

# Food Quality & Safety

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in food safety, and at what  
the future may hold



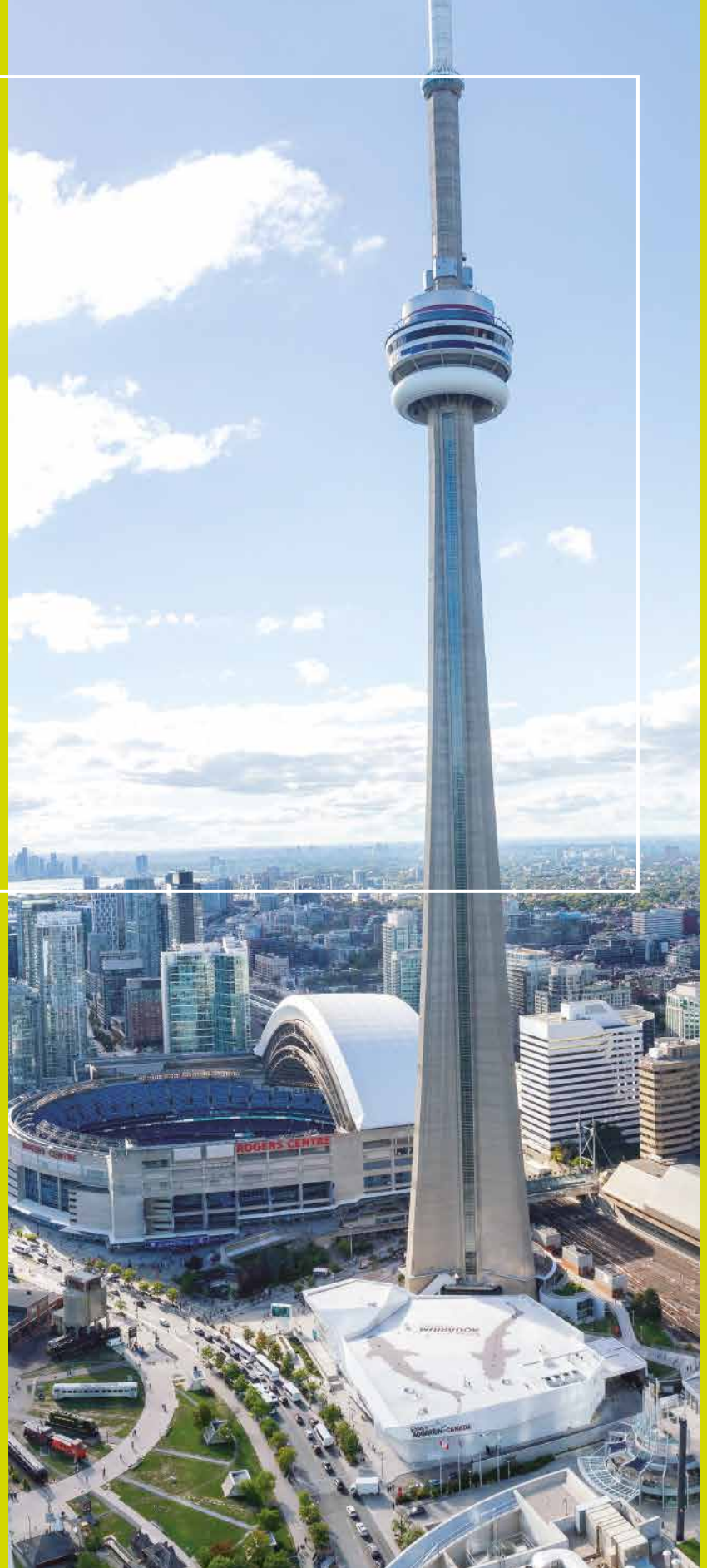
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- National Academies to Study Infant Formula Supply, Regulation
- FDA Finalizes Limit for Inorganic Arsenic in Apple Juice
- Second Cultivated Chicken Product Cleared by FDA for Human Consumption
- California Bill Aims to Remove Some Additives from Food

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# From The Editor

## Nostalgia

This issue marks the 30th year of publication for *Food Quality & Safety*, and it really took me on a trip down memory lane—not just back to the 1990s, but to the events that led me to the food safety industry.

I didn't plan to enter the food safety sector; my goal was to attend the brand-new veterinary school coming to the University of Florida, be a veterinarian, and raise horses. But vet school threw a wrinkle in my plans: There were 40 openings in the program the first year, and more than 900 applicants. Another wrinkle? No females were currently employed in field care, and the one offer I had after graduation was out of state. In Florida, I received job offers from meat and poultry processors, so that's what I did.

When *E. coli* emerged, a customer's product was involved in an outbreak. I finally used all that college microbiology, and my products were cleared, but I'll never forget the stress of thinking that I could have been responsible for making people sick—or even killing them. The new focus in science-based meat production pushed me further into the food safety services, where I met several leaders and legends who bear mentioning.

I went on to ABC Research, a lab of national recognition that included the definitive work on *Salmonella* conducted by Steve Goodfellow, PhD. While this was still very much a man's meat industry at the time, Dr. Brown never hesitated to send me wherever a client's problem needed solving. Most were grateful for the help, but a few never really believed a girl could possibly know anything helpful.

I joined the American Meat Institute (AMI) Foundation's Scientific Affairs Committee as ABC's representative. The work they did was instrumental in figuring out how to control *Listeria*, and the principles defined by that group still stand today. Along with Dr. Brown, I owe the team at AMI a debt of gratitude for shaping my food safety perspectives.

I also met the amazing legal team at Olsson, Frank & Weeda (OFW) while at ABC. In the years since leaving ABC, I spent many hours with OFW founder Phil Olsson, helping to shape House and Senate bills into what would eventually become FSMA. Olsson stands now as both a mentor and a dear friend.

This issue also marks the kickoff of *Food Quality & Safety's* video series, "Leaders and Legends in Food Safety," which is available at [foodqualityandsafety.com](http://foodqualityandsafety.com). We encourage you to watch our first set of interviews with Frank Yiannas, MPH, Dane Bernard, Randy Huffman, PhD, John Weisgerber, and John Butts, PhD. Then, let us know who your leaders and legends are.

As always, reach me at [fqseditor@pawesta.com](mailto:fqseditor@pawesta.com).

**Patricia A. Wester**

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# NEWS & NOTES



## Infant Formula Manufacturers Face FTC Investigation

The U.S. Federal Trade Commission (FTC) has launched an inquiry into the ongoing shortage of infant formula in the country. The inquiry seeks information from the public regarding the nature and prevalence of any deceptive, fraudulent, or otherwise unfair business practices occurring during the shortage.

A statement from FTC chair Lina M. Khan said that the agency will examine whether any formula manufacturers or distributors are engaging in unlawful discrimination that may be limiting remaining infant formula supplies at smaller retailers. The agency says it will also examine the pattern of mergers and acquisitions in the infant formula market to better understand current concentration, how it came to be, and how that should inform a future merger review.

The request for information seeks public comment about the following topics:

- Instances where families have experienced fraud, deception, or scams when attempting to purchase infant formula or been forced to purchase formula from online resellers at exorbitant prices;

- Consumer experiences with purchasing infant formula through the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) throughout the crisis;

- Retailers' experiences obtaining brands not ordinarily covered by their state's WIC programs and their experiences working with distributors and manufacturers throughout the crisis;

- Whether small and independent retailers have faced particular difficulties accessing limited supplies of infant formula compared to large chain retailers;

- The impact of mergers and acquisitions on the number of infant formula suppliers, capital investment, and total manufacturing capacity;

- The impact of state WIC competitive bidding on the number of infant formula suppliers, capital investment, and total manufacturing capacity;

- The impact of FDA regulations on the number of infant formula suppliers, capital investment, and total manufacturing capacity, including capacity located outside the U.S.; and

- Whether there are other regulatory barriers that have prevented companies located outside the country from entering the infant formula market.

The FTC says it will work with USDA, which administers WIC, to analyze the results of the public inquiry. Comments must be submitted at [regulations.gov](https://www.regulations.gov) by June 24. ■

## Israeli Company Announces First-Ever 3D Printed Fish

An Israeli food tech company says it has produced a 3D-printed fish product made with animal cells grown in a laboratory.

Steakholder Foods has partnered with Singapore-based Umami Meats to develop a scalable process for producing structured cultivated fish products using its 3D bioprinting technology and customized bio-inks. The printing and bio-ink customization are steps on the path to commercializing the Steakholder Foods 3D printer. Unlike fully cultivated meat products that still require incubation and maturation after printing, the grouper fish product is ready to cook immediately.

Since receiving grouper fish cells from Umami, Steakholder Foods is working on the taste and texture of its printed grouper before finalizing a prototype. Umami says that the product mimics the flaky texture of cooked fish.

Umami hopes to bring the fish to market next year, starting in Singapore. ■

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### Study: Some Melatonin Gummies Contain Unlabeled Levels of Melatonin, CBD

BY KEITH LORIA

Last year, *Morbidity and Mortality Weekly Report* published a study that analyzed calls to U.S. poison control centers involving pediatric melatonin ingestions. The researchers found that, between 2012 and 2021, poison control centers received more than a quarter of a million calls regarding melatonin ingestions in children, and that ingestions had increased 530% over the 10-year period. Of those, 27,795 children required medical evaluation, 4,097 were hospitalized, and two died.

Little was known about why melatonin products were causing these outcomes, which led another group of researchers, spearheaded by Pieter Cohen, MD, a general internist at Boston’s Cambridge Health Alliance and an assistant professor of medicine at Harvard Medical School, to study the ingredients in melatonin gummies, which are commonly used as a sleep aid. He and his co-investigators published a research letter in *JAMA* last month reporting on their findings. “These ingestions [reported to poison control centers] were usually unintentional and, while the prior study did not report if the ingestions were with gummies, capsules or tablets, we were concerned that children might take too many gummies, leading to harm,” Dr. Cohen tells *Food Quality & Safety*. “That is why we set out to study melatonin gummies. What we found was that, in the products we sampled, the jelly matrix only infrequently delivered the dose listed on the label.”

The results were quite shocking, Dr. Cohen says. They found that melatonin gummies contained much more melatonin than the amount listed on the label—up to 347% more. But excess melatonin wasn’t the only problem they discovered: A number of products also contained cannabidiol (CBD), an active ingredient found in cannabis.

While melatonin products are sold over the counter as dietary supplements or food, FDA has not approved the use of CBD for any indication in healthy children. Given these findings, the study authors recommend that clinicians should advise parents and guardians that pediatric use of melatonin gummies may result in ingestion of unpredictable quantities of melatonin and CBD. ■

### USDA Proposes Declaring *Salmonella* an Adulterant in Breaded Stuffed Raw Chicken Products

BY PATRICIA WESTER

On April 25, USDA’s Food Safety and Inspection Service (FSIS) released a proposed determination to declare *Salmonella* an adulterant in breaded stuffed raw chicken products when they exceed a very low level of *Salmo-*



*nella* contamination. This announcement is a significant first step that builds on FSIS’s proposed regulatory framework, released in October 2022, to reduce *Salmonella* infections linked to poultry products.

“USDA is taking science-based, decisive action to drive down *Salmonella* illnesses linked to poultry products,” said Agriculture Secretary Tom Vilsack in a statement. “[The] proposal represents the first step in a broader effort to control *Salmonella* contamination in all poultry products, as well as a continued commitment to protecting American consumers from foodborne illness.”

Under this proposal, FSIS would consider any breaded stuffed raw chicken products that include a chicken component that tested positive for *Salmonella* at 1 colony forming unit (CFU) per gram prior to stuffing and breading to be adulterated. FSIS also proposes carrying out verification procedures, including sampling and testing of the chicken component of breaded stuffed raw chicken products prior to stuffing and breading, to ensure that producing establishments control *Salmonella* in these products. If the chicken component in these products does not meet this standard, the product lot represented by the sampled component would not be permitted to be used to produce the final breaded stuffed raw chicken products. The chicken component represented by the sampled lot would need to be diverted to a use other than breaded stuffed raw chicken products.

In proposing the declaration of *Salmonella* as an adulterant in breaded stuffed raw chicken products, FSIS based its decision on several factors, including the fact that, since 1998, FSIS and its public health partners have investigated 14 *Salmonella* outbreaks and approximately 200 illnesses associated with these products. The most recent outbreak was in 2021 and resulted in illnesses across 11 states.

Breaded stuffed raw chicken products are pre-browned and may appear cooked, but the chicken is raw. These products are stuffed with additional ingredients, such as raw vegetables, butter, cheese, and meat, such as ham. The labeling of these products has undergone significant changes over time to better inform consumers that they are raw and to provide instructions on how to prepare them safely. Despite these efforts to improve labeling, the products continue to be associated with *Salmonella* illness outbreaks.

(Continued on p. 10)



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(Continued from p. 8)

A public meeting was held on November 3, 2022, to allow stakeholders the opportunity to provide information that would help focus the development of regulations to implement the policy. To date, more than 1,000 comments have been submitted to this docket.

Concurrently, FSIS is gathering scientific evidence relevant to the approaches presented in the proposed framework.

- The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) has been charged with providing guidance on what types of microbiological criteria FSIS might use to better prevent *Salmonella* infections associated with poultry products.

- FSIS is also completing a risk profile for pathogenic *Salmonella* subtypes in poultry and is collaborating on quantitative risk assessments for *Salmonella* in chicken and turkey that will address key risk management questions associated with this framework.

- FSIS also expanded its exploratory sampling program for young chicken carcasses to generate microbial data to help inform future policies.

- FSIS is transitioning from using presence-based tests to tests that quantify the amount of all *Salmonella*.

FSIS is seeking public comments on the proposed determination and the proposed verification sampling program. Comments may be submitted online via the federal eRulemaking portal at [regulations.gov](https://www.regulations.gov). ■

## Lawmakers Challenge Food Processors That Skirt New Sesame Labeling Law

BY KEITH LORIA

Earlier this year, a new law known as the FASTER Act took effect, adding sesame as a major food allergen and requiring the ingredient to be labeled as an allergen on packaged foods, including dietary supplements.

In an effort to adhere to the new law, some manufacturers are actually adding sesame to all of their food products and labels rather than properly cleaning their equipment between product runs to avoid allergen cross contamination. This action

is taken in an attempt to avoid the costs associated with the processes and systems controls necessary to ensure safe baking practices. Certain products can be extremely difficult to eliminate completely in the processing environment, leading manufacturers to this alternative.

In response, a group of legislators, spearheaded by U.S. Senator Ron Wyden (D-Ore.) and U.S. representatives Doris Matsui (D-Calif.) and Patrick McHenry (R-N.C.), have urged bakers to stop unnecessarily adding sesame to baked goods.



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In a letter to the American Bakers Association (ABA), the legislators condemned the actions, claiming that adding sesame to baked goods that have not previously contained the ingredient, often without notice, undermines the trust that people with food allergies place in the food industry.

The ABA noted that, given current production operations in hundreds of bakeries coupled with the existing FDA regulatory scheme, including sesame and labeling it as an allergen, is the most realistic and safest way to protect allergic consumers. “We have also encouraged the FDA to use its existing authority under the Food Allergen Labeling & Consumer Protection Act to work toward setting allergen thresholds, which would remove the need to add sesame where only traces below such thresholds might remain after applying rigorous Current Good Manufacturing Processes,” the organization noted in a statement. “Despite rigorous cleaning protocols, sesame is a uniquely challenging allergen to remove from the baking environment, and even the best practices cannot always remove traces of sesame.”

