

# Food Quality & Safety

FARM TO FORK SAFETY

## Regulating Food Safety in 2019

Uncovering  
new efforts to  
improve food  
quality standards  
and prevent  
future outbreaks



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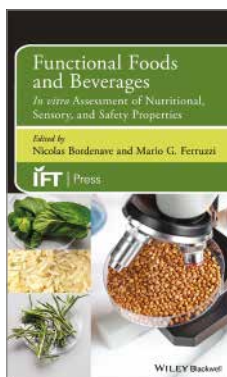
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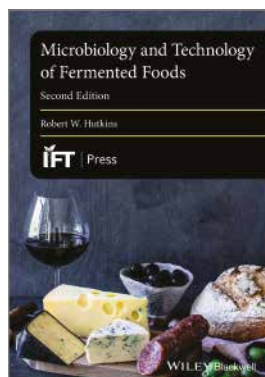
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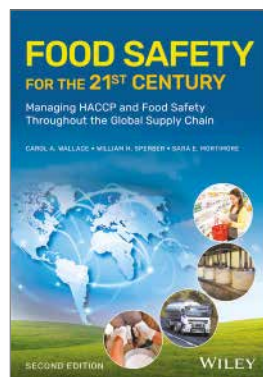
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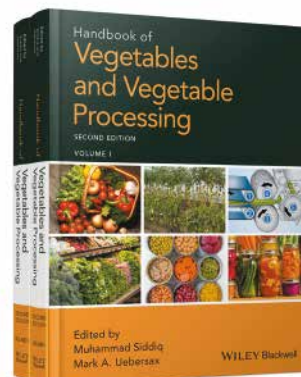
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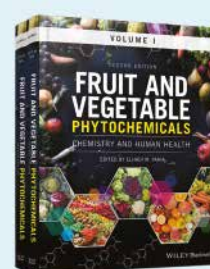
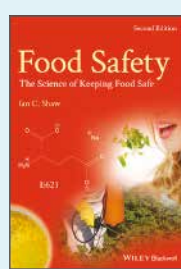
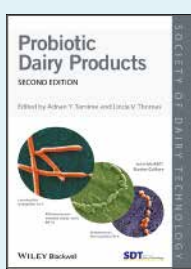
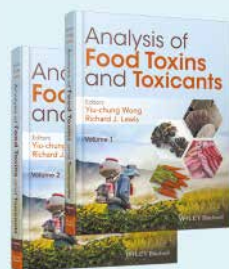
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BY BOB SCHUMANN
- Going Mobile for Internet of Things and Traceability  
BY CORY HOVANETZ
- Breastfeeding vs. Formula Feeding: Debunking Myths  
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# Addressing **EMERGING ISSUES**

throughout the **SUPPLY CHAIN** — and the **FOOD SAFETY COMMUNITY**



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## **KEYNOTE PRESENTATION**



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Co-chair of the Stop Foodborne Illness Board  
Former Deputy Commissioner for Foods and Veterinary Medicine, FDA

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# From The Editors

**T**his column was inspired by the late, great Madeline Kahn and her role as cabaret singer Lili Von Shtupp in Mel Brooks' comedy classic "Blazing Saddles." Lili was tired of men, whereas I am tired of people trying to frighten me about non-existent dangers in my food and in the environment. One surfs the internet and runs into pieces about "Top 10 Most Dangerous Fruits," or "15 Processed Foods to Avoid," or "Chemicals that Cause Cancer." Almost everything is based on bad or non-existent science, but people can write what they want thanks to freedom of speech.



As a resident of California, I am also constantly exposed to Proposition 65 warnings. Signs at hardware stores read, "This store sells products that contain chemicals deemed to be carcinogenic under Proposition 65." The same signs appear in the coffee shops, gas stations, car repair shops, and supermarkets.

We are deluged by these warnings—so much so that I wonder whether people are simply tuning things out.

Is there an answer? Well, maybe. Websites could be more diligent when it comes to reviewing the "science" that they publish, but that is a stretch.

Our best answer might be federal legislation that makes food labeling and other product claims a federal prerogative. This could eliminate future Proposition 65s and prevent states from enacting labeling laws that would affect the whole country; an example would be GMO labeling. But that is beyond me.

Unfortunately, food fadism and fearmongering are not new. Perhaps the solution is the one proposed by San Francisco Chronicle columnist Art Hoppe in his April 1989 piece entitled "Safe at Last." In the column, he tells the story of an overly cautious man named Harold who gave up every food and product that was tested and deemed hazardous to his health. It wasn't until Harold was reduced to a "safe" diet of organic rutabagas, alfalfa sprouts, and spring water that his wife pointed out that every product that is tested seems to be hazardous—so it stands to reason that *all* products will turn out to be dangerous as soon as they are tested. Seeing no choice:

*He [Harold] dug an organic hole in his backyard, placed therein an organic pine box and climbed inside. "At last," he said, as he pulled the lid down over him, "I shall be safe."*

(Read Art's column in its entirety at <https://bit.ly/2TEqEx>.)

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# NEWS & NOTES



## FDA Reports on Avocado and Hot Pepper Sampling

FDA releases two reports on its sampling of whole [fresh avocados](#) and [hot peppers](#) to determine the frequently of harmful bacteria. For the hot pepper sampling, FDA analyzed domestic and imported hot pepper samples for *Salmonella*, *E. coli* O157:H7, and other types of STEC. Of the 1,615 samples tested, 46 were positive for *Salmonella* and one was positive for STEC, but further testing revealed that the STEC strain could not cause severe illness. For the whole fresh avocado sampling, FDA analyzed 1,615 domestic and imported avocado samples for *Salmonella* and *Listeria monocytogenes*. Of the 1,615 samples, 12 tested positive for *Salmonella*. For the *Listeria* testing, the agency primarily tested the pulp of the avocado samples, and some samples of the fruit's skin. Of the 1,254 avocado pulp samples, three were positive for *Listeria*. Of the 361 avocado skin samples, 64 were positive for *Listeria*. When FDA found positive samples in domestic product, it worked with the responsible firms to conduct recalls and followed up with inspections of growers and packinghouses to ensure they were following good agricultural and manufacturing practices. When FDA found positive samples in imported product, the agency refused entry to all product in lots associated with the positive(s), and placed the firms on import alert to stop additional product from entering the U.S.

## Compliance Date for Food Labeling Rule

[FDA recently announced](#) that Jan. 1, 2022, will be the uniform compliance date for final food labeling regulations that are issued in calendar years 2019 and 2020. All food products subject to the Jan. 1, 2022, uniform compliance date must abide by the appropriate labeling regulations when initially introduced into interstate commerce on or after Jan. 1, 2022. This doesn't change existing requirements for compliance dates contained in final rules published before Jan. 1, 2019.

