven by people who basically don't know what they're doing.

A Growing Global Problem

Each month, the Joint Research Centre of the European Commission publishes a a summary of food fraud and adulteration cases brought to its attention. This summary is by no means an exhaustive list, comprising only the cases reported in press articles around the globe.

The March 2022 monthly summary of articles on food fraud and adulteration had instances from 22 countries, including four countries inside the EU and the U.K. The size of some is quite staggering. One from China involved a criminal network smuggling more than 180,000 tons of seafood. Another resulted in the closing of a factory in Cameroon that was producing fake honey by mixing water, powdered sugar, and other ingredients.

While these examples represent significant economic fraud, others such as ingredient substitutions that introduce unlabeled allergens pose a huge risk to those with food allergies.

Food fraud is clearly a significant threat to food safety, impacting consumer health, industry operations, and brand reputation. Preventing food fraud is critical, but understanding and identifying

the risky hot spots is not that easy. Sound food safety systems will always be an essential foundation, and developing these is a key challenge if food fraud is to be defeated. Current mitigation measures based on sampling and testing are useful in the short term but do not necessarily solve the problem. Detecting food fraud does not prevent it; it just postpones the issue until the fraudster has found another means of avoiding detection.

As mentioned, food fraud is very often a criminal activity driven by economic gain. The high value of the ingredient or material in saffron, honey, or beef, for example, is one motivator. Substituting or adulterating a high value item with something of a lesser value creates more profit. But even some traditionally lower-value items can make a profit for food criminals because of climate or disease impacting crop yields, such as hot weather affecting olive oil harvests, driving up the price of virgin olive oil. This makes adulteration or mislabeling even more appealing. Geopolitical tensions, such as the impact of war on availability of ingredients in the supply chain, create similar pressures.

The latter point is particularly relevant today, given the situation in Ukraine. Both Ukraine and Russia are major grain exporters. In 2019, the combined export of these two countries provided more than a quarter of the world's wheat. Despite sanctions, Russia will likely be able to export a considerable quantity, but the harvest in Ukraine will inevitably be impacted, and its seaports are effectively rendered unusable.

According to the UN's FAO Food Price Monitoring and Analysis, world wheat prices soared by 19.7% during March 2022. Maize prices posted a 19.1% month-on-month increase, hitting a record high along with those of barley and sorghum. Vegetable oils (Ukraine is a major producer) also rocketed in price, and a world shortage is predicted. We are already seeing a shortage in the stores and "rationing" by some retailers. Sunflower oil is also a major ingredient in processed food, so the risks of fraud among these items are already on the horizon.

Supply Chain Vulnerability

Longer and more complex supply chains create more opportunities for food fraudsters to infiltrate. The more often a material is transferred from one operator to the next, the more chances criminals have to make a profit. Multi-ingredient processed products, with components sourced from many regions or countries, have increased supply chain length and complexity. Ingredients may pass through many buyers and sellers from farm to fork and be transported as bulk ingredients or smaller units by road, rail, or air in frozen, concentrated, or dried forms for reconstitution at later stage. All these steps invite the opportunity for fraudsters to make money.

> The phrase "food fraud" is covers a variety of different types of fraud, among which are dilution, substitution, unapproved enhancement, concealment, counterfeit, mislabeling, and gray market.

In the past, when the food industry was made up of mainly smaller organizations and individuals, food fraud would have been perpetrated by the organizations themselves; however, it is clear that, as the scale of food production has increased, criminal organizations have become involved.

The horsemeat scandal of 2013, when horse DNA was discovered in products mainly sold as beef, was a shock to the industry. It became clear to the industry and the general public that there was money to be made in food, and if there was money to be made, criminals would be active. Generally, these criminals have no desire to make customers ill or worse. This would only call attention to their activities. But, when monetary gain is the driving factor, there will be times when greed overrides safety concerns, especially if the consequences of food adulterations are not fully understood.

Europol became involved in coordinating investigations among national authorities, raiding premises and making arrests. Following an independent review, national Food Crime Units were created, and the industry started to take the risks seriously. Food safety standards used by the various bodies and organizations involved in certifying food safety management systems were reviewed to include risk assessments linked to food fraud, in addition to those linked to food safety, using a similar methodology to hazard analysis and critical control points (HACCP).

A New Way of Fighting Fraud

Essentially, the new method involves testing and there is a risk assessment process. There is a place for testing, but obviously there are downsides. For example, are you testing for the right thing? Do you wait for the result before you use that ingredient? Can you trust the testing and are the methods to test available? Are the analysis certificates fraudulent or counterfeit? It is all about using a risk assessment approach to try to identify where those risks are and to effectively manage them. Although similar to HACCP, but it's called vulnerability assessment critical control points (VACCP).

Many of the leading global standard organizations now include VACCP as part of the auditing process for food safety systems; others require a food safety plan that includes an ingredient hazard assessment to address known cases of fraud that pose a food safety threat, as well as the more common food safety hazards. This will mean a control plan incorporating mitigation strategies and corrective procedures, which could involve audits of the entire supply chain, supplier assessment, and extensive quality control checks of ingredients and processes.

The secret of any successful food safety plan is setting up a team that is familiar with what is happening in the industry—a team that can consider every part of the process and identify vulnerable points in the supply chain, determine where the risk factors are, and decide how best to control them. It is not possible to completely eliminate the risks, but what organizations should be trying to do is control all that have been identified in order to minimize food fraud.

Steps to Minimize the Risks

A typical food fraud management system would begin with creating the team needed to operate the system, after which

(Continued on p. 36)

Quality

Assuring the Safety of Food Additives

Some foods and beverages contain multiple additives, so approvals can get complicated. A look at the process and potential complications | BY **LORI VALIGRA**

Additives, with names like magnesium oxide and thiamine mononitrate, may sound unfamiliar to some consumers, but they are key ingredients that keep the tastes, nutrition and colors people expect in processed foods and beverages.

When Kantha Shelke, PhD, principal at Chicago-based food science and research firm Corvus Blue, teaches her class at Johns Hopkins University about additives, she uses a "Jeopardy" game scenario. She poses statements to students such as: "This keeps bread mold-free and salad dressings from separating; this makes cured meats safe to eat; this gives margarine its characteristic yellow color; this allows fruit juices to be available year-round."

"The correct answer to each [statement] is the same: 'What are food additives?'" says Dr. Shelke.

Without colors and preservatives, the strawberry ice cream we expect to be a pleasant pink color would instead contain soggy brown fruit, because strawberries quickly turn brown and degrade after being harvested and put into processed foods. Food additives can be sourced from plants or created synthetically.

Additives, which are identified on the ingredient label of a food product, are intentionally added to a food supply after undergoing a peer-reviewed process by FDA or an independent panel of experts. They are put into foods or drinks for a specific purpose. For example, xanthan gum adds texture to salad dressings, chocolate milk, bakery fillings, puddings, and other foods.

FDA's Food Additive Status List website contains a detailed list, alphabetically, of the thousands of available additives. The agency has 32 categories of additives under its Code of Federal Regulations 21. It also has seven certified color additives that are considered safe to consume.

Other commonly used additives include aspartame, an artificial sweetener; sodium nitrite, a preservative that prevents bacterial growth in meat and adds a reddish-pink color; and carrageenan, a red seaweed derivative that acts as a thickener and preservative in products including almond milk, vegan cheese, ice cream and coffee creamers. "Without food additives, we would not have the range of prepared and packaged foods that you have today because the product has consistency and the flavor is enhanced," Dr. Shelke says. "All the emulsifiers, stabilizers, and anti-caking agents help the palatability and wholesomeness, and vitamins and minerals help the nutritional value."