Sesame allergies impact more than 1.5 million Americans, and reactions can be serious and life threatening. ■

## Supreme Court Rejects Challenge to California Law on Pig Confinement

In May, the U.S. Supreme Court rejected the opposition to California’s Proposition 12, which bans the sale of pork that comes from pigs kept in gestation crates. In a 5-4 vote, the court’s decision rejects a pork industry challenge claiming the legislation would unlawfully regulate out-of-state farmers.

The proposition, an animal protection law passed in 2018 known as the Prevention of Cruelty to Farm Animals Act, makes it illegal to house hens, sows, and veal calves in what the state calls “a cruel manner.” It also prohibits the in-state sale of products from caged animals raised out of state, which has been a major concern of the National Pork Producers Council and the American Farm Bureau Federation.

The industry groups say that the measure violates the Commerce Clause, a provision in the U.S. Constitution that courts have previously interpreted as only allowing the federal government to regulate interstate commerce. The groups argue that the California law violates this clause by forcing farmers outside the state to modify their practices in order to sell pork in California.

They also stated that Californians only consume 13% of the pork eaten in the U.S., so most of the product comes from pigs raised outside the state, meaning that the majority are not raised under the conditions that Proposition 12 mandates. ■



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## FAO Issues Report on Safety of Cell-Cultured Meats

BY KEITH LORIA

The United Nations' Food and Agriculture Organization (FAO), in conjunction with the World Health Organization (WHO), released a report on in early April detailing the safety of cell-cultured meats, and noting that more data generation and sharing at the global level are necessary to create an atmosphere of safety and regulation.

"The goal of the FAO/WHO publication is to capture key food safety issues in a timely manner, before products are widely available on the world market," a spokesperson for FAO says. "In this way, relevant authorities, particularly in low- and middle-income countries, will be equipped with up-to-date information and scientific knowledge on cell-based food production to consider potentially important regulatory actions and learn from experienced countries so that good practices can be shared."

The report begins with a review of the current literature on the terminology, production process, and regulatory frameworks around cell-cultured foods.

Breanna Duffy, PhD, director of responsible research and innovation for New Harvest, a nonprofit research institute that focuses on cultivated meat, notes that FAO is clear from the get-go that it is not dictating terminology to be used, though "cell-based," "cultivated," and "cultured" were revealed to be the three major phrases used by all sectors of the field. "Cell-based foods' is used to provide consistent terminology throughout the document, but the report calls for competent authorities to carefully consider which terminologies are most appropriate in their country," she tells *Food Quality & Safety*. "The report breaks it down by sector—authorities, industry, academia, and the media—providing some interesting

insights into each sector's preferred terminology and how [it has] changed over time."

One section of the report details in-depth case studies of regulatory frameworks in 10 jurisdictions, highlighting which parts of current regulations may be applicable to cell-cultured meats and where gaps remain. The report also emphasizes that there is a lack of information and data available to support regulators in making informed decisions on cell-based foods and calls for more data sharing globally.

The report contains a list of potential hazards from cell-based food production, agreed upon by 23 international experts who took part in a meeting in Singapore in November 2022, in which New Harvest played a part. "The causal chain examples for each identified hazard illustrate the chain of events that would need to occur for the hazard to reach consumers and illustrates opportunities to control the hazard at each 'link' in the chain," Dr. Duffy says. "For every hazard, there are existing mitigation and testing control measures, many of which can be taken from adjacent fields."

Paul Mozdziak, PhD, physiology graduate program director in the department of poultry science at North Carolina State University in Raleigh, says that the report's chief takeaway is that producers and scientists around the world are trying to work together to come up with consistent food safety points and regulations for the products. "A lot of the work was taking the information that was already out there and putting it into a single document," he says. "It's a place where a company or college student or anyone can learn what the technology is, what the hazards are, what the control points are, and learn the things the regulators are worried about relative to cultured meat." The hope, he says, is to see that the technology and regulations help bring these products to market. ■

(Continued on p. 12)



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(Continued from p. 11)

## Cereal Manufacturers Push Back Over Proposed Changes to “Healthy” Designation

BY KEITH LORIA

Some prominent cereal manufacturers have threatened legal action if FDA goes through with its proposed criteria for when foods can be labeled with the nutrient content claim “healthy” on their packaging.

General Mills, Kellogg, and Post Holdings are among those arguing that FDA’s changes, if enacted, would exclude more than 95% of the major ready-to-eat cereals from being labeled “healthy.”

FDA announced last fall that it was looking to reclassify “healthy” and update existing rules, which are almost three decades old. The proposed rule would allow the “healthy” designation for what the agency calls “nutrient-dense foods”; foods that contain a certain percentage of fruit, vegetables, grains, dairy, or protein. In doing so, it would limit cereals labeled as “healthy” to those with no more than 2.5 grams of sugar per serving.

These cereal manufacturers argue that ready-to-eat cereal is “an affordable, accessible, convenient, and popular nutrient-dense food that has a long history of helping consumers build healthy dietary patterns” and, therefore, should continue to be able to make the “healthy” claim.

In a filing to the FDA, the companies asked for FDA to reevaluate the framework, claiming its current solution as written would be open to legal challenge in that it violates the First Amendment by prohibiting truthful,



non-misleading claims in an unjustified manner and also exceeds FDA’s statutory authority in several ways. “The proposed rule precludes many objectively healthy products, including those promoted by the Dietary Guidelines, from engaging in truthful, non-misleading commercial expression, and these overly restrictive boundaries for ‘healthy’ violate the First Amendment,” the letter said. “Furthermore, ready-to-eat cereal is recognized for its value and nutritional benefits in federal feeding programs that reach more than 20 million participants who are nutritionally at risk.”

It’s not just cereal companies fighting the proposed changes. Numerous manufacturers that produce everything from snacks to baked goods to pastas to frozen pizzas are also challenging the rules. The Consumer Brands Association, which represents approximately 1,700 major food brands, sent a 54-page comment to FDA objecting to the proposed rule. “We are particularly concerned by the overly stringent proposed added sugars thresholds,” the group said in the letter. “We appreciate FDA’s interest in assessing added sugars intake. We believe, however, that FDA’s restrictive approach to added sugars content in foods described as healthy is unwarranted and outside FDA’s authority given the lack of scientific consensus on the relationship between sugar intake and diet-related disease.”

The agency is expected to make a final decision on the changes later this year. ■

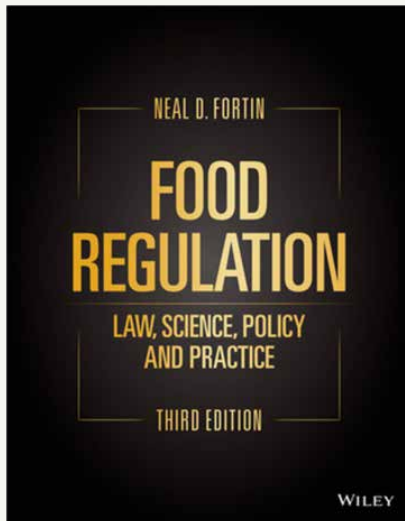
## USDA Begins Testing Bird Flu Vaccines

USDA’s Agricultural Research Service (ARS) has started vaccine trials in poultry to combat highly pathogenic avian influenza (HPAI), or bird flu. The agency is testing four bird flu vaccines—one from Zoetis, one from Merck Animal Health, and two developed by the agency itself—to be used in poultry after the CDC reports that more than 58 million birds have died or been depopulated in the current outbreak.

Should the trials be successful, the next step is to identify manufacturers interested in vaccine production. Once one or more manufacturers are identified, there are 20 discrete stages to complete before vaccine delivery. These stages begin with feasibility work by the manufacturer and culminates with product label submission and review. General timeframes are two-and-a-half to three years; however, in emergency situations manufacturers may expedite development.

From vaccine development to production timelines, to dissemination to flocks, there are many factors that make implementing a vaccine strategy a challenge, and it would take time to deliver effective bird flu vaccines. In a best-case scenario, USDA estimates an 18-to-24-month timeline before having a vaccine that matches the currently circulating virus strain, is available in commercial quantities, and can be easily administered to commercial poultry. ■





# U.S. Food Regulation for Industry

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Food Regulation: Law, Science, Policy, and Practice, 3rd Edition

By Neal D. Fortin, JD

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REVIEWED BY **PURNENDU C. VASAVADA, PHD**

Food industry professionals—from product developers to processors and marketing and managers as well as students of food science and technology—need to have a working knowledge of food regulations and the federal agencies that regulate the food industry. While textbooks and other sources of credible information on the major disciplines of food science and technology are readily available, finding textbooks that are focused on food law, regulations, and the functions of regulatory agencies also suitable for a food industry audience with very little background and familiarity with the subject matter is not an easy task.

The third edition of *Food Regulation: Law, Science, Policy, and Practice* is an excellent resource for food industry professionals across all disciplines, including food scientists, food quality and safety managers, researchers, consultants, and regulatory specialists. It would be an ideal textbook or companion book for undergraduate or graduate courses in food science and nutrition, food safety and quality management, and food law and regulations.

The textbook explores laws, primary regulatory jurisdictions between USDA and FDA, key regulations, and applicable enforcement tools. The author explains complex U.S. food regulations in a readable and understandable way.

The book is divided into six parts: Part I includes an introduction to food regulations in the U.S. and a discussion of the legal definition of food. Part II discusses regulations

**Finding textbooks that are focused on food law, regulations, and the functions of regulatory agencies also suitable for a food industry audience ... is not an easy task.**

on labeling, advertising, and claims. Part III deals with regulation of food production practices, including current GMPs, HACCP, FSMA, and the use of food additives. Part IV discusses specialized food regulations dealing with dietary supplements, genetic engineering and biotechnology, food defense, importation/exportation, and pet food. Part V discusses regulatory inspection and enforcement requirements. Part VI covers administrative law and food regulation, international food law, and professionalism and ethics.

Each chapter includes interesting case studies, exercises, and discussion questions that highlight important legal trends, policy debates, and the application of current law designed to help the reader develop critical thinking skills.

The textbook offers a detailed discussion of the historical aspects of U.S. food laws and regulations, an overview of the primary governmental regulatory agencies, and a discussion of important topics such as dietary supplements, FSMA regulations, food defense, genetic engineering, and biotechnology, as well as labeling, product liability, food safety rules, and ethics. While the textbook focuses on U.S. food law, the author has also provided an international perspective.

It's a well-written book with significant updates on U.S. food regulations regarding imported foods, including discussions of FSMA's Preventive Controls for Human Food and the Foreign Supply Verification Program. It should serve as a valuable reference for a wide audience of students and food industry professionals interested in learning about U.S. food laws and regulations and the organization and jurisdiction of regulatory agencies. ■

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# Legal Update



## Lessons Learned from COVID-19

How the food industry can move forward from the pandemic, safely

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

**A**s we pass the three-year anniversary of the declaration of a public health emergency brought about by COVID-19, we can identify and incorporate lessons we've learned from the pandemic into food safety operations. With the pandemic now mostly in the rear-view mirror, food companies would be well advised to carefully evaluate the overall impact it has had on their operations and use that assessment to determine what changes or programs could be implemented now to protect the company and its brand in the event a similar crisis occurs in the future.

As most readers know, the pandemic caused substantial disruptions within the food industry, including many that were significant for both the workforce and the

overall global supply chain. Though many food companies had crisis management plans in place prior to the COVID-19 public health emergency, many of these plans did not anticipate or consider an emergency like the pandemic. Moving forward, food companies should reevaluate their crisis management plans to account for—and incorporate—the important lessons learned from COVID-19.

### Crisis Management Plan

Though FDA and USDA's Food Safety and Inspection Service (FSIS) do not require food companies to have written crisis management programs, many companies have, nevertheless, developed such programs to help them navigate unexpected crisis situations. In addition, third-party

audit standards such as SQF and BRC do, in fact, require a crisis management or business continuity program, further increasing the number of food companies that have developed and implemented such programs.

Typically, crisis management plans evaluate all known potential dangers that could impact the company's ability to produce and deliver safe food, and then identify the methods and responsibilities for responding to the danger if it occurs. Dangers such as power outages, floods, severe weather events, and strikes are often considered in crisis management plans; however, a pandemic event may not have been considered in these programs prior to the COVID public health emergency.

Now that the food industry has experienced a pandemic and seen firsthand the disruptions one can cause, crisis management plans should be updated accordingly. Possible impacts to the company's operations should be identified by evaluating the specific impact of COVID on operations, and control measures to reduce or eliminate future disruptions should be specified in the program. Control measures to address each possible impact should be

specific, actionable, and based upon what the company learned about best practices and the feasibility of its own responses while managing COVID.

Companies that do not have crisis management plans should consider developing and implementing them. Like a recall plan, a crisis management plan allows a company and its leadership to consider how a potential event would impact the company and to determine how the company would respond if the event actually occurred. By engaging in this process long before an event occurs, the company will be better prepared to respond to ensure the event does not create a food safety concern.

### Workforce and Training

Food safety regulations require that individuals engaged in food handling, processing, or packing be adequately trained, appropriate to their position, to ensure that food remains safe. In normal operations, food companies conduct initial onboarding training to first ensure new employees are adequately trained and then require regular refresher training.

The COVID-19 pandemic, however, introduced a number of new complexities for companies when considering food safety training. First, companies faced workforce shortages as outbreaks occurred and, in many cases, an increase in new employees or additional temporary employees. Programs and plans to conduct initial onboarding training for each new employee should account for differences in the quantity of new employees, possible lack of experience of new employees, potential turnover of new employees, and the frequency of start dates.

In addition to changes in how often onboarding training will be required, social distancing recommendations may have also caused changes in how that training is provided. For example, companies that previously relied on classroom training faced difficulties in training the same number of employees within the same training space and within the same allocated times.

Moving forward, food companies should assess training programs and methods to confirm that the methods used to provide training allow for flexibility in case of crisis, but still guarantee that all food handlers are sufficiently and regularly trained to ensure food safety. For exam-

ple, in-person onboarding training can be recorded on video, and then shown to the new employees, to provide an alternative training method when necessary. Simi-

Now that the food industry has experienced a pandemic and seen firsthand the disruptions one can cause, crisis management plans should be updated accordingly.

larly, digital learning systems may provide a viable forward-looking solution for all training requirements.

### Supply Chain Disruptions

As companies around the world faced pandemic-related challenges, significant supply chain disruptions were frequent. Many food companies were unable to obtain necessary raw materials and were forced to either slow or suspend operations or to identify alternative sources for those raw materials.

Food companies typically have thorough supplier approval programs in place to ensure that raw materials do not pose a food safety hazard. In addition, where a potential food safety hazard is controlled by the company's supplier, FDA requires the company to develop and implement a supply chain program that evaluates the supplier to ensure that the hazard is adequately controlled.

When alternative sources (or alternative raw materials) become necessary to continue operations because of supply chain issues, these supplier approval and supply chain requirements must still be followed. When these programs do not allow for emergency approval under certain circumstances, additional delays in receiving raw materials could potentially occur due to the required review and assessment process. As a result, these programs can, and should, be designed to include specific approval criteria for a new supplier or a new raw material, as well as emergency approval procedures to allow for temporary approval of a new

supplier or raw material when identified criteria are fulfilled. Under an emergency approval, companies can utilize an otherwise unapproved supplier or ingredient if the company conducts a food safety assessment sufficient to prevent any food safety risk to the consumer. Emergency approval is typically limited to a short period of time, to allow the company to conduct a full approval process while continuing operations.