## Global Food Safety Issues Increasing

Through HorizonScan, FoodChain ID shares its third quarter findings, noting an increase in food integrity issues in key categories including poultry, seafood, vegetables, and nuts. Poultry and poultry products saw an increase of issues by 14.3% over last quarter, following a decline in Q1, which followed a record number of problems in 2017. These issues stemmed primarily from *Salmonella* contamination in chicken meat from Brazil. Seafood issues continue to rise, up by 23.1% due to issues such as mercury, altered organoleptics or histamines in fish, and veterinary drugs in crustaceans. There were also issues with *Listeria*, *E. coli*, and *Salmonella* in smoked/dried fish and clams. Other issues include pesticides found in peppers, peas (with pods), strawberries, and goji berries; and aflatoxins in almonds, pistachios, hazelnuts, Brazil, and cashew nuts. On a positive note, milk and dairy product hazard reports are down 4.7%, and meat and meat product issues are down 14.1% after a Q2 increase of 9.9%.



## U.S. Farm Bill Opens Door on Hemp

[As reported by Reuters](#), FDA said on Dec. 20 it will consider creating new policy regarding the marketing and sale of cannabis after President Donald Trump signed the Farm Bill, which legalized commercial production of hemp in the U.S. The FDA said in a statement that it hopes to make more efficient "pathways" for companies to introduce and market cannabis and cannabis-derived products, including cannabidiol, into interstate commerce. Hemp is a type of cannabis plant with no or extremely low concentrations of the psychoactive compound known as THC, the ingredient in marijuana associated with "high" feelings. The Farm Bill removes hemp from the Controlled Substances Act, allowing for its commercial production as long as the plants contain no more than 0.3 percent THC.

## Business Briefs

**ReposiTrak** creates a Customer Advisory Board to provide the company with insights into challenges and opportunities facing the retail industry and to better align platform development with customer needs.

**Kerry** signs a license agreement with **Renaissance BioScience** to supply Renaissance's Acryleast, a non-GMO acrylamide-reducing yeast enzyme, to food and beverage manufacturers.

**Bühler** creates a Consumer Foods segment by combining the current chocolate, nuts, bakery, and coffee business with the Haas business.

**Food Safety Net Services** opens its latest analytical laboratory for the food and consumables industry in Greeley, Colo.

**Bright Light Agribusiness** selects **TOMRA Food** as its partner for an end-to-end almond sorting solution for its new processing facility in Hattah/Victoria, Australia.

**Cloverleaf Cold Storage** enters into an agreement to merge with **Zero Mountain**, a cold storage warehousing and transportation company serving customers in Arkansas.

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# Market Initiatives

SEAFOOD



## Go Fish!

Seafood stakeholders are continually casting out advances in both safety and product development

BY LINDA L. LEAKE, MS

“In cooperation with the Association of Food and Drug Officials, the Seafood HACCP Alliance has developed a uniform and cost-effective training program for importers, processors, and distributors of fish and fishery products,” Dr. Otwell notes.

Courses have been developed for training in basic HACCP programs and the related Sanitation Control Procedures. Train-the-trainer courses are also offered. “The audience for these programs is the seafood processing and importing industry, regulatory officials, and extension agents based in the U.S.,” Dr. Otwell relates.

### Shrimp School

In 2000, Dr. Otwell initiated an annual Shrimp School based at the University of Florida that has recently been adopted under the leadership of the National Fisheries Institute (NFI). The first NFI edition was held in Manteo, N.C., in November 2018 and, based on the success of this event, a follow-up session is scheduled for April 2019 in the same location.

“Some 50,000 seafood professionals from every shrimp producing nation have attended the schools to date,” Dr. Otwell notes. “We cover how to monitor for bacteria, sensory evaluation, temperature control, as well as product quality, safety, and integrity.”

### Public Health Training

Barry Nash, MS, North Carolina Sea Grant’s (NCSG) seafood technology and marketing specialist, and Jeff French, a regional environmental health specialist with the North Carolina Division of Marine Fisheries (NCDMF), focus on training local health department inspectors and others regarding seafood safety.

“The NCSG and NCDMF developed the North Carolina Seafood Quality and Safety Workshop to focus on seafood safety and handling concerns in restaurants and re-

**W**hen it comes to reeling in seafood news, the catch of the day is that the U.S. industry is strong.

It’s no fish tale that fishing and seafood consumption in the U.S. increased in 2017, with landings and value of domestic fisheries continuing a strong, positive trend, according to the National Oceanic and Atmospheric Administration (NOAA). Across the nation, fishermen landed 9.9 billion pounds of fish and shellfish in 2017, while the U.S. imported 5.9 billion pounds of seafood, NOAA notes in its annual Fisheries of the United States report released Dec. 13, 2018. The estimated U.S. per capita consumption of fish and shellfish was 16.0 pounds in 2017.

Overall, NOAA’s report says that the highest-value U.S. commercial species in 2017 were salmon (\$688 million), crabs (\$610 million), lobsters (\$594 million), shrimp (\$531 million), scallops (\$512 million), and Alaska pollock (\$413 million). By volume, the nation’s largest commercial fishery remains Alaska pollock, which had near-record landings of 3.4 billion pounds.

NOAA notes that in 2016, estimated freshwater plus marine U.S. aquaculture production was 633.5 million pounds, netting a value of \$1.45 billion. Atlantic salmon was the leading species for marine

finfish aquaculture, with 35.7 million pounds produced. Atlantic salmon produced was valued at \$67.7 million. Oysters had the highest volume for marine shellfish production, 36.6 million pounds.

### HACCP Training

Hazard Analysis and Critical Control Points (HACCP) training is strong in the seafood industry, says Steve Otwell, PhD, seafood specialist emeritus with the University of Florida. Through the Florida Sea Grant Seafood HACCP program, Dr. Otwell serves as coordinator of the National Seafood HACCP Alliance for Training and Education.

“The alliance provides science-based information about aquatic food product safety and quality through research, publications, and community outreach programs,” Dr. Otwell explains. “Through its participation in the Seafood HACCP Alliance, Florida Sea Grant provides curriculum and essential training materials that enable seafood processors and importers to comply with federal food safety regulations, including the Food Safety Modernization Act.”

Since 1995, the Seafood HACCP Alliance has trained over 90 percent of the nation’s processors in food safety and compliance techniques.

tail outlets, which the federal rule doesn't typically cover," Nash says.