Quality and Safety

Additives are evaluated primarily in two different ways in the United States, says Roger Clemens, PhD, a food expert at the University of Southern California School of Pharmacy in Los Angeles. One is by FDA. The second, conducted independently of FDA, takes a self-affirmation approach, in which specific criteria are screened by a panel of experts to assure the additive's safety for its intended use in a particular food.

Dr. Clemens has served on such panels, which he says include physicians, including a pediatrician, along with a nutritionist, a toxicologist, and a representative from the food processing industry. The panels are coordinated and recruited by the company that wants the product reviewed, but Dr. Clemens said they use participants without conflicts of interest.

He says the panels identify the chemistry of the additive, its composition, tox-

icology, microbiology, and whether the product could degrade over time or at different room or transport temperatures. They also look at how it will be put into the food—for example, via a thermal process—and what happens to the food undergoing that process, such as whether it remains stable and is dispersed homogeneously in the food or drink. The panel also looks at pesticides if the additive comes from a fruit or vegetable.

Further, the panel assesses how the additive could affect people of different ages, from pediatrics to geriatrics and ages in between. They look at whether the additive might affect the immune, gastrointestinal, or endocrine systems of the person who consumes it.

The panel then determines whether the additive is considered safe, Dr. Clemens says. If the panel says it is, the food manufacturer can then claim the product is self-affirmed to be safe and can use it immediately. Alternately, the manufacturer can send the documentation from the panel to FDA for further review. FDA has 180 days to respond or ask questions regarding the findings.

Some foods or drinks have multiple additives, so approvals can get complicated. Cocoa, for example, is not soluble in water, so it needs an emulsifier to stabilize it. If a flavor is added, that additive could be reviewed by the Flavor and Extract Manufacturers Association. Some additives have multiple functions—for example, vitamin C could be used as a vitamin, but it also can be used to stabilize minerals over the product's shelf life or as a food color.

Additives are meant to last through the "best buy" date on the packaging. Eating food or consuming drinks beyond that date doesn't mean it is bad, Dr. Clemens says, but the additives and regular ingredients may not taste as good. For example, bread may have a bad flavor after seven to 10 days because oxygen gets through the plastic wrapper and spoils it.

Additives from Nature

The current trend toward plant-based foods and additives creates another dimension to ensuring that additives are safe. Nearly all plants contain toxins, so they must be used judiciously. What it comes down to is how much we are exposed to, says Dr. Clemens, who points to the lemon trees in his back yard in California as an example. Limonene, an extract that gives citrus its fragrance, has minor toxicity, but is also known to have anticancer benefits, he says. It is extracted from citrus peels and used as a flavoring additive in a variety of foods. "We have to look at these as an application exposure before we classify them as safe or not safe," he says. That is part of the generally recognized as safe (GRAS) assessment.

People who are vegan or who have other dietary restrictions should also become familiar with the sources of additives; they may desire to avoid them for health or personal preference reasons. Carmine, for example, is a red food coloring made from crushed cochineal insects native to Latin America.

Clean Labeling

Another trend among consumers is better understanding of what they are eating. Clean labeling, which simplifies the names and numbers of ingredients, has become popular over the past several years. Clean labeling also includes substituting synthetic ingredients with plant-based additives that consumers consider more "natural."

"The labeling movement is arguably the largest trend in the food industry," Dr. Shelke says. "Natural ingredients are another trend."

But as food labels become more consumer friendly, some of the functionality of the label to tell what is in the product is getting lost, says Mario Ferruzzi, PhD, professor and chief of the Developmental Nutrition section in the Department of Pediatrics at the University of Arkansas for Medical Sciences in Little Rock. "What worries me most is we are seeing product formulations shift to categories and ingredients that don't quite go through the same level of scrutiny as today's products," he says. "Or companies are working on extracts that are poorly characterized and we don't know perhaps what else is being carried with them into products."

One example is the colors used in products to keep them recognizable to consumers, such as yellow lemonade. He says the certified synthetic colors are some of the most well-defined and chemically analyzed ingredients that exist. But some consumers don't want synthetic colors, and manufacturers are trying different options to get the same color or texture.

"When you think about making new plant proteins or new plant extracts, you always run the risk of concentrating toxicants when you start extracting and concentrating plant materials," Dr. Ferruzzi says. "If they're not being screened for toxicants—although they should be—you're going to have instances where you may have challenges maintaining that supply consistently."

He says just because an additive is "natural" doesn't make it automatically safe to consume. The term "natural" isn't currently defined by regulatory agencies, so it could be used in misleading ways. The plant could have heavy metals in it or bacterial contamination. And it's tricky to get the same functionality as a synthetic additive with one from a plant-derived additive.

He also worries about the extent to which we may see some of the additives or finished products come from foreign markets that might not screen them as thoroughly. Those may enter the United States if their manufacturers label them as having passed safety inspections.

"Those things make you pause," he says. "Just because you are going to a cleaner label, is it a better label? Is it safe?" ■

Additives are evaluated primarily in two different ways in the United States: One is by FDA. The second, conducted independently of FDA, takes a self-affirmation approach, in which specific criteria are screened by a panel of experts to assure the additive's safety for its intended use in a particular food.

Valigra is a freelance science writer based in Maine. Reach her at lvaligra@gmail.com.

In The Lab

Ethylene Oxide Analysis

How a GC-MS/MS method can allow for sensitive and consistent quantification

BY **ŁUKASZ RAJSKI, PHD**

©DMITRICH - STOCK.ADOBE.COM

Ethylene oxide (EO) has a broad array of applications across many industries. One of the most important is as a fumigant pesticide for the preservation of dry food products, such as seeds, milled cereals, spices, and herbs. However, upon consumption, EO can have significant impacts on human health, adversely affecting the nervous system and mucous membranes, and exhibiting mutagenic and carcinogenic potential. Moreover, in food, EO readily degrades into 2-chloroethanol (2CE), which is itself considered toxic.

Such health concerns have driven a spate of strict regulations on EO's usage in food production across the globe. Most notably, EO is now banned for use in food in many countries, including all of those in the European Union (EU), where it has been banned since 1991. Currently, the EU has set maximum residue levels (MRLs) for EO at 0.02 to 0.1 mg/kg, depending on the commodity, where EO is defined as the sum of both EO and 2CE (Reg. (EU) 2015/868). Despite the ban, there have been a number of recent reports of the presence of EO residue in food products in the EU, primarily owing to inconsistent regulations globally. Between January 1 and July 31 in 2022 alone, there were 119 EO contamination alerts published in the Rapid Alert System for Food and Feed (RASFF).

This volume of alerts demonstrates the critical importance of more accurate and frequent monitoring of food for contamination with EO and its degradation products. Using current analytical methods, however, EO analysis is incredibly challenging. In this article, we will provide an overview of the current difficulties of EO determination and explore how these can be effectively overcome using an optimized gas chromatography with tandem mass spectrometry (GS-MS/MS) workflow.

Grappling with EO Determination

Because of the significant health risks posed by EO residues and owing to the low permissible MRLs set by the EU, methods for the analysis of food products for EO residues must be sensitive, precise, and accurate. At the same time, food testing laboratories must have the capability to meet the continuous and growing testing demand. In practice, this means that food laboratories must deliver an increase in sample throughput and shorter analysis turnaround times.

However, meeting these requirements using current methods—typically triple quadrupole gas chromatography mass spectrometry (GC-MS)—is challenging on several fronts due to the lower MRLs stipulated and the inherent hurdles of EO analysis.