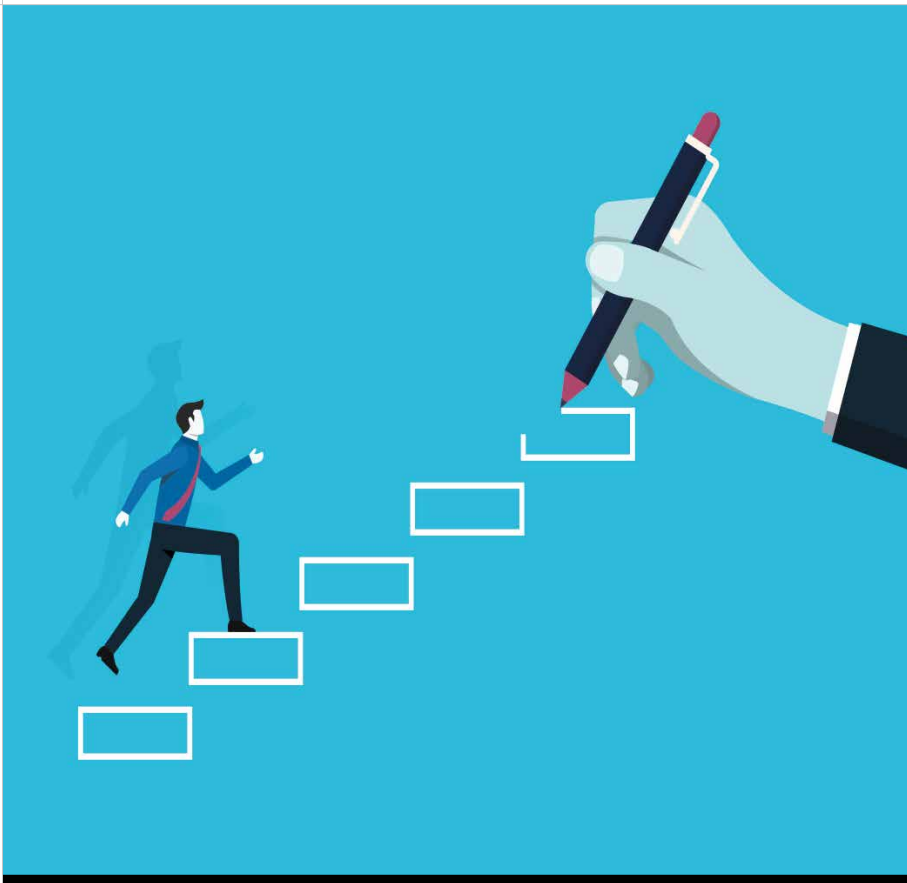
Thus, as the current supply chain continues to return to normalcy, companies should, first, confirm that any suppliers or materials that were approved through emergency procedures and still in use have been fully vetted and approved. In turn, after completing that review, supply chain and supplier approval programs should be reassessed to incorporate lessons learned from the pandemic, such as changes to the emergency approval process or supplier audit requirements.

In addition, many companies require their suppliers to participate in an annual food safety audit. As companies limited access to their facilities, many of these audits were postponed or shifted to a virtual format. When a supplier approval or supply chain program requires an annual audit, updates should be made to specify the circumstances under which a postponement will be allowed or a virtual audit will be permitted. Alternatively, if a virtual or remote audit will not be permitted to fulfill this requirement, the company should carefully evaluate how these audits would occur if access to its suppliers' production facilities is again limited in the future.

Although additional lessons from a company's response to the COVID-19 pandemic can likely be identified, every food company can review and reassess its crisis management plan, training programs, and supply chain programs to incorporate broader industry-wide learnings. Though COVID caused substantial disruption to the food industry, lessons learned throughout the pandemic can be used to significantly strengthen and improve all existing food safety systems. ■

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# Career Development



production caused by bacterial contamination were covered in FSMA regulations or overcome by cooperation with FDA. That's not to say we are now perfect, but we're learning more and more how to apply the core principles in critical food safety situations.

## All Experts Aren't Created Equally

As we acknowledge the leaders who came before, we must also recognize the real heroes of food safety. They aren't named. They aren't remembered anywhere. They are the thousands of frontline workers who practice food safety every day. They are the essential workers who showed up every day during the peak of the pandemic. They are also the select few who stepped up to work on the food safety team. The hours are tough, the manufacturing conditions are often brutal, but they stick it out and do the job. They ensure that policies and procedures are followed and don't hesitate to report when something goes wrong. They care about protecting consumers and take pride in product safety.

They do this from facilities located on the outskirts of cities and small towns across the country, in aging factories filled with old equipment and crumbling infrastructure. They often have limited resources and only the minimal training necessary to meet regulatory requirements. The internet provides some help, but they often find contrasting solutions. A lucky few get to attend food safety meetings and conferences to seek expert help, but they may or may not find the answers they seek. Food production facilities vary wildly in age, layout, and conditions, and food products vary in risk level, so finding exact solutions is nearly impossible. A minor change in facts can have disastrous effects on the outcomes. They proceed with caution, knowing that they don't know how much they don't know. They ask for advice at every opportunity.

This is a good time to remind everyone that food safety experts are not created equally, and good intentions will not pro-

## Back to the Future

Using the tenets of the past to build a new generation of food safety leaders

BY PATRICIA A. WESTER

For 30 years, *Food Quality & Safety* has chronicled some of the most significant advances in food safety, particularly in the field of microbiology. These advances took place in the lab, in the field, or in the factory, and were led by some of the most knowledgeable people of the time. They faced previously unknown challenges, chased unseen threats, and worked feverishly until they found answers. More than anything, a handful of leaders in the meat

industry had the vision to establish food safety as a noncompetitive issue, a tenet followed by the entire food industry to this day.

New challenges will always test our food safety systems, and the leaders of the past taught us that the programs and policies that protect food safety must be flexible and readily adapted to meet them. Challenges such as a rapidly changing food supply chain during a pandemic or infant formula shortages due to reduced



tect you from bad advice. To emphasize this point, the Jensen Farms cantaloupe recall in 2011 was responsible for one of the deadliest *Listeria* outbreaks in the U.S. Bad advice from an expert and a poorly executed third party audit were a lethal combination that resulted in a deadly outbreak that accounted for at least 33 deaths and 147 cases across 28 states.

FDA officials investigating the Jensen event found four strains of *Listeria* on dirty, corroded equipment, recently purchased secondhand on the recommendation of an “expert.” Previously used for potato farming, the “equipment’s past use may have played a role in the contamination” according to the government’s final report. There was no clear evidence it was even cleaned before it was placed in the line. The use of sanitizer in the wash water, a process in use before this renovation, had been discontinued. The fruit wasn’t being precooled, creating humid, damp conditions in the cooler that supported *Listeria* growth. This hardly sounds like an operation under the management of a food safety expert.

Jensen Farms declared bankruptcy in 2012 and, in 2013, charges were filed against the owners, who pleaded guilty to six counts of adulteration of a food and aiding and abetting. The owners also filed suit for negligence against the auditor hired to look at safety standards at their operations, but the work had been assigned to a subcontractor, creating a conflict of interest. Since the subcontractor had been involved in the renovations and operational changes that contributed to the outbreak, they never should have conducted the verification audit.

Sherri McGarry, a senior FDA adviser at the time, said: “We’re going to take these lessons learned, share that with our partners and industries, CDC and the states, and what we want to do is we want to really prevent this from happening in the future.” FSMA was signed into law in 2011.

The Jensen Farms case is an extraordinarily sad example of bad expert advice and misguided good intentions. Most would agree that bringing in an outside party to assess your food safety program is a good idea, just as most would agree that a third-party audit is a great way to confirm that your operation is in good shape. But the owners in this case either

failed to understand the most fundamental food safety principles, such as preventing cross contamination, the proper use of sanitizer, and the danger of dirty standing water, or they simply chose to ignore them. Certainly, the staff, if properly trained, would have noticed what the experts and owners missed. Clearly, using an expert does not replace the need for

## To build the leaders of the future, we need to create a true career path from entry-level food safety to advanced-level program management.

well-trained staff or for retaining a senior management that understands and supports product safety.

### What’s in a Training

FSMA’s preventive controls (PC) rules recognized the need for better training than previously included in HACCP programs. HACCP required a trained HACCP manager that signs off on the HACCP plan, and that’s about it, although it has added some requirements and modified some terms since FSMA’s release.

The PC rules now require all personnel to be qualified individuals (QIs) for their assigned roles and require additional training for the role of a preventive controls qualified individual (PCQI). Unlike the role of HACCP manager, the PCQI must also interact with senior management to ensure the owner, operator, or agent in charge signs off on the food safety plan. This seemingly small change makes senior management wholly responsible for the plan’s content and effectiveness, and that’s a big change.

In short, with FSMA changes and USDA updates, both regulatory branches only require a one-time training course for the most senior food safety staff, while holding management ultimately responsible for the programs’ effectiveness.

It’s time to finally acknowledge what we all know: The required training alone is insufficient to prepare personnel for the

job at hand, and the job at hand can be far tougher than just writing and following programs. We know that these jobs desperately need to be upgraded to acknowledge the true value of the critical thinking skills required to perform them effectively. In short, to build the leaders of the future, we need to create a true career path from entry-level food safety to advanced-level program management.

Once a PCQI training certificate is obtained, it’s applicable to any food sector, another potential gap our future food safety heroes must consider. From produce to candy to beverages, it’s all one course. It does include the requirement for a moderate amount of ongoing professional development, but this requirement is yet to be tested.

The necessary food safety knowledge to develop additional training for today’s food safety personnel is readily available. What is missing are the experience and knowledge in the science of teaching and learning. There are many methods for training development, delivery, and validating content retention. I’m not suggesting everyone rush off to write more in-house training plans; that would be wasteful and redundant. But there is an opportunity to increase training budgets when presenting the food safety plan for management’s signature.

To attract new talent, entry-level personnel need standardized programs that can be delivered by modern web-based platforms easily accessible to the target audience—programs that can verify user participation and track an individual’s progress over time and that offer portable achievements that follow the individual across job changes. Those that devote their time and energy to improving their work knowledge and skills should be recognized for their efforts through documentable achievements universally recognized.

We owe it to our future leaders to share the knowledge and core food safety principles of the last 30 years so they can benefit from our collective past experiences. The food safety leaders of tomorrow depend on the proper development of the new employees of today. ■

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# GUEST EDITORIAL



## The Legacy of Food Safety

By acknowledging the challenges and successes of the last 30 years, we can build a stronger and more resilient food safety culture

BY **DARIN DETWILER, PHD**

**Editor's note:** Thirty years ago, in 1993, Dr. Detwiler's 16-month-old son Riley died of *E. coli* poisoning caused by an outbreak in ground beef from the restaurant chain Jack in the Box. Following Riley's death, Dr. Detwiler became an influential food safety advocate and champion for families impacted by foodborne illness.

His work and speaking engagements over the past 30 years have brought him in front of a U.S. President and countless food safety experts, and have focused on creating awareness among the general public, pushing for regulatory reform from lawmakers, and holding the food industry accountable for keeping the food we eat safe.

**F**ast food, third-party, ghost kitchen, and quick service are concepts that seem so ephemeral in the context of the last mile for food and for food safety; however, the journey that brought safety to our food today stretches back over a generation.

As we look back at 30 years of food safety culture, we should consider the legacy of these three decades as one of progress and achievement. These decades, however, were not without examples of failure and loss. The next 30 years will bring new challenges and opportunities for the industry to build upon this legacy,

as it will play a key role in company reputations, their success, and in ensuring food safety for the health and well-being of all consumers.

### A Herculean Effort

Having a unique perspective as a participant in and observer of the development of a "food safety culture" in the three decades since my son's death from *E. coli* poisoning in 1993, I frequently speak before corporate executives not only about the true burden of foodborne disease, but also about the past and future of food safety. Highlights of my presentations are not only my family's story, but others' as well.

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We can, collaboratively and with the use of new technologies, muster the Herculean effort: the enormous amount of work, strength, and courage that is needed to prevent failures in food safety and to prevent consumers from being harmed and parents from living with a forever-empty chair at their family table.

I share how, many years ago, I met with the parent of a young boy who had survived an *E. coli* illness when he was 4 years old. His mother shared his progress with me but was sad to talk about the difficult time he had in accepting that he couldn't use his left arm, a result of the stroke he had while sick. She talked about how he knew that he couldn't play like the other boys in his school.

But then, she pulled out a crayon-colored image for me to see. She revealed how her son had said he wished someone at the food company could have done something to prevent him from becoming sick and that, in her son's words, "that person would have been his hero." He did not draw someone in a fancy business suit or in a food industry smock: no hair net, no gloves. Instead, he drew a superhero flying and wearing red tights and a cape.

This story has always reminded me of the 1906 *London Daily Times* literary review of Upton Sinclair's novel *The Jungle*, a book that gave the public a peek into the unsanitary conditions at meatpacking plants in Chicago. The review stated: "Unhappily we have good reason for believing it to be all fact, not fiction. The action of the President ... remove all doubt and give the book very great importance ... it is with nothing less than horror that we learn it to be true. The things described by Mr. Sinclair happened yesterday, are happening today, and will happen tomorrow and the next day, until some Hercules comes to cleanse the filthy stable."

While Hercules does not really exist, we can, collaboratively and with the use of new technologies, muster the Herculean effort: the enormous amount of work,

strength, and courage that is needed to prevent failures in food safety and to prevent consumers from being harmed and parents from living with a forever-empty chair at their family table.

My presentations tend to include an image of that crayon drawing of a superhero in flight. I state how each and every person in my audience plays a role in this Herculean effort. I stress that, even in this age of D.C. and Marvel movies, they are perceived as real superheroes in the eyes of those who depend on them to make their food safe. The actions of these superheroes are critical to the lives of so many.

This Herculean effort takes an unwavering commitment to safety from all employees and stakeholders involved in the food production process. This includes not only those directly involved in food production but also those in support functions such as maintenance, transportation, and packaging. Each leader and worker must be well trained and fully committed to following established food safety protocols and procedures.

The importance of corporate legacy in food safety cannot be overstated, as this defines us as individuals and as organizations. A robust food safety culture, investing in the necessary resources and technology, and demonstrating a commitment to transparency and accountability is how we build a strong reputation for food safety—one that is critical for the success of any food company.

### The Legacy

I must point out that, as we talk today about food safety legacy, we can look back in our lifetime at the events of 30 years ago

as the impetus for our current food safety culture. When we look to the future, however, we cannot lose track of the fact that whoever is at the helm of a food company 30 years from now will likely not have even been born until after that landmark event in 1993.

So, how do we make sure that what we hold on to now as a legacy is still in place and even optimized well into the future?

First, we must understand and prioritize the "why" behind our food safety mission so we can better align our values with our actions and create a lasting impact.

Second, while we should hold on to the bright spots in a company's history of food safety achievements, we must place equal importance on acknowledging the darker moments, such as incidents of food contamination or unethical business practices. By confronting these challenges head-on and learning from our mistakes, we can build a stronger and more resilient future.