This annual two-day training program is jointly organized by NCSG, NCDMF, and the North Carolina Environmental Health State of Practice Committee, French relates. "The target audiences are county-based environmental health specialists who regulate restaurants and other retail food establishments and seafood businesses, as well as the general public," he says.

According to Nash and French, topics presented include harvest methods, proper receiving and handling of seafood products, seafood-borne illnesses, economic fraud, and wholesale and retail HACCP issues. Speakers are federal, state, and local experts in seafood safety and commerce.

"This training program is important because new innovations in prepared seafood meals are starting to come from restaurant chefs and community-supported fisheries retailers who are not always familiar with the safety rules that govern the production and distribution of packaged-food products," Nash emphasizes. "This course provides an overview of the vulnerabilities and control measures that prevent, eliminate, or minimize safety issues from dock to dish."

### Best Aquaculture Practices

The Global Aquaculture Alliance (GAA), Portsmouth, N.H., offers Best Aquaculture Practices (BAP) certification to ensure that seafood products come from facilities that are managed in an environmentally, socially, and economically responsible manner, according to Steve Hedlund, GAA's communications manager.

"Established in 2002, BAP is the world's most comprehensive third-party aquaculture certification program," Hedlund relates. "It's also the world's only third-party certification program encompassing the entire aquaculture production chain. We oversee the standards development process and certification process for hatcheries, farms, feed mills, and processing plants."

Hedlund explains that these standards are audited for GAA by third-party certification bodies, of which there are six currently. "We train their auditors regularly to ensure every audit is fair, objective, and traceable," he says. "Our standards are scientific, rigorous, and always evol-

ing to meet challenges in aquaculture."

As of the end of 2018, some 2,200 facilities in 35 countries on six continents are expected to be certified against the BAP program, Hedlund reports. "Our standards cover virtually 100 percent of the finfish, crustacean, and mollusk species produced in aquaculture settings around the globe," he elaborates. "While there are other organizations that offer aquaculture auditing services, BAP is the most comprehensive and is the only one that covers food safety."

Hedlund clarifies that BAP addresses food safety for aquaculture facilities—the process, not the food. "The ultimate goal with the BAP program is that the fish are born in a BAP-certified hatchery, raised on a BAP-certified farm, fed feed from a BAP-certified mill, and processed in a BAP-certified plant," he relates.

### Resource Utilization: Gone to the Dogs

There's definitely something fishy about the new product in development for four-legged consumers at the Kodiak Seafood and Marine Science Center, a component of the University of Alaska Fairbanks (UAF) College of Fisheries and Ocean Sciences. "We are making high-end dog treats from pollock skins," says Chris Sannito, MS, an Alaska Sea Grant seafood technology specialist with this center, located on Kodiak Island.

"Currently, with pollock fillet production, only about 25 percent of the fish is recovered for consumption after harvest," Sannito notes. "Millions of pounds of product are either discharged as waste or processed for fish meal. But pollock is a valuable resource in our state, and pet treats can be a much higher-value commodity than fish meal, so our goal is to increase pollock's utilization by adding further value to this fish."

After some experimentation, Sannito determined that extrusion was the most viable manufacturing method for producing pollock pet treats. "At first, we tried a forced air drying oven, but found this would be cost prohibitive due to the amount of labor required to prepare the material for drying," he explains. "Extru-



sion offers the major benefits of labor efficiency, improved product recovery, and precise control of temperature, shape, texture, moisture, and color."

These extrusion determinations came

about in July 2016, when Sannito shipped 500 pounds of frozen fish skins via FedEx to the Clextral pilot plant in Tampa, Fla.

"We ran the skins through an extruder and it transformed them under high pressure and temperature, turning the collagen in the skin into gummy bear texture," Sannito says. "We added a few additional ingredients to achieve the desired consistency and bind up the moisture."

Sannito opted for turning the pollock skins into a green rope (similar to licorice in appearance) and then cutting it into bite-sized pieces. While experimenting with natural and artificial red and blue food colors during his day at the pilot plant, he decided the natural Army green was the best.

"The natural green color seemed healthier and we wanted clean labels showcasing a wholesome product," Sannito explains. "Our ultimate goal is to produce a high-quality product that is safe for pets to eat, shelf stable, and enticing for humans to purchase."

In May 2017, Sannito and Quentin Fong, PhD, Alaska Sea Grant's seafood marketing specialist, received the 2017 Invent Alaska award for "innovation in research leading to commercialization" from the UAF Fairbanks Office of Intellectual Property and Commercialization.

"In 2018, a new funding opportunity came through with the UAF Center Ice Seed Fund," Sannito says. "This award is making a seed fund of \$24,800 available to move the pollock pet treats forward from the experimental stage to the commercial market."

To that end, Sannito and his longtime friend and business collaborator, Jerry Pupillo, MS, a marketing consultant based in Hawaii, are currently pursuing industry partners to develop the pollock co-product for wholesale and retail sales.

According to Sannito, some pet food companies already make pet treats with fish components. "While some pet treat

*(Continued on p. 42)*

# Legal Update



## To BE or Not To BE

### USDA releases final National Bioengineered Food Disclosure Rule

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

In December 2018, the Agricultural Marketing Service (AMS) published the final National Bioengineered Food Disclosure Standard (Final Rule). Although mostly straightforward, the rule does contain some nuance and complexity, which regulated entities should become familiar with before the Final Rule takes effect.

In short, the Final Rule requires food manufacturers, importers, and retailers who package and label food for retail sale or sell bulk food items (regulated entities) to disclose the presence of bioengineered (BE) ingredients in their products. Importers and domestic entities are subject to the same disclosure and compliance requirements.

The Final Rule has been met with mixed reviews. By and large, industry

advocates have responded favorably to it. The Food Marketing Institute, for instance, lauded the Final Rule as a consistent and transparent way to provide important information to consumers regarding products containing BE ingredients.

The Final Rule is not without critics, however. They charge that the rule is deeply flawed, lacks transparency, and will likely further confuse consumers. The Organic Trade Association issued a statement expressing its deep disappointment with the new rule. The Center for Science in the Public Interest expressed concern about the potential for consumer confusion.

More broadly, critics are especially unhappy with the lack of reference to genetically modified organisms (GMO) and genetic engineering in the disclosure requirements. They argue that the term

“bioengineered” is misleading. AMS, ostensibly in response to critics, wrote that it had considered a variety of terms, “but ultimately determined that bioengineering and bioengineered food accurately reflected the scope of disclosure and the products and potential technology at issue.” Moreover, AMS was concerned that using terms such as “genetic engineering” or “genetically modified organisms” would conflict with preemption provisions.