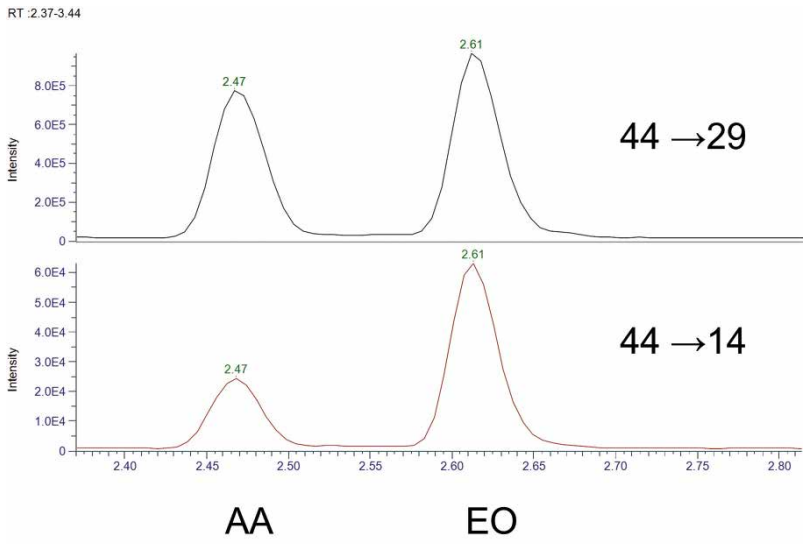
Many of the challenges in EO analysis stem from the inherent physical and chemical properties of EO itself. For example, EO is a highly volatile compound, with a boiling point of just 10.7°C. If careful precautions are not taken during sample preparation, analysts risk EO evaporation, which could lead to an underestimation of the extent of EO contamination. This means potentially unsafe food samples could make it to consumers. EO's volatility also means that it cannot be retained at all on some generic chromatographic columns and is only weakly retained by others. EO, therefore, elutes shortly after the void time, bringing a risk of interferences from other poorly retained compound that are present, which means that EO cannot be separated from the matrix. As a result, there is a significant risk of either missing EO residues or inaccurately determining the level to be safe in a given sample, when in fact it is not.

The low molecular weight of EO and its fragmentation products presents another analytical hurdle—increased susceptibility to interferences. One notable compound that commonly interferes with EO is acetaldehyde (AA), which has the same ion transitions as EO. Because of these non-selective ion transitions, insufficient chromatographic separation of the analytes (i.e., co-elution) can lead to overestimation of EO contamination in a sample. In the worst-case scenario, analysts can get a false negative result from the interference between EO and AA.

Then there are the general challenges associated with the analysis of dried food samples. Food samples are complex matrices, meaning extracts are typically rich in a plethora of co-extracted compounds. This presents two critical challenges for the analytical laboratory looking to achieve sensitive and selective EO analysis: First, continually running "dirty" samples through a GC-MS system can cause contamination of all parts of the chromatographic system, triggering the need for increased maintenance, greater down-time, and more costly operations. Second, running complex samples through instruments can directly impact the quality of the results, leading to poor chromatographic performance, retention time shifts, variable peak areas, and degraded peak shapes.

In the case of EO analysis using common methods, the impact of complex matrices is amplified by the fact that, to compensate for poor sensitivity and selec-

(Continued on p. 30)



CREDIT: COURTESY OF THERMO FISHER SCIENTIFIC.

Figure 2. Superior chromatographic separation mitigates the impact of non-selective ion transitions, demonstrated here with the clear separation of AA and EO.

(Continued from p. 29)

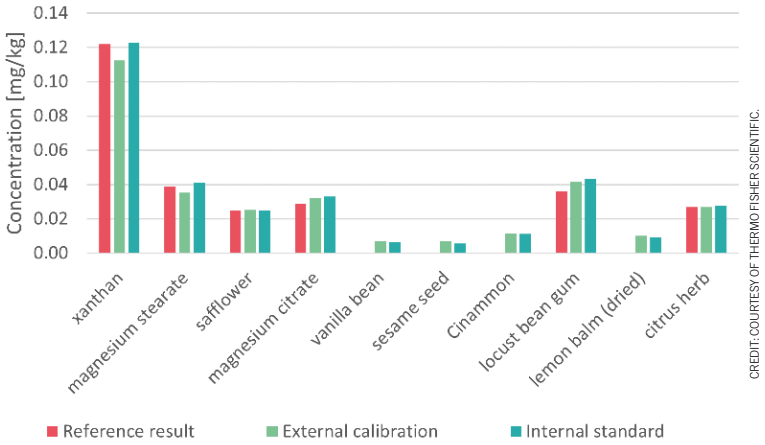
tivity, larger sample volume injections of approximately 2 µL are required.

As explained, current EO analysis is exceptionally difficult. The array of hurdles involved means analytical labs can typically only run 15 to 20 samples before maintenance or system cleaning is required. The increased downtime means samples are sitting around longer, exposing them to greater EO evaporation risk. When throughput is stifled in this way, operational- and lab cost-efficiency also suffers greatly, driving up prices that couldalso result in lower rates of testing.

An Optimized GC-MS/MS Workflow

To overcome these common challenges in EO determination, an advanced GC-MS/MS method has recently been developed. Unlike traditional approaches, this method uses triple quadrupole mass spectrometry with an expanded linear dynamic range, as well as an advanced electron ionization (AEI) source that delivers a focused ion beam with enhanced transmission. Combined, these deliver increased sensitivity, selectivity, linearity, and robustness relative to current GC-MS approaches. Critically, the increase in sensitivity means that sample injection volumes can be reduced.

More specifically, the method uses a Thermo Scientific TRACE 1610 GC system coupled to a Thermo Scientific TSQ 9610 triple quadrupole GC-MS/MS system, which is equipped with a Thermo Scientific Advanced Electron Ionization (AEI) source. Samples are injected using a Thermo Scientific TriPlus RSH autosampler. EO evaporation from samples during unattended analysis is eliminated owing to a specially designed cooled rack, which keeps samples at 7°C. Samples were prepared following the QuOil-Method (CEN/TS 17062:2019 modified) with one amendment: 3g of the samples were used rather than 2g. The method was validated according to "analytical quality control and method validation procedures for pesticide residues analysis in food and feed" (Document Nº SANTE/11312/2021).



CREDIT: COURTESY OF THERMO FISHER SCIENTIFIC.

Figure 4. Quantitation of 2CE using real food samples.

Advanced GC-MS/MS: Sensitive, Selective, and Linear EO Determination

When evaluated using standard solutions, the optimized method exhibited exceptional performance across several domains.

Greater sensitivity for smaller injection volumes. As noted above, the lack of sensitivity in current methods has meant that most laboratories need to use larger 2 µL injection volumes, which exacerbates the problems associated with multiple injections of complex sample matrices. Thanks to the enhanced sensitivity and careful method optimization, however, the method being investigated can deliver exceptional sensitivity, even at 1 µL injection volumes.

Figure 1 (which can be found at foodqualityandsafety.com) shows that all ion transitions were characterized by high signal-to-noise ratios, and ion ratios were highly stable, meeting the variability criteria of DG SANTE guidelines.

The ability to drastically reduce complex sample injection volume significantly reduces the burden on instruments, meaning equipment will need to be vented and cleaned less frequently, and throughput can be boosted as a result.

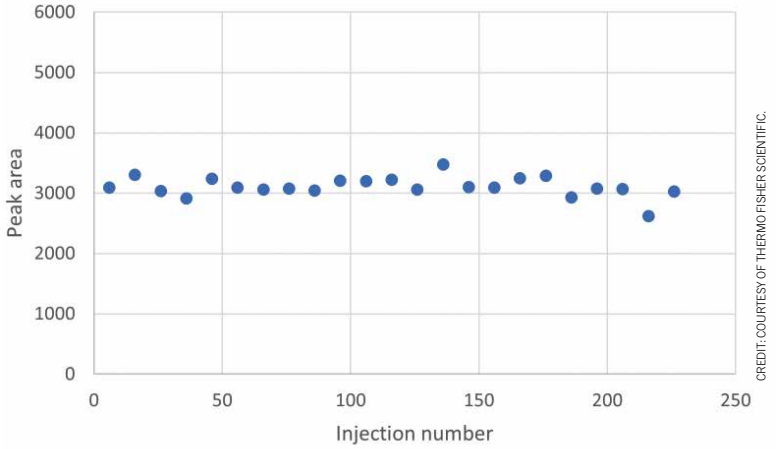
Superior selectivity to handle AA interference. As well as showing high sensitivity, this optimized method delivered exceptional selectivity. This is primarily due to the specific chemistry of the stationary phase and increased stationary phase thickness of the column, which means it can better retain highly volatile analytes such as EO and its residues. Co-elution of analytes with similar ion transitions can thus be mitigated, leading to better selectivity and more accurate results.