As we strive to keep a strong commitment to food safety, we can ensure that our Herculean effort will long continue to protect brand reputation, as well as consumers. Ultimately, neither the legacy that we leave behind, nor our consumers, should be accepted as ephemeral. ■

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# Q&A

## Frank Yiannas on Food Safety's Past and Future

FDA's former deputy commissioner of food policy and response talks to *Food Quality & Safety* about the last 30 years of food safety and what he envisions for the industry's future

AS TOLD TO **PATRICIA A. WESTER**

**Editor's note:** This interview has been edited for length and clarity. For the full video interview, visit [foodqualityandsafety.com](http://foodqualityandsafety.com) and look for our new video series, "**Leaders and Legends in Food Safety.**" In the August/September 2023 issue of *FQ&S*, we'll hear more from Frank Yiannas, specifically about his time at Walmart and his thoughts on the importance of and challenges with food traceability.

**F**runk Yiannas, MPH, is FDA's former deputy commissioner for food policy and response, a position he held from in 2018 to 2023. Before joining FDA, Yiannas served in food safety leadership roles at Walmart and the Walt Disney Company, and as president of the International Association for Food Protection. He's authored two books, *Food Safety Culture* and *Food Safety = Behavior*.

**Food Quality & Safety: Looking back over the last 30 years in food safety, what big moments stand out to you?**

**Frank Yiannas:** When I look back at the 30 years, which would go back to 1993, I think of the Jack-in-the-Box outbreak and *E. coli*. This was such a milestone event in terms of tragic consequences; hundreds of people becoming ill—lots of them children—and four deaths among kids. This is a real reminder that foodborne diseases is not about statistics, there are real faces to foodborne disease. That was such a monumental event because it started to change our thinking of the paradigm, which is that



**I think we're going to see more progress in the next 10 years than we saw in the past 30, just because of the tools available to the next generation of food safety professionals and food safety leaders.**

this just "cook it" mentality wasn't good enough; that we all had to work on reducing contamination early in the production chain.

Another one for me is in 1996, CDC launched FoodNet using pulse field gel electrophoresis with just a few states: Minnesota, Massachusetts, Texas, and the state of Washington. That was a real game changer; we could now increasingly find these needles in the haystack because of this new discriminating tool. We could

then figure out whether these cases of illnesses were associated with related pathogens.

In 2006, there was another seminal event in which we saw a pretty large outbreak in our country linked to bagged spinach. CDC and FDA advised consumers not to eat bag spinach because consumers were becoming ill with *E. coli* O157:H7. It took FDA two weeks to identify the source. That was the first outbreak that really put a spotlight on the need for better food traceability.

In more recent times, what stands out to me is the pandemic and how the food and ag industry—which I'm so grateful for—responded through that event. Although the SARS-CoV-2 virus was not transmitted by food, it wreaked havoc on food supply chains.

I'm also very honored to have worked with the men and women at FDA to launch the New Era of Smarter Food Safety at the beginning of this decade. There's some great work happening right now at the agency with the Final Food Traceability Rule and work FDA is doing on machine learning to detect violative seafood shipments.

It's a long, rich history. I would just encourage your readers to go back, understand, and study some of these monumental milestone events, because I think they're important in illuminating and informing the future.

**FQ&S: Do you think we've become any better at learning from the past?**

**FY:** You have to have very high standards when it comes to wanting to improve food safety and the wellness and quality of life of consumers. If you ask if we've learned the lessons of the past well enough and are we at a fast enough pace, the answer is no.

A perfect example is, in 2006, the bagged spinach outbreak; public health officials and regulators at the state level couldn't identify its source for about two weeks. We had to pull spinach from all grocery store shelves. The industry was devastated for a period of about seven years and spinach sales never recovered. In 2018, we have a romaine lettuce outbreak that looks very, very similar. What were the lessons learned? Why hadn't we made more progress?

In fact, this is one of the reasons I left the private sector for the public sector. One of the first things I worked on when I entered FDA was finalizing the food traceability rule, because while we're getting really good at finding what I call these needles in the haystack, we can't find the haystacks—the foods that cause the illnesses—and that's unacceptable.

Again, I encourage readers to become students of history, in general, but if this is your profession, become a student of food safety history. There are a lot of lessons to be learned.

**FQ&S: What were the challenges in promoting the concept of food safety culture?**

**FY:** In the early days, I gave a discussion at a large food safety conference on the importance of food safety culture, which was this idea that we had to leverage insights regarding behavioral science principles, concepts about human behavior, and organizational culture. Somebody who I respected came up to me afterward and said, "Frank, why are you talking about food safety culture here at this conference? This is a conference about the hard sciences and the hard stuff. Culture is 'soft stuff.'" I think, by divine providence, words came into my mouth, and I said, "It's because I think this soft stuff is the hard stuff."

I realized early in my career that I needed to get people to do food safety the right way. I'm not going to do that through HACCP plans alone. They're really import-

ant, but I need to learn a little bit more about human behavior and organizational culture. You can write the best policies and procedures. You can talk the best game. Your CEO needs to talk about it, but the thing that matters most is what your fellow employees are seeing other employees do

**Smarter food safety begins with people; food safety has to and will always be people led. ... We need to continue to invest in attracting the best and the brightest.**

on the plant floor. You can talk hand washing until you're blue in the face. When they walk into their establishment, whether it's a manufacturing facility or food service or retail establishment, if they don't see other people washing their hands, they'll say it's not part of the culture here. At the end of the day, it's what people do, not what they say that matters most.

**FQ&S: How do you think industry has embraced this concept? What do you think we could do better?**

**FY:** I think we've come a long way, but I have mixed views on the current state. I'm grateful to see that now people don't react negatively when you're talking about food safety culture. In fact, at every food safety conference people are now focused on food safety culture as being a prerequisite to effective food safety management. That's good but, in some respects, it took us a long time to get here and we're still at the point where people don't understand it well enough. People still think of "food safety culture" as a tagline or a slogan, this vague or abstract concept. We have to start really distilling down food safety culture to a blending of food science and behavioral science principles and organizational culture principles. And we need to food safety culture as a subset of our profession based on science.

**FQ&S: What do you see in the future for the industry?**

**FY:** I sincerely believe that some of our best solutions stand ahead of us. We have new tools, new approaches, and new technologies. We're living in the digital age where better food safety begins and ends with better data. It's that simple. I think we're going to see more progress in the next 10 years than we saw in the past 30, just because of the tools available to the next generation of food safety professionals and food safety leaders. I firmly believe that we'll look back on food safety 30 years from now and say, really? That's the way you guys used to do things?

**FQ&S: Tell us more about your vision for the digital age of food safety.**

**FY:** Think about a day and age where, instead of writing standards about how a facility should operate, writing HACCP plans, and then periodically going in and doing a physical inspection, imagine a world in which these food establishments and foods are given digital identities and digital voices through sensor technology where we can monitor them more regularly—some of them almost in real time. That's going to happen. The New Era is really important, and I'm excited to see how food safety is going to change. We're seeing it with food traceability. We're seeing it a big way with the predictive analytics. But there's a lot more that needs to be and can be done.

**FQ&S: Do you think we're focusing enough on the next generation of the profession?**

**FY:** While I am a big believer in the future being enhanced through tech-enabled solutions, smarter food safety begins with people. Food safety has to and will always be people led. It'll be increasingly technology enabled, but we need to continue to invest in attracting the best and the brightest. We have to continue to invest in and develop people. Some of the greatest leaders and mentors I've ever worked with took a personal interest in developing Frank Yiannas, and I hope that I and other food safety professionals can do this too. I'm encouraged about the future primarily because of the younger generation that I talk to.

The future of food safety and food and ag, in general, is very bright because of this next generation of leaders. ■

1993-1999

**30** Years of Food Safety  
1993-2023

# The Age of HACCP

A deadly *E. coli* outbreak transforms the food industry

BY KAREN APPOLD

## MAJOR MILESTONES IN FOOD SAFETY: 1993-1999

### **Jan. 1993: Jack in the Box *E. coli* O157:H7 Outbreak**

The outbreak, traced to undercooked hamburger meat containing the pathogen, sickens more than 700 people, and four children die.

### **Sept. 1994: USDA Declares *E. coli* O157:H7 an Adulterant in Raw Ground Beef**

Michael Taylor, then the newly appointed administrator of FSIS, states that the agency considers raw ground beef that is contaminated with the pathogen to be adulterated.

### **1995-1996: Key Food Safety Networks Are Created**

In response to the *E. coli* O157:H7 outbreak, several government initiatives to improve food safety intelligence are founded, including PulseNet, FoodNet, and the National Antimicrobial Resistance Monitoring System for (NARMS).

### **July 1996: Pathogen Reduction, HACCP Final Rule Enacted**

FSIS announces the Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) systems final rule for meat and poultry facilities.

### **Oct. 1996: Odwalla Juice Recall**

*E. coli* O157:H7 is identified in stool samples from people with HUS who had consumed unpasteurized juice made from blemished, fallen fruit.

### **June 1997: HIMP Project Initiated**

FSIS announces plans to develop a project for inspecting certain meat and poultry products under the HACCP-based Inspection Model Project (HIMP) as the landmark project to implement HACCP systems for all types of meat and poultry facilities.

### **Dec. 1997: Seafood HACCP Rule**

The regulation requires processors of fish and fishery products to develop HACCP systems for their operations.

**Editor's note:** As Food Quality & Safety celebrates 30 years of publication, we think it's fitting to examine the major food safety events of the period and to highlight the extraordinary efforts to make food safer over the last three decades. In this important retrospective, you'll hear food safety experts discuss—decade by decade—the monumental outbreaks, regulations, and technologies that played pivotal roles in advancing food safety, often sharing events they were there to witness and shape.

As the 1990s began, the focus of food safety in the United States was on preventing chemical residues in food. Pathogenic bacteria were considered normal flora of meat and poultry products and could only be controlled by consumer cooking, says Ann Marie McNamara, PhD, vice president of Food Safety and Quality, Supply Chain, at US Foods, Inc., a foodservice distributor in Rosemont, Ill.

But, in December 1992 and into 1993, an *E. coli* O157:H7 outbreak, which originated in contaminated beef patties that were undercooked and served at 73 Jack in the Box restaurants in the western United States, changed the way the food industry, regulatory agencies, and consumers addressed food safety threats. Four children died and, of the 732 other people across four states who were infected, 178 sustained permanent injuries, including kidney and brain damage.

“Until this time, it was unimaginable that a child could lose their life from eating a hamburger,” says Mindy Brashears, PhD, associate vice president of research and director of the International Center for Food

Industry Excellence at Texas Tech University in Lubbock, and former undersecretary for food safety at USDA. “It was a defining moment in food safety history.”

### **A Resounding Response**

Proper cooking kills pathogens on the outside of meat patties, but has little effect on those in the interior, but Jack in the Box's cooking times failed to consider cases of inaccurate grill temperatures. According to Mitzi D. Baum, CEO of STOP Foodborne Illness, a nonprofit public health organization focused on the prevention of illness and death from foodborne pathogens based in Chicago, “The Jack in the Box outbreak exposed the hidden dangers lurking in food to the entire nation; officials could no longer ignore that meat inspection methods—in place for almost 90 years at the time—were not sufficient to protect consumers from deadly bacteria. Food regulations needed to be transformed and be based on modern science to reduce risk.”

Scientists from government, industry, and academia stepped into the food space to study, develop, and validate mitigation strategies for the industry that are still practiced today, Dr. Brashears says. Processing strategies ranged from acid washes to hot water cabinets that reduced pathogen counts on carcasses during harvesting. For pre-harvest food safety, scientists extensively studied how pathogens were transmitted in cattle herds, what caused active shedding of pathogens during feedlot finishing, and the mitigations of vaccination and direct-fed microbials (probiotics).

Consumers also started paying more attention food safety. “They began to organize

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and speak out about their indescribable experiences with food-borne illnesses,” Baum says. “Consumers researched and discovered that the regulatory agencies charged with protecting public health were ineffective.” Public outcry put pressure on regulatory officials to respond with impactful and measurable interventions to prevent another tragedy, which contributed to USDA passing the Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule in 1996.

### ***E. coli* Declared an Adulterant in Ground Beef**

In September 1994, Michael Taylor, JD, the newly appointed administrator of USDA’s Food Safety and Inspection Service (FSIS), declared *E. coli* O157:H7 an adulterant in raw ground beef. This was a bold move, not all pathogens are adulterants, and any product containing an adulterant must be destroyed. “From a public health standpoint, my decision was easy because an inspection program should ensure that a product is produced safely,” Taylor says. “If a dangerous bacteria exists in a product that, under normal cooking conditions, may not be heated to a point that eliminates the pathogen, then it should be considered an adulterant.”

With his decision, Taylor wanted to establish the principle that the companies that process and produce ground beef should be responsible for eliminating these dangerous strains of *E. coli* O157:H7, even though consumers are responsible for safely cooking ground beef. Although the meat industry sued USDA over the decision, the district court upheld it. Ultimately, the decision helped to lay the groundwork for HACCP.

Taylor’s decision came just six weeks into his tenure and, he admits, occurred as a result of meeting with two women whose families were significantly impacted by the Jack in the Box *E. coli* outbreak. One woman’s son died and the other’s son was seriously injured. “They put a human face on the issue,” he says. “Speaking with them changed my entire perspective on food safety. They said it was unacceptable that the Department of Agriculture allowed pathogens in raw meat, and that something had to be done. My decision was very much catalyzed by their legitimate outrage.”

Of all the initiatives related to food safety that occurred over the last 30 years, Bill Marler, JD, president of Marler Clark, a food safety law firm in Seattle, views Taylor’s declaration as the most profound step to be taken. “It has led to fewer outbreaks and recalls, and ultimately fewer illnesses and deaths,” he said. “During the 1990s and early 2000s, 90% of my law firm’s cases were linked to *E. coli* in hamburger and, today, that number is zero. That’s a pretty remarkable change.”

### **HACCP Is Passed**

With its passing, HACCP became a landmark regulation for improving the safety of meat and poultry products. The rule supplemented the visual inspection of meat and poultry products and required industry to identify the potential biological, physical, and chemical hazards inherent in food products they produced and to identify and monitor all processes with critical control points that could control, reduce, or eliminate these hazards. “This changed the focus of meat and poultry product inspections from reactive visual inspections to a proactive, risk-based

inspection system focusing on controlling potential hazards,” Dr. McNamara says.

Furthermore, USDA’s Pathogen Reduction/HACCP Rule was the first legislation to mandate microbiological testing of meat and poultry products for bacterial pathogens and microbial process control indicators. “The rule provided industry with the latitude they requested to develop their own processes for producing safe meat and poultry products based on controlling the inherent risks of a food,” Dr. McNamara adds. *E. coli* testing by industry was designed as a process control indicator to show that their process was controlling enteric pathogens.

In addition to implementing HACCP’s policies, David Theno, PhD, Jack in the Box’s food safety director at the time, took the bold stance of empathizing with, and apologizing to, the outbreak’s victims. “This increased the visibility of food safety in the United States, and provided one of the first examples in which the safety of food was directly linked to public health,” says Lee-Ann Jaykus, PhD, distinguished professor of food, bioprocessing, and nutrition sciences at North Carolina State University in Raleigh. “It also demonstrated that the industry could be deeply rooted in assuring food safety and set the stage for later forays into the concept of food safety culture.”

### ***E. coli* Shows Up in Produce**

Another notable outbreak in the 1990s occurred when *E. coli* O157:H7 was found in Odwalla’s apple juice in 1996. A batch of unpasteurized apple juice was produced from fallen, blemished fruit that was contaminated with the bacterium. It killed a 16-month-old girl and sickened 70 people in three states and British Columbia. “Previously, this pathogen was thought to be exclusively a ground beef problem,” Dr. Jaykus says. “This outbreak demonstrated that other food vehicles could become contaminated with pathogenic *E. coli*.”