Like almost any regulations that govern highly interpretive and controversial subject matters, it is nearly impossible to achieve consensus agreement. As for the final BE Food Disclosure Rule, there are compelling arguments on both sides. It remains to be seen whether future changes will be warranted, or what types of amendments may eventually be enacted. For now, and for better or worse, we have a Final Rule.

### What Is Bioengineered Food?

Predictably, given the controversy surrounding bioengineering, much debate has centered around how to define what is (or is not) a BE food. The Final Rule adopts the statutory definition of “bioengineered food” as codified in the Amended Agricultural Marketing Act of 1946. Thus, BE foods are those foods containing genetic material that has been modified through in vitro recombinant DNA techniques, and for which the modification could not otherwise be obtained naturally or through conventional breeding. It should be noted that foods for which the presence of modified genetic material is due to incidental additives are not considered BE.

Even within the relatively technical definition adopted in the Final Rule, significant points of contention remain. For instance, there are two countervailing viewpoints regarding whether highly refined foods and ingredients should be exempted from BE disclosure requirements. One view, favored by many in the food industry, holds that highly refined products



should be exempt because the definition expressly requires the presence of “genetic material,” and genetic material is removed from highly refined foods in the course of the refinement process.

Another view, counter to the first, is that the definition of “bioengineering” ought to include highly refined products because highly refined products that are derived from genetically modified foods contain modified genetic material prior to processing and may still contain modified genetic material—albeit at undetectable levels—after processing.

After thorough deliberation (the rule’s draft documents included significant written discussion on this topic), AMS has elected to adopt the first view. Though we understand and acknowledge both positions, we believe AMS made the right choice. Just from a practical standpoint, it would be virtually impossible to determine whether a product containing no detectable genetic material was derived from modified genetic material. In any event, foods that do not contain detectable amounts of modified genetic material are exempt from BE disclosure requirements under the Final Rule.

Nevertheless, regulated entities must still be able to establish that their products do not contain detectable amounts of modified genetic material. To do so, they must maintain records that verify: 1) the food was made from a non-BE food; or, 2) the food was refined using a process validated to render the modified genetic material undetectable; or, 3) the absence of detectable modified genetic material (i.e., test results). Acceptable types of records may include, among others, supply chain records, organic certification, or documentation that the ingredient is sourced from a country that does not allow production of that specific ingredient in a BE form.

### Disclosure Requirements

Generally, regulated entities have four options for disclosing the presence of BE ingredients in their products: 1) a USDA-approved symbol; 2) on-package text; 3) electronic or digital disclosure; or, 4) a text message disclosure. The disclosure must be of sufficient size and clarity to appear prominently and conspicuously on the



label, making it likely to be read and understood by consumers under ordinary shopping conditions.

The use of a USDA-approved symbol is one form of BE food disclosure regulated entities may use to designate BE foods. AMS initially proposed three alternative symbols (with variations), all designed to disclose a food’s BE status in a non-disparaging manner. Ultimately, AMS adopted the two symbols located on this page.

For regulated entities that do not wish to utilize the symbol, there are other permissible means of designating BE foods. One is on-package text. For foods (e.g., raw agricultural commodities or ingredients produced therefrom), the required text disclosure is “Bioengineered Food.” For multi-ingredient foods that contain both BE and non-BE ingredients, the required text disclosure is “contains a bioengineered food ingredient.”

Disclosure of BE ingredients may be also made through an electronic or digital disclosure. Such disclosures must include instructions to “scan here for more food information” or similar language. Alternatively, regulated entities can use a text message disclosure, stating, “Text [command word] to [number] for bioengineered food information.”

In terms of placement, the disclosure may be placed anywhere on the principal display panel or on the information panel adjacent to the statement identifying the name and location of the manufacturer/distributor. If there is insufficient space on these panels, then on any other panel likely to be seen by a consumer under ordinary shopping conditions.

Small food manufacturers have additional options, such as directing consumers to call or visit a website for more food information. This requires an accompanying phone number and/or website URL. Disclosure on small and very small packages may use an abbreviated disclosure.

AMS affirmatively decided against prescribing specific type sizes for different disclosure options because, given the enormous breadth and variety of available packaging options,



prescriptive requirements were deemed too difficult to implement.

### Recordkeeping Requirements

Every regulated entity subject to mandatory BE disclosure must maintain customary or reasonable records that establish compliance. Records may be kept in any format (hard copy or electronic) and may be stored at any business location. Examples of such records include invoices, bills of lading, supply chain records, country of origin records, process verifications, organic certifications, and lab test results. Records must be maintained for two years after the food is sold or shipped. USDA may request records, in which case records need to be produced within five business days.

AMS maintains a [list](#) of BE foods on its website. Foods on the list must be disclosed unless records are available to demonstrate they are not BE. Restaurants and similar retail food establishments, as well as very small food manufacturers (< \$2.5 million in annual receipts) are exempted from the rule. The purpose of the BE foods list is to provide a straightforward method of determining whether a food requires a BE disclosure. For products that contain a food on the list, regulated entities would either make a disclosure consistent with the National Bioengineered Food Disclosure Standard or not disclose if they believe the food is not required to have a BE disclosure.

### Compliance Deadlines

This Final Rule becomes effective on Feb. 19, 2019, and must be implemented by Jan. 1, 2020, except for small food manufacturers, whose implementation date is Jan. 1, 2021. The mandatory compliance date is Jan. 1, 2022. Regulated entities may voluntarily comply with the Final Rule until Dec. 31, 2021. All food manufacturers must comply by Jan. 1, 2022.

The proposed compliance date of Jan. 1, 2020, is intended to align with FDA’s proposed rule to extend the compliance dates for the changes to the Nutrition Facts and Supplement Facts label final rule and the Serving Size final rule from July 26, 2018, to Jan. 1, 2020, for manufacturers with \$10 million or more in annual food sales.

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# Food Defense



## Food Defense Is Good for Business

Addressing compliance qualifications and responsibilities under the Intentional Adulteration rule reinforces honest and effective communication between all stakeholders

BY DAVID K. PARK

I am grateful to Food Quality & Safety magazine for the opportunity to share my professional viewpoints and personal experiences on the subject of food defense and its critical importance to overall product security. As a new column, I hope Food Defense will provide subject matter knowledge, insight, and thought-provoking conversation regarding experiences, challenges, and opportunities that confront us in managing food defense responsibilities.