Figure 2 shows that the column enabled a good separation of EO and AA, with a retention time difference of more than 0.1 minute (see p. 29). As a result, despite the non-selective ion transitions, the

©ELENATHEWISE - STOCK.ADOBE.COM

©M.STUDIO - STOCK.ADOBE.COM

©M.STUDIO - STOCK.ADOBE.COM



CREDIT: COURTESY OF THERMO FISHER SCIENTIFIC.

Figure 5. Response of isotopically labelled 2CE standard in every 10th injection of the sequence, spanning 230 injections in total.

risk of AA interfering with EO results was eliminated.

Broad linearity reduces the need for dilutions. The method showed excellent linearity across both EO and 2CE, made possible by the extended linear dynamic range of the mass spectrometer's detector. In the investigated concentration range of 0.002 mg/L to 5 mg/L (corresponding to 0.007 mg/kg to 16.5 mg/kg in the sample), all back-calculated concentrations were within ± 20% of the true concentrations, meeting the criterion of the DG SANTE guidelines (see Figure 3, which can be found at foodqualityandsafety.com).

A method that can deliver such a broad linear range means that samples with a high concentration of analyte do not need to be diluted and reinjected. For the lab, this translates to reduced analysis time, which opens the possibility of greater throughput.

Real-World Robustness

While the method excelled in evaluations of sensitivity, selectivity, and linearity using standard solutions, challenging the method using complex food samples, at high throughput, is required to fully demonstrate its applicability to the food testing laboratory.

With that in mind, the method was used to evaluate 10 different food samples encompassing a range of foods. Here, external calibration curves were applied for both EO and 2CE, and samples were spiked with deuterated 2CE to provide an additional internal standard suitable for 2CE. Reference concentrations were also obtained in a laboratory accredited under ISO/IEC 17025:2005, using the same optimized GC-MS/MS method.

While EO was not detected in any sample (which is common given its instability), 2CE was detected in all samples. Excellent results agreement was seen between our laboratory and the external laboratory (see Figure 4, p. 30). Additionally, results from the internal standard also matched the external calibration curve as such, demonstrating the suitability of the quantitation method for real food analysis.

To meet the high-throughput needs of food testing laboratories, analytical methods must provide long-term, maintenance-free operation, which is no easy feat given the repeated injections of complex samples required. To evaluate whether this new method could deliver on this critical need, a sequence containing the 10 samples was injected continuously over three days. This amounted to a total of 230 injections. During this period, there was no instrument maintenance, tuning, or other interruption of the system.

The method exhibited remarkable robustness across the injections. Evaluation of the peak characteristics of isotopically labelled 2CE showed the system's function was highly stable, with no degradation of chromatographic separation. Excellent consistency of peak areas was also observed (relative standard deviation ± 8.8%), and retention times deviated by less than 0.01 minute, an order of magnitude lower than the limit set by SG SANTE guidelines (see Figure 5, p. 31). This was all achieved despite there being visible sample matrix residue in the liner at the end of the experiment.

As demonstrated, the reduced sample volume enabled by the sensitivity of triple quadrupole mass spectrometry and an enhanced AEI source ensures a highly robust method.

Advanced GC-MS/MS: Better Analysis, Better-Protected Health

The risk posed by EO and its residues in food is significant but the inherent properties of EO, the performance of current analytical methods in the context of low MRLs, and the ever-increasing demands of the food testing sector are making EO determination unnecessarily slow and costly.

However, an optimized GC-MS/MS method that uses chromatography columns that can separate volatile analytes, an enhanced AEI source, and the sensitivity of triple quadrupole mass spectrometry can alleviate these challenges. The method described here does just this, delivering exceptional sensitivity, selectivity, linearity, and robustness to meet the needs of food testing labs.

In adopting such methods, laboratories will be able to detect EO and its residues more accurately, reduce method duration for increased throughput, and significantly increase the cost effectiveness of their operations. Ultimately, this means better protection of human health, and safer food products for consumers. ■

Dr. Rajski is product specialist for gas chromatography mass spectrometry for Thermo Fisher Scientific. Reach him at lukasz.rajski@thermofisher.com.

Figures 1 and 3 of this article can be found on our website at foodqualityandsafety.com.

Microbial Challenge Testing

How challenge testing can help ensure a food's safety

BY **ANDREA TOLU**

For consumers, the concept of food's shelf life of food is quite simple: follow the storage instructions indicated on the label, and you can be reasonably sure that the product will still be good to eat at least until the expiration date. The work that goes on behind the scenes to make that happen, however, is more complicated.

There are two important measures that food manufacturers must apply to ensure microbiological safety: killing unwanted microorganisms during processing and preventing their growth during shelf life. Under the Food Safety and Modernization Act (FSMA), these measures fall into the category of process preventive controls, which are the only ones requiring written validation of their effectiveness.

How well a kill step or a food formulation will work depends on several variables. For example, the heat resistance of *Salmonella* will vary depending on the strain and the combination of macronutrients, water, salt, and pH. These intrinsic factors, together with the use of preservatives, will also have a direct effect on the growth of microorganisms during shelf life.

The interaction of these variables can make validation challenging: "Every organism has an absolute limit: it won't grow below a certain level of pH, salt content, or water activity. But when these are combined, it can be difficult to know what will happen," says Peter Wareing, a food safety consultant based in the UK. "If the pH is high enough to allow the organism to multiply, but salt content is also high and water activity is low, then those two factors might prevent the organism from growing."

Quite often, food manufacturers can use published literature to validate process preventive controls. For example, the efficacy of milk pasteurization is well established and will require no further evidence; however, for many recent products there is not sufficient data to know whether the combination of kill steps, formulation, and storage conditions will ensure shelf stability. The only way to find out is to adopt an empirical approach and conduct a microbiological challenge test.

In a challenge test, a food sample is inoculated (challenged) with a known microorganism or a surrogate, to observe how an antimicrobial treatment or the composition of the food itself will affect lethality and growth. The two main types are inactivation and growth challenge tests.

Will It Die?

In an inactivation challenge test, a food sample is first inoculated and then put through the intended kill step, such as thermal treatment or high-pressure processing (HPP), and finally analyzed to verify how many cells survived.

When this test is conducted in a lab, says Alvin Lee, PhD, associate professor of food science and nutrition at Illinois

Institute of Technology in Chicago, it's important to closely mimic the conditions the product will go through. "If you're validating the cooking process in the production of soup, for example, you'll have to apply not only the same time and temperature but also the ratios between produce and water," he adds.

Inactivation challenge tests can also be done directly at the manufacturer's plant. "On-site challenge tests allow you to use the actual processing equipment and take into account all of the unknowable variables," says Rob Limburn, group manager of industrial process microbiology at Campden BRI, a food and beverage research organization based in the UK. "In this case, we wouldn't use an actual pathogen, but a non-pathogenic surrogate with similar inactivation characteristics." Typical examples of surrogates, says Limburn, include *Enterococcus faecium* or *Pediococcus* spp for *Salmonella*, *Listeria*, or *E. coli* in dry products. In some cases, non-pathogenic strains, such as *Listeria innocua*, may be appropriate.