This was also one of the first high-profile outbreaks that brought produce-related food safety risks to the forefront. Odwalla was heavily fined and donated money to provide funding to support food safety research, Dr. Jaykus says. The event helped set the stage for FDA’s Juice HACCP Rule, which became effective in 2002.

### **Food Contact Substances Targeted**

In 1997, another significant piece of legislation was passed—the Food and Drug Modernization Act, which amended the Federal Food, Drug, and Cosmetic Act of 1938. Specifically, it expanded FDA’s authority to regulate health and nutrient content claims, and expedited the process companies used to get food contact substances, formerly called indirect food additives, approved without jeopardizing safety, says Robert Brackett, PhD, senior vice president and dean of IEH Academy, IEH Laboratories & Consulting Group in Lake Forest Park, Wash.

Previously, companies had to petition FDA for pre-market approval for substances and packaging that came into contact with food. With this legislation, unless FDA disagrees with the evidence submitted in the notification application within 120 days of a submission for approval, food companies could go ahead and use it. “FDA would allow and encourage companies to have a pre-notification consultation with them, so they could do it right the first time and avoid rejection,” Dr. Brackett adds. “The new process



## LEADERS LOOK BACK



“The Jack in the Box outbreak exposed the hidden dangers lurking in food to the entire nation. Officials could no longer ignore that meat inspection methods—in place for almost 90 years at the time—were not sufficient to protect consumers from deadly bacteria. Food regulations needed to transform and be based on modern science to reduce risk.”

—Mitzi D. Baum, *STOP Foodborne Illness*



“If a dangerous bacteria exists in a product that, under normal cooking conditions, may not be heated to a point that eliminates the pathogen, then it should be considered an adulterant.”

—Michael Taylor, *former administrator of USDA’s Food Safety and Inspection Service*



“[HACCP] changed the focus of meat and poultry product inspections from reactive visual inspections to a proactive, risk-based inspection system focusing on controlling potential hazards.”

—Ann Marie McNamara, *PhD, US Foods, Inc.*



“PCR [opened] the door for employing molecular amplification to detect common foodborne pathogens, such as *Salmonella*, and eventually allowed for more rapid detection. It also began to make it possible to detect non-cultivable pathogens such as enteric viruses.”

—Lee-Ann Jaykus, *PhD, North Carolina State University*

was much more streamlined: Companies benefited from getting faster approvals, and FDA didn’t have to apply as many resources to evaluate submissions.”

Gary Nowacki, CEO of TraceGains, a supply chain solutions company based in Westminster, Colo., adds that, in short, the revised process gave manufacturers the benefit of the doubt, relaxing packing regulations to accelerate market innovation. The law also extended procedures in which FDA could authorize health and nutrient content claims without reducing the statutory standard.

### **Listeria Rears Its Ugly Head**

In 1998 and into January 1999, an outbreak of *Listeria monocytogenes* was found in Sara Lee Corp.’s hot dogs and deli meats. Some sources put the death toll as high as 21, which was the third deadliest outbreak of foodborne illness in the United States since the CDC started tracking them in the 1970s. Unlike *E. coli*, which resides in the gastrointestinal tracts of animals and enters the food supply through cross-contamination during slaughter, *Listeria* can come from anywhere, so the hunt for the contamination source was extensive. It was finally found in the facility’s

environment, well hidden from routine daily sanitation activities. “This outbreak demonstrated yet another potential vehicle for *Listeria* contamination and disease,” says Dr. Jaykus, who also notes that the first highly publicized *Listeria* outbreak in the United States was with Jalisco cheese in 1984 and 1985 in Southern California. “The dairy industry took the hit for this one, and better detection methods, as well as targeted controls for dairy food products and the industry, developed over the next decade,” she says.

The Sara Lee incident highlighted the unrecognized risks associated with allowing extended shelf lives for refrigerated processed meat products. This spurred research into better controls for managing the production environment at a microscopic level and the development of food additives that inhibited *Listeria* growth. FSIS conducted a comprehensive risk assessment, which was a motivator for development of the agency’s compliance guidance on controlling *Listeria monocytogenes* in post-lethality exposed ready-to-eat meats and poultry in 2014, Dr. Jaykus adds.

### **Emerging Technologies**

Some notable trends in food safety testing developed during this period. Previously, microbiological methods that relied on culture, biochemical, and serological identification of *E. coli* O157:H7 and other foodborne pathogens were used. “These time-consuming and labor-intensive procedures took up to two days to presumptively identify a positive lot of ground beef and three additional days to confirm that the bacteria present was indeed *E. coli* O157:H7,” Dr. McNamara says.

This lengthy process drove academic, industry, and government microbiologists to recognize that more rapid methods that relied on bacterial DNA, such as the new polymerase chain reaction (PCR) technique, or immunological methods were needed to detect pathogens more quickly, Dr. McNamara said.

“Since PCR is theoretically able to detect one single copy of the target genome sequence, food microbiologists were initially encouraged that they would be able to forego the necessity of cultural enrichment,” Dr. Jaykus says. “However, that didn’t occur, mostly due to matrix interference, which reduced assay sensitivity.”

“PCR did open the door for employing molecular amplification to detect common foodborne pathogens, such as *Salmonella*, and eventually allowed for more rapid detection. It also began to make it possible to detect non-cultivable pathogens such as enteric viruses,” Dr. Jaykus adds. Many PCR-based kits for foodborne pathogen detection hit the market.

As part of the FSIS “War on Pathogens,” initiated in 1993, Dr. McNamara oversaw the prioritization of research grants that included significant funding for developing and comparing commercial PCR test kits to rapidly identifying pathogens in meat, which helped to establish PCR testing as the gold standard for rapid testing for pathogens.

### **Epidemiological Surveillance Systems Emerge**

Another key development that originated in the 1990s was a collaboration among CDC, FDA, and FSIS to establish key public

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2000-2009

**30** Years of Food Safety  
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## Food Safety in the New Millennium

The decade sees *Listeria* outbreaks in meat and poultry,  
*E. coli* in leafy greens, and the creation of allergen labeling

BY **KAREN APPOLD**

## MILESTONES IN FOOD SAFETY: 2000-2009

### **2000: Global Food Safety Initiative Founded**

GFSI is launched by a group of leading food safety experts to collaboratively reduce risks.

### **2002: *Listeria* Found in Processed Turkey**

The outbreak of listeriosis linked to Pilgrim's Pride Corp. kills seven people, sickens 46, and causes three miscarriages. The company recalls more than 27 million pounds of poultry, the largest recall in the U.S.

### **Jan. 2002: HACCP Rules for Juice Implementation Deadlines Published**

FDA circulates HACCP rules for production of fruit juice and juice concentrate.

### **2005: ISO 22000 Management Standard Released**

The International Organization for Standardization (ISO) promulgates ISO 22000, which stresses interactive communication, systems management, and HACCP principles.

### **Jan. 2006: Food Allergen Labeling Legislated**

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), an amendment to the Federal Food, Drug, and Cosmetic Act, requires the labels of foods that contain a "major food allergen" to declare the presence of the allergen.

### **Aug.-Oct. 2006: Multi-State *E. coli* O157:H7 Outbreak in Spinach**

The outbreak results in 205 confirmed illnesses in 26 states and three deaths, according to FDA. CDC reports that 102 people were hospitalized and 31 developed HUS. All spinach implicated in the outbreak is traced to a California firm.

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**T**he 2000s saw an increased regulatory focus on food safety, advances in new technologies designed to testing for and detect foodborne pathogens, globalization of the supply chain, a focus on traceability, the reliance on third-party certification audits to verify the safety and quality of a company's products, and an increase in consumer awareness of food safety, says Tracy Fink, director of scientific programs and food safety at the Institute of Food Technologists in Chicago. Several deadly outbreaks of foodborne illness also occurred during this time period, many of which significantly impacted the future of the safe food production.

The new millennium started off with the private sector establishing the 2000 Global Food Safety Initiative (GFSI), which was created by the Consumer Goods Forum to collaboratively drive industry improvement to reduce food safety risks and increase consumer confidence in the delivery of safe food. A group of leading food safety experts including manufacturers, retailers, and suppliers, launched GFSI to establish a global standard for food safety management systems, says Gary Nowacki, CEO of TraceGains, a supply chain solutions company based in Westminster, Colo.

The organization immediately sought to synchronize the world's food safety audit standards to help mitigate retailer liability exposure and eliminate audit duplication, Nowacki says. In addition, GFSI added "benchmarking" to the accredited certification model, an additional step that determined equivalency between existing food safety schemes while preserving choices in the market.

Early adopters of GFSI, including Walmart, Nestle, Coca-Cola, Carrefour, and Tesco, played significant roles in mainstreaming the initiative. In fact, in 2008, Walmart became the first national retailer in the United States to require suppliers of its private label and other food products to have their factories certified against one of the internationally recognized GFSI standards, Nowacki says.

Companies had to address and fix internal problems before earning certification. Certification ensures audit deficiencies are tracked and corrected in a timely manner, which allowed companies to direct resources to other areas that required improvement. Today, the organization comprises 45 retailers and manufacturers.

### **Deadly *Listeria* Outbreak**

The 2000s were riddled with deadly foodborne illness outbreaks. In 2002, *Listeria monocytogenes* in processed turkey from Pilgrim's Pride Corp. killed seven people, sickened 46, and caused three miscarriages. The company recalled more than 27 million pounds of poultry, the largest recall in history.

This was one of the first examples in which PulseNet was used to identify a large outbreak in near real time, facilitating a more rapid response, says Lee-Ann Jaykus, PhD, professor of food, bioprocessing, and nutrition sciences at North Carolina State University in Raleigh.

The incident, along with other high-profile outbreaks of the late 1990s, ushered in an era in which class action lawsuits for large outbreaks became more commonplace. The bacterial outbreaks at Pilgrim's

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## In the mid-2000s, both consumers and the media began to take a heightened interest in food safety, which correlated with the growth of social media and its impact.

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Pride, Jack in the Box (1993), and Sara Lee (1998), among others, served as an impetus for either establishing consumer advocacy groups promoting food safety, such as STOP Foodborne Illness and the Center for Foodborne Illness Research and Prevention, or increasing an organization's visibility, such as in the case of the Center for Science in the Public Interest, Dr. Jaykus says.

### LGMA Created After *E. coli* Outbreaks in Produce

Bagged greens were the target of two *E. coli* outbreaks in the mid-2000s. In 2005, at least 23 people in Minnesota were infected with *E. coli* O157:H7 after eating contaminated Dole brand lettuce. The FDA later reported that as many as 245,000 bags of Dole lettuce may have been contaminated.

Then, in 2006, an *E. coli* O157:H7 outbreak occurred in bagged baby spinach packaged by Natural Selection Foods, marketed by Dole. More than 200 illnesses and several deaths were attributed to this outbreak. Ultimately, FDA and the California Department of Public Health determined that a single field managed by Earth-Bound Farms in California and processed by their Natural Selection Foods plant was the most probable source of contaminated spinach. "This event was probably the key catalyst for change in major supply side sectors for food safety systems and rapid pathogen testing implementation," says Trevor V. Suslow, PhD, professor, Extension and Applied Research, Plant Sciences at the University of California in Davis.

After the 2006 outbreak, California farmers made an unprecedented commitment in 2007 to protect public health by creating the California Leafy Green Products Handler Marketing Agreement (LGMA), Dr. Suslow says. The program's goal is to ensure safe leafy greens and increase confidence in government-recognized and audited food safety programs.

### *Salmonella* Outbreak in Peanuts Leads to Criminal Charges

A 2008-2009 *Salmonella* outbreak in peanut butter products from Peanut Corp. of America (PCA) resulted in nine deaths and approx-

imately 22,500 illnesses related to the bacterium in this low-moisture, heat treated food. Many of the contaminated products were used as ingredients in other products, resulting in thousands of other recalls. "The event shook the industry because it resulted in criminal charges, including conspiracy, fraud, and obstruction of justice," Fink says. "It was a wake-up call for stronger penalties for companies that violated food safety standards."

PCA's owner knowingly shipped contaminated peanut products and ignored positive test results for *Salmonella*, making this the first event that held corporate, personal, and criminal liability. "It was the first significant incident in which a company willfully and intentionally shipped contaminated products to promote its bottom line and with complete disregard for public health," Fink says. "The owner put profits before people."

Many lessons can be learned from the event, including why it's important to require robust testing and inspections of products and facilities, Fink says. Another takeaway was the need for greater enforcement and authority of USDA and FDA, so each governing body could have stronger penalties for companies that didn't comply with food safety standards.

For supply chain actors, the downstream fallout of the PCA recall highlighted the importance of traceability and supplier quality management. PCA supplied manufacturers, foodservice operators, and retailers who were faced with the challenge of iden-

## LEADERS LOOK BACK



"[The 2006 *E. coli* O157:H7 outbreak in bagged baby spinach] was probably the key catalyst for change in major supply side sectors for food safety systems and rapid pathogen testing implementation."

—Trevor V. Suslow, PhD, University of California, Davis



"The 2006 *E. coli* outbreak in bagged organic baby spinach event drove companies to devote more resources to food safety—not only because they didn't want to make anyone sick, but also to prevent reputational damage associated with an outbreak,"

—David Acheson, MD, CEO and president of The Acheson Group



"[The Peanut Corp. of America *Salmonella* outbreak] shook the industry because it resulted in criminal charges, including conspiracy, fraud, and obstruction of justice. It was a wake-up call for stronger penalties for companies that violated food safety standards."

—Tracy Fink, Institute of Food Technologists



"The buzz around traceability arguably began in earnest in 2006 when FDA, unable to quickly determine the source of contaminated spinach, shut down the industry. Until that point, traceability had been associated with tracking the movement of live animals."

—Jennifer McEntire, PhD, Food Safety Strategy

# The downstream fallout of the Peanut Corp. of America recall highlighted the importance of traceability and supplier quality management.

tifying and removing the affected products from commerce, resulting in a domino effect throughout the supply chain.

By the end of 2009, the event involved more than 350 companies and 3,913 different products that were manufactured using PCA ingredients. Some of these downstream actors faced lawsuits over claims of negligence for failure to adequately manage their supply chains and mitigate risk of contamination, Fink adds.

## Consumer Awareness Increases

In the mid-2000s, both consumers and the media began to take a heightened interest in food safety, which correlated with the growth of social media and its impact. “Message sharing and information moving around put the lens on food companies to be more responsible; consumers would walk away from commodities or brands if there was a problem,” says David Acheson, MD, CEO and president of The Acheson Group in Bigfork, Mont. The impacts of food safety issues shifted from individual companies being in the hot seat to entire commodities being boycotted.

For example, the 2006 *E. coli* outbreak in bagged organic baby spinach decimated the spinach market for years, even though it was traced back to one supplier. “This event drove companies to devote more resources to food safety—not only because they didn’t want to make anyone sick, but also to prevent reputational damage associated with an outbreak,” Dr. Acheson says.

The 2006 *E. coli* outbreaks in spinach, along with the 2008-2009 *Salmonella* outbreak in peanut butter from PCA, set the

stage for the passage of FDA’s Food Safety Modernization Act early in the next decade.