In case food defense-related news has escaped your attention lately, a continuing pattern of intentional adulteration and economic fraud incidents have been reported by both private and government media sources around the globe in 2018. Exam-

ples of recent intentional adulteration—economic and otherwise—include:

- Australian-sourced fresh strawberries, intentionally adulterated with sewing needles, with subsequent copycat metal contamination incidents, were discovered in New Zealand and Singapore, causing consumer injury and significantly disrupting global trade;
- The seizure of 45 tons of quality-expired, chemically-treated tuna from three seafood processing businesses in Spain that marketed and sold the seafood as “fresh;”
- Two Missouri-based U.S. pet food ingredient companies and several individuals were convicted on a misdemeanor count of selling misbranded

pet food ingredients for economic gain (i.e. they substituted inferior ingredients)—the company was ordered to pay \$7 million;

- A man from Belmont, Miss., plead guilty in a U.S. District Court to diverting a possible 180 truckloads of packaged food and beverage products from 10 companies that were destined for destruction or use in animal feed, reselling these same goods for human consumption on the open market and also falsifying records on the purported “destruction” of these goods;
- A seafood business owner in Newport News, Va., was charged with committing Lacey Act (as amended) and the Food, Drug, and Cosmetic Act (FD&CA) (as amended) violations for blending foreign-sourced crab meat with Atlantic blue crab and mislabeling the crabmeat as “Product of USA;” and
- In December 2018, after a long State food fraud investigation, the New York Attorney General reported the “common practice” of seafood fraud as verified by “rampant” high levels of species mislabeling found in genomically-tested seafood samples taken from New York State supermarket chains.

These examples are what new FDA Food Safety Modernization Act (FSMA) intentional adulteration regulations, soon to be implemented, address. Regardless of the perpetrator’s motive (e.g., terrorism, sabotage, extortion, counterfeiting, theft, or economically motivated adulteration), intentional or unintentional food tampering can cause serious harm to humans and animals.

The arrival of FDA “Mitigation Strategies to Protect Food Against Intentional Adulteration” (or as it’s perhaps better known, “Intentional Adulteration (IA) Rule”), originally published as a Final Rule in the Federal Register on May 27, 2016 (81 FR 34166), will soon usher in new regulatory requirements for large food businesses that must follow this rule. This requires certain businesses that manufacture, process/pack, or hold food must not only be already registered with FDA as a Food Facility, but now must meet provisions of Section 415 of the FD&CA, conduct a formal Vulnerability Assessment, and

develop and implement a Food Defense Plan. The IA Rule's upcoming implementation and compliance date of July 26, 2019, is nearly upon us. If you must comply and haven't already addressed required facility tasks that underpin the rule, the time to act is now!

### IA Rule Basics

Acts of intentional adulteration may take several forms: Acts intended to cause wide-scale public health harm, such as acts of terrorism focused on safety of the food supply, and acts of disgruntled employees, consumers, or competitors and their economically motivated adulteration for financial gain. Acts intended to cause wide-scale public health harm are associated with intent to cause significant human morbidity and mortality. Other forms of adulteration are typically not intended to cause wide-scale harm, although public health harm results from unintended adulteration consequences that are unknown to the perpetrator prior to the attack. Attacks intended to cause public health harm to both humans and animals are appropriately ranked as the highest risk.

Food defense experts Capt. Jon Woody, Ryan Newkirk, and Colin Barthel of the FDA Center for Food Safety and Applied Nutrition Food Defense and Emergency Coordination Staff have made every effort to make all stakeholders aware and inform and educate the global food industry and regulating bodies, writ large, on agency expectations in how to comply with the new FSMA IA Rule. In addition, these agency "owners" have also been instrumental in developing "Mitigation Strategies to Protect Food Against Intentional Adulteration: Draft Guidance for Industry" (published in June 2018 with the public comment period closed in December 2018), on how to best comply with agency IA Rule expectations prior to the publication of its final guidance document.

The IA Rule applies to the owner, operator, or agent in charge of a domestic or foreign food facility that manufactures/processes, packs, or holds food for consumption in the U.S and is required to register under section 415 of the FD&CA, unless one of the exemptions provided in 21 CFR 121.5 applies. (21 CFR 121.1)

Let me briefly review the key FDA-directed food defense facility compliance

qualifications and responsibilities as contained within the IA Rule. In regards to the qualifications:

1. Are you the owner, operator, or agent in charge of a domestic or foreign facility that manufactures/processes, packs, or holds food for consumption in the U.S and is required to register with FDA? (21 CFR 121.1)

**As a food-related facility covered under the requirements of the IA Rule, trustworthiness must be earned by partnering with others occupying space in the global supply chain.**

2. Does your business (including any subsidiaries and affiliates) average less than \$10,000,000, adjusted for inflation, per year, during the three-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee)? If so, your facility is exempt, except that you are required to provide for official review, upon request, documents sufficient to show your status as a very small business. (21 CFR 121.5(a))

3. Does your facility hold food, except the holding of food in liquid storage tanks? (21 CFR 121.5(b))

4. Does your facility pack, re-pack, label, or re-label food where the container that directly contacts the food remains intact? (21 CFR 121.5(c))

5. Is your facility a farm mixed-type facility that conducts activities that fall within FDA's "farm" definition? (21 CFR 121.5(d))

6. Does your facility produce alcoholic beverages? (21 CFR 121.5(e))

7. Does your facility manufacture, process, pack, or hold food for animals? (21 CFR 121.5(f))

8. Is your facility a farm mixed-type facility whose only activities that would be subject to section 418 of the FD&CA are on-farm manufacturing, processing, packing, or holding of eggs (in-shell, other than raw agricultural commodities) and certain game meats? (Note that this is limited to small and very small businesses. (21 CFR 121.5(g)) If applicable, your business is exempt from compliance with the IA Rule.

If you must comply with the IA Rule, the following are the principal tasks your food-related business must formally address:

1. Develop and implement a written Food Defense Plan that includes (21 CFR 121.126):

- A vulnerability assessment, including required explanations, to identify significant vulnerabilities and actionable process steps (21 CFR 121.130(c));
- Mitigation strategies, including required explanations (21 CFR 121.135(b));

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# Allergen Control



## Simplifying Complex World of Allergen Control

Practical tips on allergen swabbing and choosing a testing system

BY STEVE L. TAYLOR, PHD AND JOE L. BAUMERT, PHD

**F**DA has not mandated the use of allergen residue testing to assess the effectiveness of preventive allergen controls such as cleaning of shared equipment. However, the prudent use of such methods is very useful in determining whether allergen cleaning procedures (SSOPs) are effective and consistent. Increasingly, food companies do use swab testing of equipment surfaces for SSOP validation.