To make on-site test results more reliable and efficient, says Limburn, it's important to identify the points in a static system, or the path through a continuous processing line, where the product receives the least severe process: "For example, if you have a conveyor belt with several lines of products going into an oven, there's likely going to be a gradient of temperature, depending on where the fans are positioned and other factors. In that case, rather than placing more samples across the belt, the best point will be the coldest channel: If it's effective there, it will be effective anywhere else on the belt."

What Foods to Challenge

Certain types of foods are more likely to require an inactivation challenge test: "With a moist system, like sauces or ready meals, you can measure time and temperature and rely on long-established microbial inactivation kinetics," says Limburn. "But with products with low water activity, like nuts, seeds, snack bars, crisps, spices, or flour, these can be very different. *Salmonella* in particular is a lot more resistant to dry than moist heating. In those cases, microbial challenge testing would be recommended," says Limburn.

Even if a product is a good candidate for an inactivation challenge test, it doesn't necessarily need one: "Many businesses have a large portfolio of products and couldn't really do a challenge test for every single one of them. One way around that is to categorize them and conduct the challenge test on the most protective one out of a particular category. It could be the product containing a high-risk ingredient or with the lowest moisture. This way, you'll know that everything within that category would require a less severe process," says Limburn.

©GORODENKOFF - STOCK.ADOBE.COM

Many businesses have a large portfolio of products and couldn't really do a challenge test for every single one of them. One way around that is to categorize them and conduct the challenge test on the most protective one out of a particular category.

—ROB LIMBURN

Even when there is enough data available, however, performing a challenge test might still be a good idea: "No two food products are the same. When fruits are grown at different locations, the hazard or the pH could be slightly different. Even if there's an established process, we always recommend manufacturers do a challenge test, so if anything were to happen, at least they have their own data to back it up," says Dr. Lee.

A category where it wouldn't be necessary are canned and pickled products, where, says Wareing, you normally rely upon the time and temperature and the internal characteristics of the food to make sure they're safe. "If they don't survive throughout the shelf life, then it means there's something seriously wrong with the process," he adds.

Will It Grow?

In a growth challenge test, it's a finished product that gets inoculated. The goal is to find out whether the formulation provides an environment that inhibits the growth of unwanted microorganisms during shelf life. A typical target, says Wareing, are microorganisms that you already know will survive the kill step:

(Continued on p. 34)

(Continued from p. 33)

"For example, if you use pasteurization to inactivate non-spore-forming pathogens like *Salmonella*, *Listeria*, and *E. coli*, you probably won't completely eliminate spore-forming *Clostridium botulinum*. Rather than applying a stronger thermal process, you might want to inoculate the food to see if the control factors, which could be a combination of pH and salt, with the addition of an antimicrobial and chilled storage, will prevent its growth over the shelf life."

Statistical Issues

Quite often, an inactivation challenge study is followed by a shelf-life test: "A typical example where we would do it is with fruit juices," says Dr. Lee. "The FDA requires that after the antimicrobial treatment there is no growth of pathogens throughout the shelf life. So, after inoculating the product and putting it through the process, we evaluate it over the shelf life, for example, 30 days, to see if anything comes back, in particular, sub-lethally injured microorganisms that may recover over time. In fact, we would prolong the period and even incorporate some abuse conditions into it, to better simulate the temperature variations the food product is likely to experience."

The reason for this additional step, says Lee, is to verify the lethality of the process without having to sample everything: "Microbiological testing can only go that far. You only need one cell for the pathogen to multiply and make food unsafe again. But that cell may not be present in the samples you analyze. With shelf-life testing, you're trying to find out whether that one cell is there or not."

The problem of the statistical validity of samples is also the main reason for doing a growth challenge study, as opposed to a shelf-life test without inoculation: "When you look at the statistical analysis of sampling, it's quite complicated," says Wareing. "If the microorganism is present only in certain parts of the batch you want to analyze, and/or at very low counts, you won't find it unless you take enough samples. By inoculating the product, you're making sure that you've got enough of it in there to show up when you take your microbiological samples after the challenge test is over."

Designing the Right Test

The reliability of a challenge test depends largely on how well it's designed. When selecting the target microorganism, a key aspect to consider is risk: "We normally use strains that are found in actual outbreaks," says Dr. Lee. "For example, we're conducting a challenge study right now that involves seafood, where we're targeting *Listeria monocytogenes* strains that were isolated in seafood products."

Once the pathogen is identified, it's always better to try and recreate the worst-case scenario: "Different strains behave in different ways," says Jeff Kornacki, PhD, president and senior technical director of Kornacki Microbiology Solutions, a firm that provides food safety and quality consulting services and is based in Madison, Wisc. "I would choose a serotype that is known to have high heat resistance for that type of food. An even better approach would be to use a cocktail of different strains, so you can cover variability of growth models."

In preparation for a challenge test, says Dr. Kornacki, there are two important checks to do to eliminate confounding factors: "One is to analyze the background microbiota in the food sample that might have the same appearance as the target microorganism on a petri dish. If *Salmonella* is supposed to form a black colony on a certain medium, and I just assume that everything that makes a black colony is *Salmonella*, the final count might be inaccurate."

Another good practice, continues Dr. Kornacki, is to consider the effect of the food sample on the target microorganism: "In an inoculated sample, the population of the microorganism might start to decline as a consequence of its interaction with the food. This, however, might create inaccurate results, because what you're measuring is the lethality of the process, not of the food itself. It's therefore best to wait until the population has stabilized before you put the inoculated sample through the process."

A useful tool for designing challenge tests is predictive microbiology, a computer-

> No two food products are the same. When fruits are grown at different locations, the hazard or the pH could be slightly different. Even if there's an established process, we always recommend manufacturers do a challenge test, so if anything were to happen, at least they have their own data to back it up.
>
> —ALVIN LEE, PHD

Logs and D-Values

The lethality of an antimicrobial process is measured in logs, which equal to a ten-fold decrease of the initial population of microorganisms; 1 log reduction means that the number of surviving cells is reduced to 10%, 2 logs to 1%, 3 logs to 0, 1% and so on. The D-value is the time required to reach 1 log reduction at a given temperature.

Typically, each food (or food category) has a target reduction established by regulations or GMPs. For example, the FDA requires 4 logs for *Salmonella* in California almonds; in ready-to-eat foods, the recommendation for *L. monocytogenes* is 5 logs, or even 6, if a higher contamination is expected.

When there's not sufficient data available on the lethality of a process, the goal of an inactivation challenge test can also be to understand the inactivation kinetics of the pathogen and define the time and temperature necessary to achieve the required reduction.

A key metric in this case is Z-value, which is the temperature required to achieve a tenfold reduction of a D-value (for example, to go from 1 log to 10 log reduction for the same hold time): "To calculate the D-value, you take different samples of an inoculated product at different times at a specific temperature," says Limburn. "When you've found it, you can repeat the test at further temperatures to obtain the Z-value. These references will be the building blocks to determine the minimal process you need to achieve a safe product."—*AT*

based system that calculates the effects of a process and food formulation, giving an indication of what microorganism might survive. "The results from a predictive model can help you narrow down the parameters for the study," says Dr. Lee. "For example, if you're trying to identify the right concentration of an antimicrobial, and the predictive modeling says that the ideal concentration is 25 ppm or above, you can limit your sampling range of the growth test to between 20 ppm and 30 ppm."

The result of a predictive microbiology test can also indicate whether it makes sense to challenge the food in the first place: "If the predictive model says that the target microorganism will grow, then there's no point in doing the study, because the result is likely to be the same," says Dr. Kornacki. "However, if the predictive model says that an organism won't grow, then you probably should do the study to make sure that it's true." ■

Tolu is a freelance science writer based in Spain. Reach him at andrea@andreatolu.com.