A lesser-known recall involving pet food occurred in 2007. When pet owners began reporting illnesses and deaths, mostly in dogs, it was ultimately linked to an imported ingredient that was toxic. A Presidential Working Group was formed to look into the safety of imported foods, and raised awareness about the importance of pet food safety.

## Traceability Initiatives

In addition to heightening consumer awareness, deadly bacteria outbreaks in spinach and peanut butter in the 2000s also spurred traceability efforts. “The buzz around traceability arguably began in earnest in 2006, when FDA, unable to quickly determine the source of contaminated spinach, shut down the industry,” says Jennifer McEntire, PhD, founder of consulting firm Food Safety Strategy, based in Frederick, Md. “Until that point, traceability had been associated with tracking the movement of live animals, mainly due to concerns of mad cow disease and other animal health issues.”

The spinach outbreak shifted the conversation to solving outbreaks (trace back), while the 2008-2009 *Salmonella* outbreak in peanut butter from PCA revealed gaps in the recall process (trace forward), Dr. McEntire adds. The Institute of Food Technologists conducted some foundational work on traceability as part of FDA contracts, and efforts continued through their Global Food Traceability Center. Industry efforts, notably the Produce Traceability Initiative, launched in 2008, but implementation was limited due to its voluntary nature. ■

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### 2007: California Leafy Green Products Handler Marketing Agreement Created

After the 2006 *E. coli* outbreak, California farmers make a commitment to protect public health by creating the LGMA. The agreement establishes a set of food safety best practices that are implemented on leafy greens farms throughout the state.

### 2007: Pet Food Recalled

President Bush initiates multiple investigations into the importation of pet food from China after thousands of pets are reported to be ill or to have died. The outbreak was determined to be due to the intentional introduction of wheat gluten containing melamine to artificially boost the amount of protein. Commonly used methods for protein analysis do not distinguish between nitrogen from protein and from non-protein sources. An estimated 8,500 dogs die.

### 2008-2009: *Salmonella* Outbreak from Peanuts

The Peanut Corp. of America’s products are the source in an outbreak of *Salmonella typhimurium* illnesses that kill nine people and sicken more than 700. The recall prompted by the outbreak involves thousands of products made by more than 300 companies.

### 2009-2010 The Food Protection Plan Emerges

A team led by David Acheson, MD, creates a three-pronged approach to overhaul FDA to shift from a reactionary organization to a more proactive agency per congressional request. A modern agency would emerge by defining risk-based preventive controls for industry and holding industry accountable for product safety, by using risk-based inspections to meet newly established inspection mandates, and by developing a rapid response to crises. The plan also requests new regulatory authorities that allow FDA to accomplish the plan’s goals.

2010-2023

**30** Years of Food Safety  
1993-2023

## FSMA and the New Era

The extensive Food Safety Modernization Act ushers in hope for change, and a new era of traceability and genome sequencing begins

BY KAREN APPOLD

**A**lthough it's undeniable that food safety has made progress in the past 30 years, what hasn't changed is that regulations are updated or improved upon as a reaction to an outbreak, crisis, or tragedy, says Mitzi D. Baum, CEO of STOP Foodborne Illness in Chicago. "Shifting the ingrained cultures of regulatory agencies from reactivity to prevention continues to be elusive, although there was much optimism that change would occur when the Food Safety Modernization Act (FSMA) became law in 2011," Baum says. FSMA's basic tenet is a proactive approach to food safety.

Numerous outbreaks, recalls, and other food safety events culminated in FSMA's passing when Michael Taylor, JD, was FDA's deputy commissioner. "The breadth of food system stakeholders—industry, consumer groups, and policymakers—all supported its passage, funding, and implementation," says Jennifer McEntire, PhD, founder of Food Safety Strategy, a consulting firm based in Frederick, Md.

FSMA is widely considered to be the most sweeping update of the U.S. food regulatory system in decades, Dr. McEntire says. It required FDA to issue rules governing produce safety on farms as well as the safety of imported products, and required registered facilities to assess and manage food safety risks, including those related to intentional adulteration, improving traceability for certain foods, and much more.

The U.S. Congress underestimated the time and effort needed to issue the rules, which were ultimately released as the result of consent orders stemming from consumer group lawsuits. Although FSMA was signed into law a dozen years ago, some of its major rules, such as 2016's Final Rule on Produce Safety's agricultural water requirements and 2022's Food Traceability Final Rule, are not yet fully implemented. "It's too soon to tell if FSMA has improved public health, but—without question—it's fundamentally changed the way food safety is managed in the United States, and even globally," Dr. McEntire says.

**The New Era of Smarter Food Safety**  
Nearly ten years later, in 2020, the New Era of Smarter Food Safety was ushered

in under Frank Yiannas, MPH, who, at the time, was FDA's deputy commissioner of food policy and response. The initiative addressed traceability, digital technologies, evolving food business models, and food safety culture.

According to Gary Nowacki, CEO of TraceGains, a supply chain solutions company, universal traceability based on industry-wide technology adoption and interoperability between solutions has the potential to provide greater supply chain visibility and accelerate industry responses to contamination and other issues. "The FDA wants to increase tech adoption for traceability across the industry, working not only with brands and manufacturers, but also with technology providers serving the industry," he says.

Another component of the blueprint is to employ smarter tools and approaches for prevention and outbreak response. "Making the most of available data remains one of the most valuable resources the industry has at its disposal," Nowacki adds. According to a speech by FDA Commissioner Stephen Hahn, MD, FDA wants to do everything it can to "attain better quality data, conduct a more meaningful analysis of it, and transform streams of data into more meaningful, strategic, and prevention-oriented actions."

FDA is also focusing on new business models and retail modernization by doubling down on budding business models to produce and deliver food. "These new business models and delivery channels demand next-generation efforts to ensure food safety," Nowacki says. "Continued innovation in areas such as meal kits and fresh and frozen food items available by delivery are creating new challenges, as delivery channels not previously used for food delivery become part of last mile food delivery to consumers."

Finally, the "New Era" initiative looks beyond plant floor protocols and safety schemes and addresses human behavior and how employees think about food safety. "FDA wants to encourage the embrace of technologies and platforms, including social platforms and the networked ingredient marketplace, that workers use to carry food

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**May-Nov. 2010: Outbreak of *Salmonella enteritidis* in Eggs**  
CDC identifies a nationwide increase in cases of *Salmonella enteritidis* infections uploaded to the PulseNet database. Nearly 2,000 reported illnesses are likely associated with the outbreak, and epidemiologic investigations point to eggs as the source; a nationwide recall follows.

**July 2010: New Egg Safety Regulations Implemented**  
Food safety requirements for egg producers with 50,000 laying hens or more take effect. The new rules require producers to adopt preventive control measures and to use refrigeration during egg storage and transportation.

**Jan. 2011: FSMA Signed into Law**  
Public Law 111-353, The Food Safety Modernization Act (FSMA), is signed into law by President Obama.

**Aug.-Oct. 2011: *Listeria* Outbreak Found in Whole Cantaloupes**  
An outbreak of *Listeria monocytogenes* infections sickens almost 150 people in 28 states. The outbreak is blamed for a reported 33 deaths and one miscarriage.

**2012-2023: FSMA Foundational Rules Finalized**  
Human Food, Animal Food, Produce Safety, Sanitary Transport, Intentional Adulteration, Foreign Supplier Verification Program (FSVP), and Voluntary Qualified Imported Program (VQIP) and Accredited Third Party Certification are finalized. Many other rules are necessary to fully complete the requirements set forth by Congress. These rules, along with more than 50 guidance documents, other reports, and pilot studies make FSMA a huge regulatory undertaking that will update food safety for decades to come.

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safety concepts beyond traditional training methods and create an industry culture in which strong practices are deeply embedded,” Nowacki adds.

### A Shift to “Natural” Ingredients

The 2010s saw many trends emerge in food safety, mostly related to what consumers deemed healthier options. These trends included a desire for more “natural” ingredients and “clean label” products and ushered in an increased interest in plant-based products, cell-cultured meats, and novel foods.

David Acheson, MD, CEO and president of The Acheson Group in Bigfork, Mont., believes these trends took shape as more consumers became aware of foods’ impact on health. “More American consumers sought to create healthier lifestyles, and believed that what they ate was important, he says.

Along these same lines, Bill Marler, JD, president of Marler Clark, a food safety law firm in Seattle, says that more consumers became aware of the negative effects of eating salts, sugars, and fats; of mass-produced foods; and of ultra-processed foods, as well as overeating, on diabetes, heart disease, and cancer. This awareness motivated consumers to look for products that they believed were safer.

### Plant-Based Foods and More

The trend toward more plant-based foods was also driven by health concerns, in addition to environmental issues, says Tracy Fink, director of scientific programs and food safety at the Institute of Food Technologists in Chicago. The use of plant-based ingredients to produce food products continues to expand as more companies, chefs, and entrepreneurs experiment with novel and innovative ways to create delicious and nutritious options. Plant-based foods are often made from pea protein, soy, wheat, lentils, chickpeas, beans, nuts, grains, fruits, and vegetables.

Companies were motivated to grow plant-based foods, as well as cell-cultured foods indoors, in the hope that they would avoid problems with dangerous bacteria such as *E. coli*, *Salmonella*, and *Listeria*. “However, that was wishful thinking as dangerous bacteria can be found on manufactured and food contact surfaces,” Marler says.

Knowing that meat lovers desired plant-based food products to look, smell, and taste like meat, food companies jumped at the opportunity and got creative. Production of novel food products made using animal cells to grow cell-cultured meats is still in the early development stages, as are safety and regulatory requirements regarding these new products. “Part of the complexity of cell-cultured meat is the difficulty of large-scale production of the cell-cultured medium,” Fink says.

A desire for plant-based foods also gained momentum as environment-focused groups touted the belief that animals are bad for the environment due to methane gas emissions and manure disposal, Dr. Acheson says. They praised plant-based foods for having less of a carbon footprint.

Another component of the eating healthier movement was an increased desire for organic foods, which involved raising foods without pesticides, chemicals, and drug residues, Dr. Acheson adds.

## LEADERS LOOK BACK



“It’s too soon to tell if FSMA has improved public health, but—without question—it’s fundamentally changed the way food safety is managed in the United States, and even globally.”

—Jennifer McEntire, PhD, Food Safety Strategy



“Temporary workforces [during COVID] created big challenges because they weren’t familiar with complex procedures and processes, required training, and were prone to making mistakes.”

—David Acheson, MD, CEO and president of The Acheson Group.



“Making the most of available data remains one of the most valuable resources the industry has at its disposal.”

—Gary Nowacki, CEO of TraceGrains

Interest in purchasing organic foods has steadily increased in the United States since 2012. The market reached an all-time high in 2022, at \$67.6 billion dollars for the year, according to the Organic Trade Association. Sales of organic produce totaled \$22 billion, accounting for 15% of all U.S. fruit and vegetable sales and making it the continued top seller of all organic categories.

### Whole Genome Sequencing

Also known as next generation sequencing or massive parallel sequencing, whole genome sequencing can be used to reveal an organism’s complete DNA. This makes it possible to better understand variations both within and between species and to differentiate between organisms with unmatched precision.

FDA is using this technology to perform foodborne pathogen identification during foodborne illness outbreaks to reduce illnesses and deaths, says Marc W. Allard, PhD, a research microbiologist in the division of microbiology at FDA. The agency coordinates efforts with public health officials both nationally and internationally to sequence pathogens collected from foodborne outbreaks, contaminated food products, and a variety of environmental sources that may be related to a contamination event’s root cause.

FDA scientists and the National Center for Biotechnology Information at the National Institutes of Health collaboratively developed the GenomeTrakr, the first integrated network of laboratories to use whole genome sequencing in tracking foodborne pathogens to improve outbreak response and effective monitoring of preventive controls. Now in its 11th year, the network comprises a federal, state, and academic collaboration of genomic laboratories that sequence and contribute to a publicly available global database containing the genetic makeup of more than one million foodborne disease-causing bacteria, says Eric W. Brown, PhD, director of the division of microbiology at FDA.

The GenomeTrakr network and database can be used to track down the sources of bacterial pathogen contamination of current



and future outbreaks, pinpoint the environmental conditions and root causes associated with contamination of high-risk agricultural and processed food products, and identify the underlying genes that drive pathogen survival, persistence, and adaptive change on farms and in food facilities, Dr. Allard adds.

The GenomeTrakr's functions also include driving development of new and rapid methods, such as a number of culture-independent microbiological tests that coalesce what was once expensive and time-consuming tests into a single genomic workflow, Dr. Brown says. These new data also help FDA support its many stakeholder functions, including risk assessment, compliance, guidance and preventive control development, and genomic epidemiological traceback of foodborne outbreaks.

Additionally, whole genome sequencing plays an important role in the New Era of Smarter Food Safety, which is intended to leverage technology and other tools and approaches to create a safer and more digital traceable food system.

### Global Impact on Supply Chain Issues

The COVID-19 pandemic, avian flu, and the war in Ukraine, have all affected the food supply chain in recent years.

The United States' processing capacity for livestock plummeted in early spring 2020 due to harvest facilities closing as a result of the coronavirus. Pork, beef, and poultry capacity dropped below 50%, and flocks of chickens and turkeys and barns full of pigs were being depopulated, says Mindy Brashears, PhD, associate vice president and director of the International Center for Food Industry Excellence at Texas Tech University in Lubbock, who was, at the time, USDA's undersecretary for Food Safety.

Nearing the end of April 2020, the U.S. faced a food security problem. Several elements contributed. First, some facilities didn't have enough healthy workers to operate plants. In other places, local health departments wouldn't allow facilities to stay open, Dr. Brashears says.

Additionally, Dr. Acheson adds that "temporary workforces created big challenges because they weren't familiar with complex procedures and processes, re-

quired training, and were prone to making mistakes."

CDC teams were sent out to facilities to evaluate plant operations and provide input on how to make facilities safer to prevent illnesses from spreading, Dr. Brashears says. The industry had already implemented strong programs, including social distancing, employee screening programs, and testing.

USDA's Food Safety and Inspection Service (FSIS) made labeling accommodations to shift stores of product destined for schools and restaurants to grocery stores. Many facilities closed for days—some for many weeks—until conditions were safe, or operated under reduced capacity, Dr. Brashears says. Some facilities were unable to process specialty cuts of meat or other products and only focused on key items.

Post-COVID, many production facility workers didn't return to their jobs and instead chose employment options with different working conditions. "The supply chain still hasn't recovered from this shift," Dr. Acheson says.

Meanwhile, highly pathogenic avian influenza (HPAI) has had a significant impact on the supply of eggs and poultry products. "The flu is cyclical; the last season was a bad one with a lot of birds being destroyed," Dr. Acheson says. "This has driven up the cost and availability of poultry and eggs. I think this outbreak will go away but likely return at some point in the future."

Although Ukraine is a big supplier of grains and other food commodity staples, as well as fertilizer, Dr. Acheson says the war's impacts haven't been felt significantly yet—at least not in North America.

### Traceability Efforts Continue

Traceability is a tool that's here to stay. FSMA included a requirement for FDA to build on existing recordkeeping requirements stemming from 2002's Public Health Security and Bioterrorism Preparedness and Response Act, specifying additional records associated with specific foods. The emergence of many "traceability solution providers" pushed industry to consider the need for interoperability between systems, based on standards, says Dr. McEntire.