The Food Safety Modernization Act (FSMA) stipulates that allergens are a potential hazard. FSMA requires preventive allergen control implementation in manufacturing facilities that handle allergens. The food industry makes extensive use of shared manufacturing equipment for multiple formulations, some containing allergenic foods or ingredients and others not. The cleaning of shared equipment is a critical preventive allergen control step. While FDA has not yet released its anticipated guidance on preventive allergen control, it has already begun to conduct FSMA inspections, and some of those inspections have included assessment of preventive allergen controls. Thus, food companies using allergenic foods or ingredients should

develop an Allergen Control Plan, and effective and consistent procedures for the cleaning of shared equipment.

In the U.S., the major allergens are defined as milk, eggs, fish, crustacean shellfish (shrimp, crab, lobster), peanut, soybean, tree nuts (walnut, cashew, etc.), and wheat. Ingredients derived from the major allergenic foods are also considered allergens for labeling purposes, although the comparative allergen loads (the amount of protein from the allergenic source) are highly variable from non-detectable (e.g., butter oil, cold-pressed soybean oil) to low (e.g., lactose) to high (e.g., wheat flour, soybean flour, casein, whey protein concentrate). The effectiveness of allergen SSOPs is typically focused on the major allergenic foods and ingredients derived from them, especially ingredients with high allergen loads.

### Allergen Swab Testing

Allergen swabs can be effective in assessing the cleanliness of equipment surfaces. The swabs can be tested directly using certain commercial kits such as Neogen Alert kits. More commonly, swab use is coupled with lateral flow devices (LFD),

also known as strip tests. Many allergen-specific commercial companies offer LFDs, including Neogen, r-Biopharm, Romer Labs, and 3M. Commercial LFDs exist to detect residues of peanut, milk, egg, soy, gluten (wheat, rye, barley), various tree nuts, crustacean shellfish, and fish.

LFDs and swab tests are highly specific and based upon antibodies that bind to protein(s) from the allergenic food. These test methods are qualitative but capable of detecting very low residual levels of allergens on equipment surfaces. These methods can also be used for detection of residues in clean-in-place (CIP) final rinse water samples. Some companies use these qualitative methods on ingredients or processed food samples, but their use for such purposes is not recommended unless careful evaluations have been done to ensure that the food matrix does not interfere with the detection of residues using LFDs.

Because food allergens are proteins, allergen-specific swabs and LFDs are the most relevant approach to determine if allergen residues remain on equipment surfaces. However, other swab approaches are available, including general protein tests (e.g., 3M Clean-Trace) and ATP tests (e.g., Charm AllerGiene). General protein tests detect protein residues from any source, allergen or not. ATP is a molecule found in all biological organisms, so ATP testing will detect soil residues on equipment surfaces from many sources. In our experience, general protein and ATP swab methods are slightly less sensitive than allergen-specific LFD methods. Due to their specificity, allergen-specific swabs with LFDs are more suitable for validation of SSOP effectiveness.

### Deciding on a Testing System

Careful thought should be given to selection of the optimal commercial kit. The following are some tips on choosing the correct test to help ensure allergen SSOPs are as effective as possible.

**Choose the right swab.** Swabs must remove protein residues that may adhere to equipment surfaces, but must also be adsorbent. Swabs must also release the proteins back into an extraction solution. The swabs provided with commercial kits, such as the environmental swabs from Neogen, outperform regular cotton swabs.

Sponges should be avoided for allergen testing, as they tend to hold on to proteins, failing to release them into extraction solutions. Furthermore, some sponges may contain microbial growth media made from allergenic foods such as milk and soy.

**Choose the most appropriate test method.** The choice of an LFD that fits your purpose is relatively straightforward: It must be able to detect the allergen residues in the product matrix of concern. Essentially, will the LFD detect residues on the equipment surface before cleaning?

Different commercial LFDs targeted at residues of the same allergenic food are not created equal. LFDs contain antibodies raised against the allergenic food or specific proteins from the allergenic food. Each commercial LFD kit has its own proprietary antibody/ies that may respond differently to the residues left on equipment surfaces. Food companies use a variety of ingredients derived from a particular allergenic food (e.g., milk-derived ingredients can include non-fat dry milk, caseinates, or whey derivatives). Don't assume that a given LFD will detect all forms of milk equally well—some commercial milk LFDs do not detect whey or whey-based ingredients, for instance. The sensitivity levels of different commercial kits for the same analyte will also vary and be dependent on the nature of the ingredient derived from the allergenic source.

Processing conditions also affect a system's ability to detect allergen residues on equipment surfaces. Heat processing causes protein aggregation, resulting in difficulty with removal of residues from the surface and challenges with solubilization. Fermentation can alter proteins through proteolysis, again affecting antibody recognition on the LFD.

False negative results due to overloading LFDs is a particularly important concern. Due to the "hook effect," high levels of allergen residues can cause false negatives. The hook effect occurs when high

levels of the allergen residue are present, which overwhelms the detector antibodies in the strip causing most (perhaps all) of the allergen-antibody complexes to miss binding to the allergen-specific antibodies bound at the test line in the strip—resulting in a false negative response. Some commercial LFDs have overload lines while others do not, and the level of allergen needed to generate a false negative due to overloading will be different for each commercial kit. With milk, overloading occurs at concentrations from 100 ppm up to >10,000 ppm (expressed as ppm NFDM),

Multiple swabs should be taken, especially in the initial stages of cleaning validation on a processing line to identify the spots that are hardest to clean.

depending upon the type of commercial kit. Serial dilutions of the swab or CIP rinse water extraction solution can be used to avoid overloading.

**Set an achievable cleaning goal.** LFD swabs are used to validate the effectiveness of SSOPs for removal of detectable allergen residues from shared equipment surfaces (or CIP final rinse water). Each product and processing line should be evaluated separately. If formulations have similar physical attributes (e.g., dry powders), similar cleaning approaches can be used on multiple formulations. When formulations contain multiple allergens, the assessment can sometimes be limited to the allergen that is present in the highest allergen load.

A corporate target level for effective allergen cleaning should be set, such as no detection of allergen residues on swabs using a specific LFD with a particular sensitivity level (e.g., no detection of milk protein residues with an LFD having a detection limit of 5 ppm). The LFD sensitivity level will vary to some degree with the nature of the food matrix, but a general statement such as "no detection by swab with LFD" is usually sufficient.

**Use the right technique.** Swabbing of hard-to-clean spots on the processing lines (nooks and crannies) is important. Multiple swabs should be taken, especially in the initial stages of cleaning validation on a processing line to identify the spots that are hardest to clean. Those spots can then become the focus of subsequent cleaning validations and verifications. Allergen cleaning protocol effectiveness should be re-validated periodically or whenever anything changes (product formulation, equipment matrix, processing conditions, etc.). The frequency of re-validation is not fixed and is dependent upon the frequency of changeovers. When using the recommended environmental swabs, the swabbing technique can vary without much effect on the observations. Swabs and surfaces can be either wet or dry.