Designing for Food Safety *(Continued from p. 22)*

Hygienic equipment design enhances cleanability, decreasing the risk of biological, physical, and chemical contamination. Equipment that is designed and constructed to meet hygienic principles will also be easier to maintain and will reduce the risk of physical hazards contaminating the product. Overall, the operating costs of hygienically designed equipment are usually lower than costs for equipment that has not been designed with the same level of care, and such lower running costs must be considered when comparing the investment costs of different systems.

Hygienic design principles encompass a range of different factors, such as material choice, surface finish, and construction methods, as well as the design of the equipment itself—avoiding lips, crevices, and sharp angles where cleaning chemicals or product may build up or remain after cleaning. To facilitate cleaning underneath and around equipment, it should be elevated above the floor on legs or mounted in a frame, as is the case with skid-mounted systems.

When designing equipment, different standards may be applied to food-contact and non-contact surfaces; surfaces that come into contact with product must generally be smooth, non-toxic, non-absorbent, and resistant to corrosion. For this reason, stainless steel is popular. Welding and joints are also important; continuous butt welds should be used and ground to a smooth surface, while bolts and threads used within the food contact zone must also be of a hygienic design.

It is important to maintain the movement of fluids and materials within equipment and connecting pipework, and this is equally true for products and cleaning solutions. Maintaining flow and preventing fouling is also a key priority in heat exchanger design and is one of the benefits of corrugated tube or scraped surface designs. Closed coupled connections should also be used on equipment to prevent the creation of dead spaces, and to ensure that, where necessary, equipment can be fully drained or emptied for cleaning or product changeover. Other considerations in basic equipment design and construction include avoiding the use of O-ring seals in grooves, avoiding ledges around top rims, and ensuring that shafts are sealed with double seals where necessary.

Reducing Waste while Maintaining Safety

There is a wide range of heat exchange and ancillary equipment for use in the food and beverage sectors, from basic tubular heat exchangers to fully integrated pasteurization/sterilization and aseptic filler systems, as well as a number of specialist products such as evaporators, ice crushers and melters, direct steam injection systems, air removal systems, and pumps. All of these items, and others, must be hygienically designed from the start to facilitate clean operation and prevent the types of product contamination discussed above, while meeting 3A Sanitary Standards for optimum design.

Some equipment has been specifically designed to facilitate product removal and subsequent cleaning. It has always been a challenge for food and drink businesses to implement effective and rigorous clean-in-place (CIP) regimens that meet the necessary standards in a way that minimizes the loss or degradation of saleable or useful product, but some recent designs of rotating scraped surface heat exchangers can physically remove product without the need for traditional pigging or flushing systems.

Such heat exchangers are suitable for a range of heat transfer applications, and their design enables high-viscosity products to be pumped with reduced back pressure and lower energy use. Some products use a helical spiral fitted with scrapers, which scrapes the surface of the tubes to prevent fouling in normal use, and such designs can also be run in reverse; enabling valuable product to be recovered prior to routine cleaning or product changeover. This design feature means that much of the product can be removed from the heat exchanger without the need for additional pumps or pressure systems, reducing both capital expenditure and operating expense.

Automated product recovery systems, a further development of this type of technology, combine the continual monitoring of a set parameter (Brix, pH, or viscosity) with three-way valve technology. These systems ensure that all product meeting the pre-set parameters is utilized, while only that which falls outside specification (such as product that has been diluted during CIP) is discarded. Such monitoring also helps to validate the effectiveness of CIP and ensures that, following a cleaning cycle, only product that meets the required specification is allowed to proceed.

The hygienic design and construction of food processing equipment is an essential but often overlooked aspect of controlling the safety and quality of food and drink products, playing a crucial role in preventing contamination and allowing other food safety procedures to be carried out. ■

Hale is international sales and marketing director at HRS Heat Exchangers. Reach him at matt.hale@uk.hrs-he.com.

Hygiene Inspections *(Continued from p.23)*

Routine risk assessments and audits help to control the introduction of foreign material into products. External eyes provide a different perspective. Many internationally recognized audits follow set standards and provide a complete 360-degree review, and some audits can be performed virtually.

Hygiene protocols should be formalized and included in staff training, and every cleaning process should be verified and documented. As part of a validation process, regular tests, including swabs of critical control points, should be scheduled to ensure that these areas are hygienic and allergen free.

For in-process contaminant inspection equipment, look for smooth, crevice-free contact surfaces on conveyor, pipeline, and gravity systems. This is partly to ensure that no traces of product, allergens, or bacteria are left, and also to reduce the risk of cleaning agents not being fully rinsed away.

When developing an inspection system, take care to identify equipment with an ingress protection rating appropriate to the washdown regime and water pressure being applied. Product residues, including allergens, can be especially troublesome in pipeline systems processing liquids, semi-liquids, and slurries. Pay special attention to the reject unit; ideally, it will be easy to roll out, dismantle, and clean working parts before securely reattaching the unit to pumps.

Good housekeeping is ultimately common sense. Most food processors are strong custodians of hygiene and safety practices; however, given the numerous critical control points in a manufacturing plant, I advise customers to revisit potential hygiene hazards regularly and systematically as part of a regular risk assessment and food safety program. ■

Di Girolamo is a director at Fortress Technology. Reach him at pdigirolamo@fortresstechnology.com

A Global Perspective on Food Fraud *(Continued from p. 25)*

all the materials or groups of materials would need to be listed and studied. This would allow identification of potential fraud issues, fraud issues that pose a food safety risk, and evaluation of the degree of risk under current procedures. The next step would be to evaluate any need for further controls or processes and thereafter record and implement all additional measures. The final step is common to all successful management systems: regularly reviewing and verifying activity and resolving any non-conformities and carefully documenting the outcomes.

Organizations need to adopt a unique management system for several reasons:

- There is no single, prescribed method of conducting a vulnerability assessment; any structured approach to identifying the risks can be used.
- The choice of methodology may therefore be a matter of personal preference, of company policy, or of the complexity of the situation.
- The vulnerability assessment is a specialized form of risk assessment, and it is therefore logical to consider similar tools and methods.
- Some organizations have found tools such as threat assesment and critical control points (TACCP) and VACCP useful.

Knowledge of the supply chain, mapping, and monitoring are the key items needed for developing a consistent strategy to prevent food fraud, together with adequate auditing programs focusing not only on food safety and quality but extending their scope to counter fraud elements including traceability. The traceability element is also important because it is part of standards like ISO 22000:2005. This enables companies to test the vulnerability of their chain and check on their robustness. ■

McCarthy is the global food and beverage manager for DNV Business Assurance, a UK-based food certification body. Reach her at amanda.mccarthy@dnv.com.

NEW PRODUCTS

Traceable Quality System Modular Design

WIPOTEC-OCS, has developed a Traceable Quality System Modular Design (TQS-MD) that uses a "building block" concept. The unit offers one user interface, which makes product changes, article setup and layout modifications less error-prone and more user-friendly. The series can comprise a wide array of configurations. Typically applied to print "best before" dates, batch codes, or lot numbers on boxes, the basic setup marks, verifies, and weighs products on a footprint of 1 meter in length and can be upgraded to execute full serialization where required. Another TQS-MD setup, geared toward food applications, can weigh, label, and inspect for metallic foreign bodies in a single process step. And by adapting product handling modules to a larger dimension, TQS-MD models also can be arranged to handle big boxes such as shipping cartons. **WITOPEC-OCS, Inc., wipotec-ocs.com/us**.