As technology continues to evolve, companies increasingly consider how

(Continued from p. 31)

### 2020: New Era of Smarter Food Safety

FDA's New Era of Smarter Food Safety is ushered in under Frank Yiannas, MPH, who was FDA's deputy commissioner of foods policy and response at the time. The initiative addresses traceability, digital technologies, evolving food business models, and food safety culture.

### 2022: Passage of the Food Traceability Final Rule

FDA's requirements for additional traceability records for certain foods establishes traceability recordkeeping requirements, beyond those in existing regulations, for organizations that manufacture, process, pack, or hold foods included on the Food Traceability List. The compliance date is in January 2026.

traceability can help their bottom lines by building consumer trust, authenticating claims, reducing shrink, and improving efficiency, Dr. McEntire adds. With FDA's Food Traceability Final Rule passage in November 2022, regulatory compliance will be required for a subset of foods by 2026, but the ability to trace products can provide value for the breadth of the supply chain.

### Looking Ahead

The 2010s saw significant progress on the food safety front in the United States with the passing of FSMA and the New Era of Smarter Food Safety, but more needs to be done. "Consumers continue to wait for significant cultural change within the regulatory establishment and the food industry to ensure food safety," Baum says. "Here's hoping that, in the next 30 years, we're not still discussing what can't be done, but rather focusing on collaborative solutions to protect consumers—the people for whom the regulations were developed." ■

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# Safety & Sanitation

## Putting a Dust Hazard Analysis into Practice

The dust safety plan and dust collection system design

BY ALYSHA YINGER



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**Editor's note:** This is part two of a two-part series focused on dust hazard analysis. Part one, which appeared in the April/May issue, focused on the dust hazard analysis process. This article details how to put an analysis into practice at your food plant.

So, you've completed your dust hazard analysis (DHA). Now what? The DHA is just step one of your dust safety plan. Now it's time to put the DHA recommendations into practice. That includes identifying and mitigating potential hazards and designing a dust collection system that complies with National Fire Protection Association (NFPA) guidelines.

### Elements of a Dust Safety Plan

Creating or updating your dust safety plan will typically start with the DHA. A new DHA should be completed every five years or when new processes, system changes, materials, or environmental hazards are introduced. It will typically include:

- Material characterization results (from specific dust testing or, in some cases, based on industry-standard values for food dust explosibility);
- Process characterization;
- Identification of specific hazards;
- Evaluation of existing safeguards;
- Mitigation recommendations; and
- A process for documentation and verification of hazard reduction activities.

### Hazard Identification and Prioritization

The dust safety plan begins with understanding the specific hazards presented by your dust, your processes, and your environment. The DHA should identify areas where hazards exist that could lead to a dust cloud explosion, including nodes where both oxygen and dust are present, potential ignition sources, (including heat sources from processes as well as static build-up, friction, or sparks from mechanical systems), and areas where dust tends to form clouds (e.g., dump points, batch

mixers) and where dust clouds are enclosed (e.g., bins, silos, ductwork).

Hazard prioritization goes a step further. In this process, hazards are quantified and ranked using two metrics:

1. The likelihood that a combustion event could occur, given both the inherent hazards and the efficacy of any existing mitigations already in place; and
2. The potential severity of an explosion should one occur, given the characteristics of the dust (e.g., explosion indices), dust volume, physical facility layout, and the presence of other hazards, such as dust accumulation, that could fuel a dangerous secondary explosion.

One simple way to prioritize hazards is to rank each issue on a scale of one to four for both likelihood and severity. Multiplying likelihood by severity gives you a numeric value for each hazard, from 1 to 16, with 1 being the lowest risk and 16 being the highest (see figure 1, below).

Each hazard is then assigned an overall risk level, which can be used to priori-

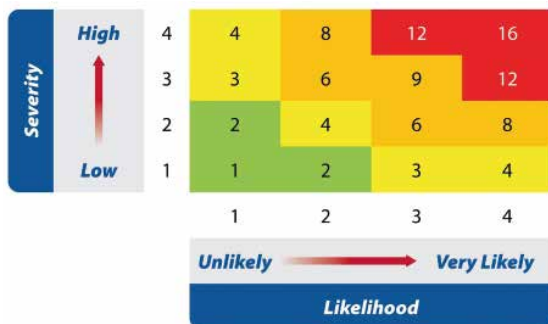


Figure 1. Example hazard ranking analysis.



Figure 2. Example risk level prioritization chart.

COURTESY OF ROBOVENT.

tize risk mitigation activities (see figure 2, p. 34). Hazards with the highest risk levels should be addressed first; however, keep in mind that any issue that puts the facility out of compliance with Occupational Safety and Health Administration (OSHA) regulations and NFPA guidelines must be addressed in a timely manner, even if the overall risk level is determined to be low or moderate.

### Making Risk Mitigation Decisions

Once you have risks prioritized, you need to start making mitigation decisions. There is no single solution when it comes to combustible dust hazard mitigation. The tools and strategies used will depend on many factors and may include:

- Material substitution (though this is not always an option when dealing with food ingredients;
- Changes to processes (e.g., removing or shielding an ignition source, changing the design of conveyance systems or dump points to reduce cloud formation, etc.);
- Administrative standards and changes to worker behavior (e.g., using an NFPA-compliant vacuum system instead of brooms for housekeeping, limiting the number of people who have access to high-hazard areas, and providing worker training and education); and
- Engineering controls, including dust collection.

The explosion pentagon is a good place to start when evaluating potential risks and making mitigation decisions (see figure 3, above). All five elements of the pentagon must be present for an explosion to occur: a combustible dust, dispersion in a cloud, enclosure of the cloud, oxygen, and a source of ignition. Eliminating one or more of these elements will prevent an explosion from taking place.

When making risk mitigation decisions, it is important to remember the hierarchy of controls, a framework used to prioritize safety measures in the workplace (see figure 4, above). According to the hierarchy, companies must first attempt to find solutions higher on the hierarchy, such as elimination of hazards, before resorting to solutions lower on the hierarchy, such as offering personal protection equipment (PPE). For example, eliminating an ignition source must be considered, where



Figure 3. The explosion pentagon.

possible, instead of simply telling people to avoid a hazardous area. By the same token, engineering controls—that is, engineering systems or physical changes to the work environments that minimize the risk of an explosion occurring or reduce the potential for damage should one occur—must be put into place wherever possible instead of asking people to change their behavior or wear PPE.

Engineering controls for combustible food dust can take many forms. For example, ventilation and/or dust collection systems, which prevent dust from accumulating in the ambient facility air and reduce dust build-up on surfaces and enclosures can be used to contain dust and prevent it from propagating through the facility. Enclosures must be paired with an effective dust collection system to prevent dust clouds from forming inside the enclosure and amplifying the risk of an explosion.

### Dust Collection System Design for Combustible Food Dust

A dust collection system is almost always part of a mitigation strategy for combustible food dust. Here are some general considerations in the design of a dust collection system for combustible food dust.

**Hood or enclosure design.** Dust collection for combustible food dust is usually source capture—that is, the system is designed to collect dust close to the source where it is generated. A source capture system prevents dust from escaping to other places in the facility and building up on surfaces. It also will keep food dust out of the breathing zone, which reduces health and safety concerns for workers. Some processes are fully enclosed, such as an enclosed conveyance system. Others may use overhead hoods or fume arms to capture dust as it is created. Hood design

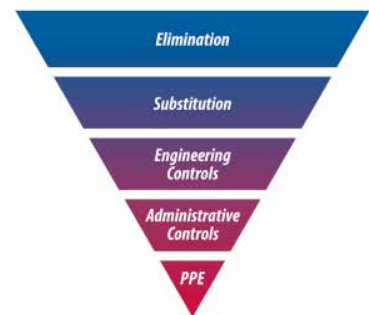


Figure 4. The hierarchy of controls.

will have a significant impact on the overall efficiency of the system. Some considerations in hood design for combustible food dust:

- The enclosure should have tight seals and joints to prevent dust from leaking out;
- The hood or enclosure must be constructed using appropriate materials, such as heavy-duty steel, to withstand an explosion; and
- Fully contained enclosures and ductwork should be equipped with explosion venting to safely release the pressure of a combustion event.

**Capture efficiency.** The dust collection system must be able to prevent dust from accumulating inside the enclosure and ductwork in concentrations that will allow an explosion to occur (minimum explosive concentration [MEC]). Dust collectors are rated by cubic feet per minute (CFM), or the volume of air they are able to move each minute. The dust collector must be sized appropriately for the volume of air it must move and the velocities that must be maintained for efficient capture of the dust. Reducing the volume of air that must be moved (for example, by using a smaller enclosure or minimizing the length of ductwork) will improve the efficiency of the system.

**Dust collector type and filter selection.** There are many different types of dust collectors to choose from. In the food industry, baghouse collectors and cartridge collectors are the most used. A cartridge dust collector is a good choice for most food processing applications. Cartridge collectors come in a wide range of sizes for applications ranging from single processes to entire facilities with multiple dust collection points. They also have

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higher efficiency and a smaller physical footprint per CFM than baghouse collectors. Finally, they offer many options in filter media selection, including filters for coarse/abrasive dust, ultrafine dust and powders, and sticky or hygroscopic dust. For combustible food dust, a static-free filter media may be advised to reduce the risk of static sparks generating an explosion inside the collector.

**Dust collector placement.** Placement of the dust collector is another important consideration when collecting combustible food dust. It is often advisable to place the dust collector outside or in a separate, explosion-proof area away from workers and equipment. Clear safety zones must be established around the collector. If the dust collector is placed inside, it must meet strict NFPA guidelines for explosion venting, isolation, and suppression (see below).

**Fire and explosion safety.** The dust collector and ductwork present one of the largest areas of risk for a food dust explosion. The dust collection system must be designed in accordance with NFPA guide-

lines to mitigate fire and explosion risks inside the system. Elements may include:

- A deflagration system (including explosion vents and isolation valves) to mitigate the damage of an explosion inside the collector;
- A fire suppression or extinguishing system;
- A damper system to cut off airflow if a fire is detected; and
- Control of potential ignition sources near the dust collector or ductwork intake.

**Operation and maintenance.** Dust collector operation and maintenance are also critical for dust collector safety. Necessary maintenance includes changing filters as they become loaded, emptying collection bins when they are full, cleaning the dust collector chamber and ductwork (if improper duct velocities) to prevent accumulation of dust and deposits inside the system, and inspecting and maintaining all electrical and mechanical components, including the motor and blower, to minimize the risk of friction or sparks inside the collector becoming an ignition risk.

**Verification, documentation, and monitoring.** All decisions for dust collection system design and other dust safety mitigations must be carefully documented. Documentation is used to confirm compliance with regulatory requirements, provide a road map for personnel who may not have been part of initial design decisions, and make it easier for engineers to adjust later. Verification and ongoing monitoring are also essential to ensure that mitigations, including dust collection, are having the intended impact.

A combustible dust plan for food processing facilities must continually evolve as processes, ingredients, equipment, and regulations change. A third-party engineering firm can interpret the results of the DHA, evaluate your current mitigation strategies, and help you design a dust control system that meets your needs and is fully compliant with OSHA regulations and NFPA guidelines. ■

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## The Age of HACCP: 1993-1999 (Continued from p. 25)

health surveillance systems targeting foodborne pathogens. The most significant systems were FoodNet and PulseNet, both established in 1996.

These developments married epidemiological principles to food safety and facilitated more rapid identification of multi-state foodborne disease outbreaks and greater appreciation for disease burden associated with pathogens historically associated with foodborne illness, Dr. Jaykus says. The systems also strengthened the relationships among the agencies relative to food safety.

In 1999, Paul Mead, MD, MPH, and his team at the CDC produced a pivotal paper suggesting that viruses were the leading cause of food-related disease (*Emerg Infect Dis.* 1999;5:607-625). This was followed by an updated paper by Elaine Scallan, PhD, and her CDC colleagues in 2011 that confirmed this finding (*Emerg Infect Disease.* 2011;17:7-15). “Previously, viruses were not recognized as important causes of foodborne disease,” Dr. Jaykus says. “Further, norovirus was the major culprit, a previously poorly characterized gastrointestinal virus.”

Few scientists in the food safety world even knew about these viruses before this time, let alone worked with them, Dr. Jaykus adds. “This shifted research and training priorities to include a

new classification of foodborne pathogens as the new millennium began.”

### Industry’s Actions

The 1990s closed with an escalating number of *Listeria* outbreaks that continued into the early 2000s. The meat industry attacked this pathogen head on, investigating a wide range of interventions in the hopes of discovering a process change that would finally defeat these dangerous bugs. Many were discarded as ineffective, impractical, or both. Others are still in use to this day. But, an important lesson emerged along the way: There was, and is, no single intervention, no “silver bullet” that eliminates all pathogens from any process. After many trials and errors, this industry determined that it took a series of hurdles, each reducing the bacterial load or risk of contamination, to be the most effective approach.

One of the most significant outcomes came when industry leaders and organizations such as the American Meat Institute met to declare food safety a noncompetitive issue: Research was shared and practical tools were developed for all to use. Hear their stories in our new “Leaders and Legends of Food Safety” video series, available at [foodqualityandsafety.com](http://foodqualityandsafety.com). ■





# Environmental Monitoring Programs

How to build a robust plan that is specific to your product and your facility

BY TREVOR CRAIG

**A**lmost every food manufacturer must manage a food safety program that includes an environmental monitoring program (EMP). Initially, it might sound straightforward—pick some testing sites, take some sponges/swabs, and run pathogen testing—but, as you build a program or start to analyze your data, you may realize that running an EMP is not as easy as it seems.

There is no one-size-fits-all approach to starting an EMP. Most regulation or auditing bodies are not going to give the best testing details on how much, how often, when, or sometimes even what to test for. Most of the time you are only required to have an EMP that matches your hazard risk. This vagueness is because there are thousands of food product types, and the ingredients you use and how you make the product can be different, even in similar products. On top of that, even if you make the exact same product using the

same ingredients, your people, facilities, equipment, and traffic patterns are different and can introduce different risks. Because there are so many moving parts to developing an EMP, it's difficult and risky for regulatory groups to provide a specific process without knowing your facility.

As a consultant, I find that, most of the time, companies struggle just to get started. My first piece of advice is to just dive in. An EMP isn't set in stone and, in fact, should grow and be flexible so you can adjust it as needed based on collected data. The main goal of any EMP is to search and destroy: Find the bacteria niches in your facility and address them. Getting into the details of how to do that and what practices are going to work best is where complication come in. In addition, running a hazard analysis can be complicated and time consuming.

Here are steps you can take to build an effective EMP from the ground up that's specific to your product and company.

## Determine Your Product Process

The first piece of information you need to figure out is what you do with your product after you make it. It's in your best interest to test all areas of contact, both food and non-food, so you have a better idea of the risk level and cleanliness of your facility. You must be careful because presumptive positive environmental monitoring results can indicate that a product could also be contaminated. Do you hold your product for a few days and have the time to wait for results from your EMP to come back? Or are your products made, packaged, and out the door in just a few hours?

If you're able to hold the product, then you can complete pathogen testing in the highest-risk, food contact sites. If something comes back positive for *Salmonella*, *Listeria*, or pathogenic *E. coli*, then you can catch the implicated product before it leaves the facility. However, if your product is out the door as fast as you can make it, then a presumptive positive sponge/swab on a contact surface can cause you to pull back the product or issue a recall, which is a can of worms you want to avoid.