**Interpret the results.** LFDs offer qualitative results. Thus, results should be interpreted primarily as negative or positive. The goal for cleaning validation should be "negative by swab" after documenting that the chosen LFD is fit for purpose.

Commercial LFDs provide sensitivity limits in concentration terms, such as ppm, and relate to the allergen concentration in the swab extraction solution. This term has no bearing on the allergen concentration that might be found on a finished product that comes in contact with the equipment surface. Swab test results should instead be provided in terms of  $\mu\text{g}/\text{cm}^2$ , but that presumes users will swab uniform areas of the equipment surface. Since irregular surface areas are swabbed, the most appropriate expression of results would be  $\mu\text{g}/\text{swab}$ . And since the degree of hazard to the finished product cannot be determined from a swab result, the goal should be "negative by swab" as noted above unless you are brave enough to test finished product (see below).

**Know when to test finished product.** The results of equipment surface swabs cannot easily be translated to finished food products. Swabs with LFDs offer qualitative results while finished product testing is usually quantitative. LFDs tend to be extremely sensitive; they can detect extremely small amounts of allergen on equipment surfaces. When the subsequent product is manufactured on the shared equipment, allergen residues will likely

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# Regulating Food Safety in 2019

Uncovering new efforts to improve food quality standards and prevent future outbreaks

BY TED AGRES

**B**oth FDA and industry will come under increased pressure in 2019 to improve food safety, largely in response to last year's widespread outbreaks of *E. coli* O157:H7 from romaine lettuce and other leafy greens from the growing regions of Yuma, Ariz., and California. Hundreds of people nationwide were sickened and hospitalized, and five people died after consuming contaminated romaine lettuce.

Last year also saw scores of smaller outbreaks and recalls involving *Listeria* in deli ham, pork, vegetable dip trays, salad mixes, and imported crab meat; Shiga toxin-producing *E. coli* O26 in ground beef; and *Salmonella* in breakfast cereal, shell eggs, ground beef and turkey products, and even boxed cake mix.

Foodborne outbreaks occur with some regularity, but recent advances in whole genome sequencing (WGS) and other technologies are allowing regulators to identify microbial pathogens with greater accuracy than ever before. Even so, tracing a contaminated food product through the supply chain remains complex and time consuming, requiring numerous regulatory and public health agencies to collect and evaluate thousands of records.

While the magnitude of food-related illnesses appears to be increasing, FDA officials suggest this may be an appearance due to improved detection capabilities. Nevertheless, FDA, USDA, and state and local agencies are finding food safety regulation to be increasingly challenging, especially in this era of constrained budgets and—for routine FDA inspections early this year—furloughs because of the federal government shutdown.

## Focus on Prevention

The Food Safety Modernization Act (FSMA) is intended to reduce food-related illnesses by shifting the emphasis from inspection by government agencies to prevention by the food industry. But several key FSMA provisions are still being adopted by industry, such as the Produce Safety Rule and the Foreign Supplier Verification Program, and some major areas remain largely unaddressed.

**If FDA doesn't shorten the compliance deadlines for agricultural water, more wide-spread recalls of leafy greens and other produce are likely,**



**predicts David Acheson, MD, founder and CEO of The Acheson Group.**

A prime example is water used for agricultural purposes. Last year, canal water containing *E. coli* O157:H7 was used to irrigate romaine lettuce and other leafy green crops in the Yuma, Ariz., growing region. While a concentrated animal feeding operation (100,000-plus cattle) was located adjacent to a stretch of the implicated irrigation canal, the source or sources of the outbreak-related contamination remain unclear, according to FDA and CDC.

This year, more farms will be subject to FSMA's Produce Safety Rule, and starting this spring, FDA will begin inspecting farms for compliance. But the agency has delayed the provision of the Produce Safety Rule pertaining to agricultural water. FDA has extended the compliance deadline for the testing and safety of water used in agriculture (other than for sprouts) by an additional two to four years to ensure the standards are "feasible for farmers to adopt in all regions of the country." As a result, agricultural water compliance will not begin until January 2022 for the largest farms, January 2023 for small farms, and January 2024 for very small farms.

"This is unacceptable in the wake of last spring's outbreak and the deaths and illnesses it caused," says Sandra Eskin, food safety

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project director at the Pew Charitable Trusts. “FDA must end these delays and promptly finish any revisions [of the rules] guided by results from relevant environmental assessments and outbreak investigations.”

Further, federal and state agencies “should use their authority over canal water quality to require that water be treated to reduce foodborne pathogens before being used in produce fields,” Eskin

## FSVP Violations

Failure to develop a FSVP was the single-most frequent food safety violation cited by FDA investigators last year, with 278 Form 483s issued to U.S. companies for not having verified that the food they import meets the same safety standards as domestically produced items.

FSVP requires all U.S. food importers (not just those registered with FDA) to develop plans to and actively monitor their foreign suppliers’ compliance with FSMA provisions.

Late last year, FDA’s Office of Regulatory Affairs released [summaries](#) of routine field inspections and enforcement activities conducted during fiscal 2018 (Oct. 1, 2017, through Sept. 30, 2018). The summaries identify the statutory areas under which thousands of Form 483s were issued to companies having conditions or practices that may violate FDA requirements.

As in previous years, other common food safety violations involved sanitation monitoring (188 citations); pest control (183 citations); controls for sanitary manufacturing, processing, packing, and holding (175 citations); sanitary plant maintenance (167 citations); and HACCP plan implementation (136 citations). In total, nearly 2,600 Form 483s were issued for food safety related violations last year.

U.S. importers are required to develop, maintain, and follow a foreign supplier verification plan (also called an FSVP) for each food they import, unless an exemption applies (such as for juice and seafood, which are covered by separate HACCP regulations, and certain low-acid canned foods).

While fiscal 2018 was the first full year that FSVP regulations were in effect, not all U.S. companies had been required to comply, depending on the size of their foreign suppliers (rather than the size of the U.S. firm) and the types of food products. This year (fiscal 2019, Oct. 1, 2018, through Sept. 30, 2019), more U.S. companies will come under FSVP’s purview. As such, the number of FSVP violations is likely to increase.

Furthermore, FDA’s focus last year had been on education, generally allowing companies an opportunity to come into compliance with FSVP, unless dangerous problems were uncovered. This year, FDA inspectors are more likely to issue violations than warnings. “We’ll see more FSMA enforcement in 2019 than in the past,” says David Acheson, MD, former FDA associate commissioner for foods. “FDA’s been in a mode of education, but more enforcement is likely to be coming this year.”—T.A.

says, noting that farmers in the Yuma region had already begun planting their winter romaine crops. “It is unclear whether they are being irrigated with untreated canal water,” she adds.