Foam Polypropylene Processor Trays

Tekni-Plex Consumer Products has announced foam polypropylene processor trays for fresh food products such as meat, poultry, pork, fruits, and vegetables. Foam polypropylene is durable, lightweight, heat-resistant, and FDA approved for direct food contact. The material is also a drop-in replacement for common foam polystyrene trays, so there is no need for businesses to take on the extra work or cost required to retool packing equipment. Like foam polystyrene (recycling code 6), foam polypropylene requires less material to create high-quality products using minimal resources. When compared to solid PET trays, for example, foam polypropylene weighs half as much. **Tekni-Plex Consumer Products, tekni-plex.com**.

Odor Eliminator

Orkin Scent Services now offers new product to keep your food plant smelling fresh: AirRemedy acts as an odor eliminator to help remove foul smells and leave your facility smelling fresh and clean. The product doesn't just mask foul odors; it uses cold fusion technology to attack and help remove the odors in the air, leaving a clean, fresh scent. The diffuser system delivers a dry, invisible vapor that floats evenly across large, designated areas, such as garbage and recycling rooms, compactor areas, and more. **Orkin, orkin.com**.

Food Waste Estimator Virtual Tool

Kerry has launched a tool to raise awareness of food loss and waste. The Food Waste Estimator allows consumers and manufacturers to quantify and understand the financial and environmental impact of reducing food waste either in the food chain or in the home. The estimator allows food manufacturers to determine the impact they can have in reducing global food waste by using shelf-life extension technology across their portfolios. The tool can be accessed at explore.kerry.com/food-waste-estimator. **Kerry, kerry.com**.

(Continued on p. 38)

(Continued from p. 37)

X-Ray Inspection System

Mettler-Toledo Product Inspection has launched an X-ray inspection technology that is able to detect low-density contaminants in packaged food products. The DXD and DXD+ dual energy detector technology is optimized for identifying foreign bodies such as calcified bone, low-mineral glass, rubber, and some plastics, and is available in two versions, giving customers two levels of dual energy x-ray performance: DXD can operate in the same environments as single energy solutions and can be used with line speeds typically up to 100 m/minute; DXD collects more data about the product being inspected, and improved image analysis software provides clearer images with higher resolution, and can be used with line speeds typically up to 45 m/minute. **Mettler-Toledo, mt.com**.

Vacuum Gassing Seamer

JBT Corporation's PLF International has launched the PLF VGS vacuum gassing seamer, which can process up to 30 cans per minute with low gas consumption of 21cm³ per hour, providing a smaller footprint than other existing technologies on clean room floors. The solution's vacuum gassing and seaming operations are carried out separately in the PLF design. This allows container rims to be sealed during the vacuum-gassing process and keeps them clean for subsequent seaming, preventing powder from migrating out of containers. Customers also benefit from the technology's efficient changeovers of multiple SKU short runs via the solution's single seaming head and realistically achievable reverse osmosis levels of 1% or less. **JBT PLF International, jbtc.com.**

Electronic Horns and Combination Units

Rockwell Automation has initiated a series change for selected frame sizes of Allen-Bradley 855H industrial electronic horns and combination units (horns with attached beacon) to offer a higher degree of performance and to address a broader range of audible and visual applications on the plant floor. This series change also will affect the 855H recordable horn combination units as well as the company's metal horn combination units. The new 855H units are also offered with a multifunction LED beacon capable of operating in eight different modes (steady, blinking, and six different flashing patterns) easily selected by the

user via DIP switch. The new series also employs solid-state technology rated for continuous use, offers volume adjustment, and features multi-tone and multistage capabilities. Additionally, the updated products maintain the same dimensions and ingress protection ratings, making them a drop-in replacement suitable for indoor and outdoor use. **Rockwell Automation, rockwellautomation.com**.

From the Leader in Spectral Data

Accelerate Spectral Analysis with KnowItAll

Powerful Software. Quality Data. Results You Can Rely On.

KnowItAll Solutions for IR MS NMR Raman UV-Vis

Supports multiple techniques and instrument vendor formats to streamline your workflow.

KnowItAll offers solutions to **identify, analyze, and manage your data**.

Combined with the **world's largest spectral reference databases**, it provides one of the most advanced technologies available for fast, reliable spectral analysis.

And with the **NEW KnowItAll 2023**, Wiley continues to add even more tools to automate and accelerate analysis!

Learn more or get a trial
www.knowitall.com/fqs2022

WILEY

SCIENTIFIC FINDINGS

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

Impact of Caramel and Roasted Wheat Malts on Aroma in Wheat Beer

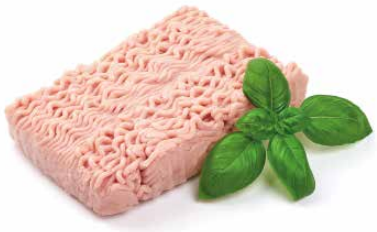
Top-fermented wheat beers are known for their unique aroma. However, the impact of specialty wheat malts on the aroma of these beers and the transfer of odor active compounds from malt to the beer has not been investigated in detail. In this paper, three beers were brewed with different malt composition. The grist for each beer contained 50% kilned barley malt and 50% different wheat malts: beer kilned wheat malt, beer kilned wheat malt and caramel wheat malt, and beer kilned wheat malt and roasted wheat malt. The odor active compounds in the beers were identified by aroma extract dilution analysis and their individual impact on aroma was evaluated by quantitation and calculation of odor activity values (OAVs). The results were verified sensorially by comparing aroma reconstitution models with the original beers. The aroma of the roasted wheat malt beer was characterized by smoky and phenolic compounds 2-methoxyphenol and 4-methylphenol. Important beer odorants were quantified in the malts to assess their transfer from malt to beer. The results suggest that direct transfer of the odor active compounds in beers was not significant and that they were formed and/or released during the brewing process, confirming earlier results with different barley malts and bottom-fermented beers. ***Journal of the Institute of Brewing*. Published September 2, 2022; doi: 10.1002/jib.701**.

Potential Applications of Hemp Extracts in Food

Edible hemp products or superfood refers to *Cannabis sativa* or industrial hemp. In general, hemp is a rich source of functional metabolites, such as tetrahydrocannabinol (THC), cannabidiol (CBD), and other cannabinoids. Hemp has been widely used in food products, such as bread, cookies, meatballs, energy bars, cooking oil, snacks, and crackers; however, the use of hemp is far below its potential because of major challenges such as its costly extraction and isolation, the stability and toxicity of the extracts, and legislation related to the use of the extracts. This review analyses major phytochemicals in hemp and hemp extracts, and also discusses the most common challenges in applications of hemp-derived phytochemicals and hemp extracts in food products such as stability, toxicity, legal limitations, isolation/extraction, and purification. ***International Journal of Food Science and Technology*. Published September 30, 2022; doi: 10.1111/ijfs.16116**.

E. coli in Ground Chicken

Meat and poultry are prone to contamination with foodborne pathogens sourced from livestock or introduced in processing environments. In this study, for the retention of meat quality while assuring microbial food safety, mild levels of high hydrostatic pressure were hurdled with food-grade additives (i.e., allyl isothiocyanate [AITC] and acetic acid [AA], functioned as antimicrobials) to inactivate pathogenic *E. coli* in ground chicken. The reductions of Shiga toxin-producing *E. coli* (STEC) O157:H7 and uropathogenic *E. coli* (UPEC) were described as a function of high hydro-static pressure (200–350 MPa), process-holding time (10–25 min), AITC concentration (0.05%–0.20% w/w), and AA concentration (0.10%–0.30% w/w) using a full factorial design. The antimicrobials had little influence on bacterial inactivation without high pressure. Without the antimicrobials, a high-pressure treatment at 300 MPa and 4°C for 15 min reduced *E. coli* O157:H7 and UPEC by 1.52 and 2.52 log, respectively. A 5-log reduction was achieved when AITC and AA were combined with high pressure, indicating a synergistic effect. The survivors were further reduced to below the detection limit of 1 log CFU/g after subsequent storage tests at 4 and 10°C for 10 days. The STEC O157:H7 was found slightly more resistant than UPEC in this test matrix. ***Journal of Food Safety*. Published October 1, 2022, online ahead of print. doi: 10.1111/1750-3841.16346**.