## Zone Your Facility

Next, select where you're going to test, so you should define what the high-hygiene area is. For RTE products, this area starts where the raw product exits the cooking step as fully cooked, and extends to the point in the process where the product is fully enclosed in a sealed package. Everything prior to the cook step would be considered the raw area and the post cook hygiene area must be strictly off limits to personnel and equipment from the raw side. Personnel access to the high-hygiene area must be controlled and monitored to ensure the strict procedures for entering and leaving this area are followed.

Once the hygiene area is defined, you can determine the zones of your facility. The first zone is easy to identify—does it directly touch your product? Is it directly over exposed product after cooking or is it touched by hand-held utensils, or even the inside of the product packaging? If it's around these areas or closely adjacent to any zone one and could easily be touched

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and transferred to your zone one, it's going to likely fall into zone two.

If it's in your production/manufacturing high-hygiene area but not zone one or zone two, it's likely going to be zone three, which includes floors, walls, drains, and parts of equipment outside the scope of zone two in the hygiene zone. It can also include surfaces subject to backsplash from zone two.

Finally, if it's part of the facility accessible to RTE and raw personnel but not part of the production/manufacturing area, then it's probably going to fall into zone four. These include shared employee welfare areas, locker rooms, and common traffic routes. In some cases, this can also include office areas.

It's not always that easy, however, to determine hygiene areas and sampling zones when looking at a facility. You must be aware of the entire area before and after the lethality step, or even after your product is sealed in its package. Zone one can be difficult to test if your machinery is complicated or not open to the environment. Some equipment, tools, and personnel can move between areas causing added risks. Don't stress; not everything is set in stone, so depending on results or observations you might start with a site being classified as a zone three, but as you learn more you can easily move it to a zone two. You should use your data to change and improve your EMP. Spend time observing the process with a team to look for these changes.

Next, companies must determine what to test for. Usually, this is *Listeria* but can include other pathogens such as *Salmonella*, pathogenic *E. coli*, or indicator organisms such as aerobic plate count, *Enterobacteriaceae*, coliform, or generic *E. coli*. Sometimes you can even look for contaminants of high concern such as yeast and mold or *S. aureus*.

You should monitor the organisms that are high risk for the environment and the products that you make. For example, if your product contains meat or dairy, it doesn't make sense to only monitor for *Listeria*, since *Salmonella* and *E. coli* could also be concerns for your product. If you can't monitor for pathogens for zone one you can use indicator organisms mentioned above. This won't directly

implicate your product but can give you an idea of how high the bacteria counts are and, thus, the risk for contamination. For example, just because you have a high *Enterobacteriaceae* count does not mean you have a *Salmonella* contamination, but it can give you a good indication that the environment can support the

An EMP isn't set in stone and should, in fact, grow and be flexible so you can adjust it as needed based on collected data.

growth of *Salmonella*, and because you have not killed or removed the *Enterobacteriaceae*, there is a high contamination risk.

#### How Often to Test

Now that you have worked through the questions of where to test and what to test for, you'll need to determine when and how often to test.

These changes are based on the secondary goals of your EMP. Are you aiming to verify effective cleaning and sanitation? Or, are you looking to see how the day is progressing and how your facility is staying clean? If you have raw product/production that is naturally going to have bacteria and be cooked at home, your EMP is most likely going to be focused on making sure your sanitation process is effective at killing harmful bacteria spread during production. In this case, you're going to want to take samples after cleaning and once sanitizer is dried, or before production to ensure surfaces are starting off in the best condition.

If your product is ready to eat and includes a bacteria-killing step during production, then your EMP should focus on ensuring that your production is not getting contaminated during day-to-day processing. When it comes to determining the best times to test, it is best to take samples during the production day, approximately two hours after the start of operations.

How frequently you carry out this testing is based on your product's risk rate. If

you have a high-risk product and are making a lot of it using very fast processing, you'll want to monitor it more frequently. Some clients take samples every day, every week, once a month, or even once a quarter. I do not ever recommend doing less than that. It is always easier to test more frequently and then dial back. Each time you monitor, you cover the time between sampling. If you wait too long and have a problem, you potentially run into a gap where you're not sure how clean your conditions were.

If you produce an RTE product and you test zone one samples, your plan must define what happens when a positive result is reported, or a quantitative indicator organism test is out of spec. The investigative sampling procedure must be outlined, in addition to the conditions that must be met to return to routine sampling.

If you test more frequently and discover you don't have an issue, however, it's much easier to justify to your team and your auditor why you should test less frequently. You do not want to run into a situation where you go three to four months with no results and then suddenly find a facility with several *Salmonella* or *Listeria* positives and have no idea how long it's been a problem.

Finally, don't forget other items you might have to monitor in your facility, such as water, wastewater, and passive and compressed air. You typically don't need to monitor these as frequently, but they can contribute to contamination in your products.

#### Finding the Right Partner

These are the basic elements that I use to help a facility start its program. Break it down, follow these steps, and document what your decisions are. From there, you can pick an accredited laboratory partner and get the supplies to start your testing.

Your EMP doesn't have to be perfect, and getting one started is the first step in making it better. Safe and high quality products are critical to a company's growth and to protecting public health. If you need more help or just expert advice, there are professionals available who focus on partnering with companies to set up EMPs. ■

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# NEW PRODUCTS



## Paper Band for Food Bundles

Mondi, a sustainable packaging and paper manufacturer, has collaborated with Swiss converter ATS-Tanner to create a paper band that can hold individually labelled products or bundles, reducing plastic use. ATS-Tanner uses Mondi's kraft paper Advantage MF Spring-Pack and converts it into a band by adding a barrier on both sides of the paper. The paper is then sealed using ultrasound, eradicating the need for any adhesive. This ensures that the products are secured with minimum packaging, reducing waste and delivering a cost-efficient solution. The coated band are marketed under the name TruePaper. The band can hold weights of up to 20 kg, making the band perfect for fruit and vegetable bundles as well as multipacks of bottles and other consumer goods. The paper used for the band is made from renewable, responsibly sourced, and certified materials. **Mondi, [mondigroup.com](http://mondigroup.com); ATS-Tanner, [ats-tanner.com](http://ats-tanner.com)**

## Continuous Lab-Scale Evaporator

The Rotothem Mini is designed for continuous evaporation and liquid-to-powder drying of heat-sensitive materials. Unlike vertical evaporators, the evaporator has a horizontal orientation, which provides researchers with complete control over residence time. This allows for liquid-to-powder drying in a single pass and improved product yield. The instrument features a high-speed rotor that uses centrifugal force to create an agitated thin-film. It is capable of processing viscous or foaming liquids and slurries. In addition, the stainless steel fixed-clearance



rotor provides for easier cleaning. It also provides researchers with the ability to develop continuous processes at lab-scale that can be scaled-up for production. **Artisan Industries, [artisanind.com](http://artisanind.com).**

## Glass Washer

Auto-Chlor System has introduced the UCR Glass Washer, a fast, water-efficient, and energy-efficient machine that accommodates all glass sizes and shapes. The washer is ideal for high-volume glass applications in hotels, pubs, bars, cocktail lounges, wineries, and breweries. The complete wash cycle is 60 seconds. A three-compartment, rotating rack allows washing to occur in one section while soiled items are loaded into a second section, and cleaned items are ready for removal from the third section. The 11.5-inch cavity height accepts full size mugs, stemware, pitchers, carafes, and more. The compact 38-inch overall height, with an ergonomically positioned load area, is designed for high volume bar-glass washing applications. A rotating sprayer delivers powerful wash and rinse pressure for consistently clean results. The machine functions on low voltage electrical service.

**Auto-Chlor System, [autochlor.com](http://autochlor.com).**



## Sonic Cleaner

Diverclean Sonic is a pre-cleaning technology that tackles highly soiled areas, functioning to eliminate the pre-rinse step and reducing the cleaning window by an average of 35%. It also cuts down on water consumption, wastewater, and energy use, enhancing a processor's sustainability footprint and helping gain back production time while simultaneously reducing costs and meeting a higher standard of hygiene. **Diversey, [diversy.com](http://diversy.com).**

# SCIENTIFIC FINDINGS

For access to the complete journal articles mentioned below, go to “Food Science Research” in the June/July 2023 issue at [foodqualityandsafety.com](http://foodqualityandsafety.com), or type the headline of the article into the website’s search box.



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## Characteristics of Low-Fat Whipped Cream Containing Fat Replacers

Fat replacers are used to alleviate functional and sensory deficits in whipped cream caused by fat reduction. Of all known fat replacers, proteins have shown the most effective ability to replace fat due to their nutritional attributes and functional properties. Recently, several protein-based fat replacers were investigated, but among all of them, the use of milk proteins and modified proteins, especially

their complex with polysaccharides presented promising results. Therefore, due to the growing interest in this field, this review focuses on the mechanism for fat replacement with proteins and their complexes and the characteristics of low-fat whipped cream affected by these proteins. The authors also considered the challenges and perspectives for the future. *International Journal of Dairy Technology*. 2023;76:276-290.

## 3D Printed Chocolate

The use of 3D printing (3DP) for food applications is gaining attention both as a research topic and for industrial applications. Chocolate is one of the most common food commodities used for 3DP, owing to its melt extrusion capability and popularity in the high-end food industry. However, chocolate remains a difficult substrate to work with due to its complex composition as well as rheological properties. The quality of cocoa beans and the processing conditions of chocolate manufacture influence the quality of 3DP. This review briefly covers areas such as the processing of chocolate, types of 3D printing of chocolate, rheology of chocolate inks, textural attributes, and sensory evaluation of 3D chocolate products. *International Journal of Food Science and Technology*. 2023;2811-2828.



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## Minimizing Ethyl Carbamate in Wine

Ethyl carbamate (EC) is a probable carcinogenic compound commonly found in fermented foods and alcoholic beverages and has been classified as a category 2A carcinogen by the International Agency for Research on Cancer. Alcoholic beverages are one of the main sources of EC intake by humans; therefore, many countries have introduced a standard EC limit in alcoholic beverages. Different survey results showed that the detection rate of EC in wine was almost 100%, while the maximum content was as high as 100 µg/L, necessitating EC content regulation in wine. The existing methods for controlling the EC level in wine primarily include optimizing raw fermentation materials and processes, using genet-

ically engineered strains, and enzymatic. This review focused on introducing and comparing the advantages, disadvantages, and applicability of different methods for controlling EC, and proposes two possible new techniques: changing the fermentation strain and exogenously adding phenolic compounds. In the future, it is hoped that the feasibility of this prospect will be verified by pilot-scale or large-scale application to provide new insight into the regulation of EC during wine production. The formation mechanism and influencing factors of EC in wine are also introduced and the analytical methods of EC are summarized. *Comprehensive Reviews in Food Science and Food Safety*. 2023;22:1495-1516.



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### Removal of Residues and Toxic Elements in Rice



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This study examines the effects of various treatments on removing pesticide residues and toxic elements in rice. In parallel, nu-

tritional elements, magnesium (Mg), potassium (K), and phosphorous (P), were measured to investigate the effect of these washing treatments on the nutritional value of rice. A naturally contaminated rice sample containing five widespread used pesticides (azoxystrobin, buprofezin, carbendazim, and propiconazole) and toxic elements, arsenic (As), cadmium (Cd), and essential elements, was washed using several washing agents, including boiling water, 5% sodium bicarbonate, 5% acetic acid, 5% citric acid, and 5% sodium chloride. The washing method was chosen based on its availability and widespread usage; soaking for 10 minutes was assumed to be reasonable.

The results showed that using 5% acetic acid significantly reduced azoxystrobin by 63%, buprofezin by 70%, carbendazim by 75%, and propiconazole by 61%. However, As and Cd were significantly reduced in sodium chloride by 57% and 32%, respectively. Furthermore, a significant reduction in essential nutrient elements was found in Mg (42%), K (37%), and P (23%) when rice was treated with 5% citric acid. Overall, washing agents reduced analytes in the following manners pesticides, toxic elements, and essential elements when using acetic acid, sodium chloride, and citric acid separately. *Journal of Food Science*. 2023;88:2168-2177.

### Improving Poultry Health, Food Safety, and Food Security

Poultry is thriving across the globe. Chicken meat is the most preferred poultry worldwide, and its popularity is increasing; however, poultry also threatens human hygiene, especially as a fomite of infectious diseases caused by the major foodborne pathogens (*Campylobacter*, *Salmonella*, and *Listeria*). Preventing pathogenic bacterial biofilm is crucial in the chicken industry due to increasing food safety hazards caused by recurring contamination and the rapid degradation of meat, as well as the increased resistance of bacteria to cleaning and disinfection procedures commonly used in chicken processing plants. To address this, various innovative and promising strategies to combat bacterial resistance and biofilm are emerging to improve food safety and quality and extend shelf-life. In particular, natural compounds

are attractive due to their potential antimicrobial activities. Natural compounds can also boost the immune system and improve poultry health and performance. In addition to phytochemicals, bacteriophages, nanoparticles, coatings, enzymes, and probiotics represent unique and environmentally friendly strategies in the poultry processing industry to prevent foodborne pathogens from reaching the consumer. Lactoferrin, bacteriocin, antimicrobial peptides, cell-free supernatants, and biosurfactants are also of considerable interest for their prospective application as natural antimicrobials for improving the safety of raw poultry meat. This review aims to describe the feasibility of these proposed strategies and provide an overview of recent published evidences to control microorganisms in the poultry industry,



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considering the human health, food safety, and economic aspects of poultry production. *Comprehensive Reviews in Food Science and Food Safety*. 2023;22:1555-1596.

### New Coffee Brewing Control Charts

The classic Coffee Brewing Control Chart (BCC) was originally developed in the 1950s. It relates coffee quality to brew strength and extraction yield, and it is still widely used today by coffee industry professionals around the world to provide guidance on the brewing of coffee. Despite its popularity, recent experimental studies have revealed that sensory attributes and consumer preferences actually follow much more complicated trends than those indicated by the classic BCC. Here, the authors present a methodology to synthesize the results of these recent studies on drip-brewed coffee to generate new versions of the BCC: a new Sensory BCC that displays



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a broad array of statistically significant sensory attributes across typical total dissolved solids and percent extraction ranges, a new Consumer BCC that highlights the existence of two preference clusters with different likes and dislikes across those ranges, a new Sensory and Consumer BCC that combines both sensory descriptive and consumer preferences on the same chart, and a more streamlined BCC that omits consumer preferences and focuses on the overarching sensory descriptive trends. The new BCCs provide more accurate insight on how best to brew coffee to achieve desired sensory profiles. *Journal of Food Science*. 2023;88:2168-2177.

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## Events

### JULY 2023

16-19

#### IFT First Annual Event and Expo

Chicago, Ill.

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

16-19

#### International Association for Food Protection

Toronto, ON, Canada

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

### SEPTEMBER 2023

11-13

#### Pack Expo Las Vegas

Las Vegas, Nevada

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

### OCTOBER 2023

16-18

#### Cannabis Quality Conference

Parsippany, N.J.

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

16-18

#### Food Safety Consortium Conference & Expo

Parsippany, N.J.

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

### MARCH 2024

14-15

#### Future Food Tech

San Francisco, Calif.

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

12-16

#### National Products Expo West

Anaheim, Calif.

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

### MAY 2024

6-9

#### Food Safety Summit

Rosemont, Ill.

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

### JULY 2024

14-17

#### IFT First Annual Event and Expo

Chicago, Ill.

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

14-17

#### International Association for Food Protection

Long Beach, Calif.

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

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