©IURII KACHKOVSKYI - STOCK.ADOBE.COM

©GGSDESIGN - STOCK.ADOBE.COM

©CUBODELUZ - STOCK.ADOBE.COM

©BAIBAZ - STOCK.ADOBE.COM

Red Wine Coloration

Color is one of the most distinctive qualities of red wine. Despite new knowledge in the field of pigment identification, copigmentation, and oxidation being forthcoming, there is still a large gap between the fundamental research and practical winemaking outcomes. This review introduces up-dated knowledge about the primary pigments in wine, with emphasis on their physicochemical properties. It discusses the mechanisms of copigmentation and oxidation, along with their relative contributions to wine color. Finally, the practical effects of copigmentation and microoxygenation (MOX) in winemaking are summarized and discussed. In general, wine coloration is ultimately determined by the anthocyanin flavylium cation, which is greatly influenced by wine pH. In young red wine, grape-derived anthocyanins and nonanthocyanin polyphenols (as copigments) are the foundation for wine coloration. During aging and storage, anthocyanin derivatives are formed via various chemical reactions, where moderate oxidation plays a vital role, whereas copigmentation constantly decreases. The essence of wine color evolution relates to the changes of physicochemical properties of primary pigments in wine, where the hydration equilibrium gradually diminishes. In practice, the effects of copigment addition and MOX during real vinification can be viewed as somewhat controversial, considering that many studies showed different effects on wine color and pigment concentration. ***Comprehensive Reviews in Food Science and Food Safety.*** **2022;21:3834-3866.**

©ATOSS - STOCK.ADOBE.COM

Nonthermal Pasteurization of Pineapple Juice

Pineapple juice is susceptible to spoilage and a common practice is to pasteurize it at 70°C to 95°C for 0.5 to 5 minutes. However, the characteristic flavors and phytochemicals are negatively influenced by the intense time–temperature treatment. To retain the thermosensitive compounds in

the juice, some nonthermal technologies such as high-pressure processing, pulsed electric field, pulsed light, ultrasound, and ultraviolet treatments have been explored. These techniques ensured microbi-al safety (5-log reduction in *E. coli, S.* Typhimurium, or *S. cerevisiae*) while preserving a maximum ascorbic acid (84% to 99%) in the juice. The shelf life of these nonthermally treated juice varied between 14 days and six months (clarified through microfiltration). This review discusses the potential of several nonthermal techniques, and discusses the pasteurization ability of the combined hurdle between mild thermal and nonthermal processing. The article also summarizes the target for pasteurization, the plan to design a nonthermal processing intensity, and the consumer perspective toward nonthermally treated pineapple juice. The techniques are compared on grounds such as the safety, stability, and quality of the juice, which should help readers select an appropriate technology for pineapple juice production. ***Comprehensive Reviews in Food Science and Food Safety*****. Published on October 1, 2022; doi: 10.1111/1541-4337.13042.**

©SOMMAI - STOCK.ADOBE.COM

Heavy Metals in Butter

The transfer of heavy metals to products during food processing forms serious health concerns. This article evaluates the impact of cultured-cream butter washing with hydrogen-rich water (HRW) on the deaccumulation of arsenic (As), cadmium (Cd), antimony (Sb), mercury (Hg), and lead (Pb) in butter. The authors washed raw cultured-cream butter with ordinary water or HRW prepared with molecular hydrogen (H2) and magnesium (Mg). While ordinary water-washed butter samples exhibited an increase in As (7%), Cd (62%), and Pb (206%) and a decrease in Sb (26%) and Hg (17%) levels, HRW samples showed a decrease in As, Cd, Sb, and Hg levels ranged be-tween 14% and 74% except for Pb, which increased by only 29% (Mg) and 3% (H2). The authors propose a green and eco-friendly strategy to solve the transfer problem of heavy metals to food products. ***Journal of Food Safety*****. Published September 2, 2022. doi: 10.1111/jfs.13005.**

Infared Spectroscopic Techniques for Cheese Authentication

Infrared spectroscopy has been shown to be efficient in cheese authentication due to the advantages of high sensitivity and speed of analysis, especially when associated with chemometrics. This review discusses approaches on the authenticity, the principles of near- and middle-infrared techniques and the importance of chemometrics for cheese authentication. The spectroscopic techniques proved to be promising for the cheese geographical origin identification, analysis of adulterants and monitoring of maturation stages. The application of principal component analysis, partial least squares and linear

©AZURE - STOCK.ADOBE.COM

discriminant analysis associated with spectroscopy has provided powerful tools for the cheese authentication. ***International Journal of Dairy Technology*****. 2022;75:490-512**.

Have something to say? Send your thoughts to skuehne@wiley.com.

Advertiser Directory

ADVERTISER	PAGE
Best Sanitizers Inc.	44
Malasian Rubber	2

ADVERTISER	PAGE
Wiley	5, 39, 43

©REENYA - STOCK.ADOBE.COM

Events

OCTOBER 2022

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

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

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

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

NOVEMBER 2022

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

JANUARY 2023

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

MARCH 2023

1-3
Consumer Food Safety Education Conference
Arlington, Va.
Visit cfsec.org.

18-22
Pittcon
Philadelphia, Penn.
Visit pittcon.org.

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

APRIL 2023

24-28
Conference for Food Protection
Houston, Texas
Visit foodprotect.org.

MAY 2023

8-11
Food Safety Summit
Rosemont, Ill.
Visit food-safety.com/food-safety-summit.

20-23
National Restaurant Association Show
Chicago, Ill.
Visit nationalrestaurantshow.com.

JULY 2023

16-19
International Association for Food Protection
Toronto, ON, Canada
Visit iafp.org.

Have an Upcoming Event to Promote?

If you have an upcoming industry event that you would like considered for inclusion in our online and print listings, go to foodqualityandsafety.com/events for info or contact Vanessa Winde at vwinde@wiley.com.

ADD FOOD QUALITY & SAFETY TO YOUR FEED

FOLLOW US:

@FQSMAG

Food Quality & Safety
FARM TO FORK SAFETY

www.twitter.com/FQSmag

BEST SANITIZERS INC.™

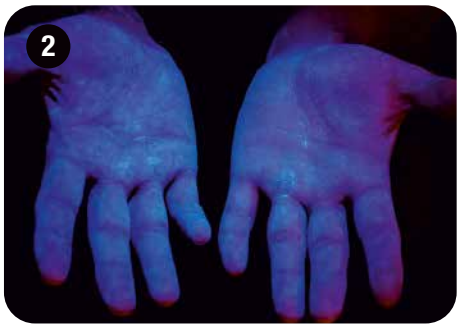
Have you scheduled your

Hand Hygiene Training Session?

Best Sanitizers, Inc. is here to educate your team and help meet your training requirements for hand hygiene compliance.

Look at everything you'll get:

Comprehensive PowerPoint driven training presentation on the what, when and why of proper hand hygiene.



Glo Germ black light demonstration to illustrate cross-contamination and the effects of improper hand washing.

Proper hand washing technique demonstration to teach employees the correct way to wash their hands.

Question and Answer session followed by a hand hygiene quiz to help evaluate your team's knowledge and readiness.

Certificate of Training to show auditors your team has been trained by a Best Sanitizers hand hygiene expert.

Schedule your onsite or web-based hand hygiene training session today!

888-225-3267

sales@bestsanitizers.com

Learn how to practice proper hand hygiene, improve compliance and reduce the risk of cross-contamination in your facility.

Food Safety is Our Priority