If FDA doesn’t shorten the compliance deadlines for agricultural water, more widespread recalls of leafy greens and other produce are likely, predicts David Acheson, MD, former FDA associate commissioner for foods and founder and CEO of The Acheson Group.

“FDA has kicked the can down the road,” Dr. Acheson tells Food Quality & Safety. “They don’t know how to control risks in water very well through testing.” And should irrigation-related outbreaks continue after farm inspections begin, “there will be continued criticism of the regulatory agencies and effectiveness of produce inspections overall,” he says.

## Traceability and Labeling

As good as WGS is at identifying specific pathogens, the traceback investigation of a contaminated commodity, such as romaine lettuce, remains complex and cumbersome.

“It’s a labor-intensive task. It requires collecting and evaluating thousands of records while also trying to accurately document how the contaminated lettuce moved through the food supply chain to grocery stores, restaurants, and other locations where it was sold or served to the consumers who became ill,” said FDA Commissioner Scott Gottlieb, MD, and Deputy Commissioner Frank Yiannas, in a [recent joint statement](#).

While accurate records are essential for traceability, FSMA (implemented with the Bioterrorism Act of 2002) requires FDA-registered firms (not including growers, retailers, or restaurants) to be able to trace only one step forward and one step backward in the supply chain. Late last year, after CDC warned consumers not to eat romaine lettuce, the industry adopted an FDA proposal to voluntarily label produce entering the market with the growing region and harvest date. “If it does not have this information, you should not eat or use it,” FDA announced.

Consumer groups were less than enthusiastic. “[I]t relies on the shopper standing in the produce aisle to know first that there has been an outbreak, then remember which part of the country is involved, and also realize that they can check the label for the information,” [Consumer Reports said](#).

Acknowledging that labeling alone is not a long-term solution, FDA plans to use technology “to improve our ability to track and trace products through the supply chain. We’ll be launching a comprehensive effort in early 2019 to advance our work in this area,” Dr. Gottlieb and Yiannas announced in December 2018, without offering details.

But many observers expect FDA to encourage industry to adopt blockchain and similar technologies to enhance product tracking and traceability this year. Prior to joining FDA as deputy commissioner for food policy and response, Yiannas was vice president for food safety at Walmart, where he had championed the mandatory adoption of blockchain on the part of its leafy greens suppliers, starting this year.

“We have a guy starting...the former head of food safety at Walmart who is going to be coming to the FDA to help us put in

Shawn K. Stevens, food industry attorney,  
Food Industry Counsel LLC, recommends  
manufacturers “play FDA for a day”  
and do their own extensive testing  
using WGS or other  
environmental sampling.



place among other things better track-and-trace using tools like blockchain maybe to even do track-and-trace on the food supply chain,” Dr. Gottlieb told CNBC in an interview.

### FSMA Compliance Deadlines

A number of FSMA regulations become effective in 2019 for companies and farms, depending on the size of their business and the products they produce or handle. They include the following.

**Produce Safety Rule** requires domestic and foreign farms to have preventive measures in place for growing, harvesting, packing, and holding fruit and vegetables. Small and very small farms (less than \$500,000 and \$250,000 in annual revenues, respectively), became subject to the Produce Safety Rule (except for agricultural water) in January. Routine farm inspections for compliance with the rule are set to begin this spring.

**Foreign Supplier Verification Program** (FSVP) requires U.S. importers to verify that the food they import meets the same safety standards as domestically produced items. This year U.S. companies importing from “small” foreign suppliers (fewer than 500 full-time employees) and “very small” foreign suppliers (less than \$1 million in average annual sales) are subject to FSVP.

**Intentional Adulteration Rule** is designed to protect the food supply from widespread public harm. Large businesses become subject to the rule in July. FDA is releasing draft guidance in installments throughout the year.

**Voluntary Qualified Importer Program** (VQIP) gives U.S. companies with a high level of control over the safety and security of their import supply chain expedited review and importation of their foods. Applications are being accepted through May, and the first VQIP starts in October.

### Other Regulatory Activities

Other activities taking place in the coming year include the following.

**Enhancing food recalls.** This year, FDA plans to disclose the names and addresses of stores where recalled products may have been sold. Previously, the agency had felt constrained because of confidentiality agreements between suppliers and retailers. Now, FDA will disclose retailer information when the recalled product is not easily identifiable from its packaging (such as without a barcode or Universal Product Code) and when the food is likely

to still be in the consumer’s possession based on shelf life or perishability.

**GMO labels.** Starting this year, food manufacturers may begin using USDA’s approved “Bioengineered” symbol on labels to disclose the presence of GMO ingredients. Under a final rule issued last December, food manufacturers must disclose the presence of foods or ingredients made from genetic engineering when the bioengineered portion exceeds 5 percent by weight of each ingredient. Mandatory disclosure starts Jan. 1, 2022, but companies can voluntarily begin disclosure starting Feb. 19, 2019, when the final rule takes effect.

**Cell-based meat.** USDA and FDA this year may hammer out draft regulations for overseeing the production and distribution of cell-based meat, or animal tissue produced without growing or slaughtering animals. FDA will oversee cell collection, cell banks, and cell growth and differentiation. USDA oversight will begin from the cell harvest stage, and will continue during the production and labeling of food products.

### Inspections and Enforcement

Of wide industry interest, FDA inspectors this year will ramp up testing for pathogens. “FDA will be pressing to make sure there are no more repeats of past outbreaks,” says Shawn K. Stevens, food industry attorney with Food Industry Counsel LLC, Milwaukee, Wis. “The agency will be working very aggressively to make sure food companies are following the rules,” he tells Food Quality & Safety.

Stevens recommends manufacturers “play FDA for a day” and do their own extensive testing using WGS or other environmental sampling. “You should find out what’s there and respond to those findings aggressively and appropriately before the FDA arrives,” he suggests. Dr. Acheson agrees. “It’s better to know what’s going on in your food plant before the FDA tells you,” he says.

However, possessing that information is probably discoverable by FDA. If a manufacturer does have a resident bacterial strain in the plant and is trying to eradicate it, “the agency needs to be lenient and not penalize the company for it,” Dr. Acheson says. “We need more regulatory clarity on this point because sometimes oversight shuts down good food safety practices at the plant level out of fear of discovery.” ■

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# Safety & Sanitation

PEST CONTROL



possible—require a strong partnership between the facility manager, employees, and the pest management professional to implement and continue to improve over time. Traceability is also an integral part of a strong IPM program, as it can help prevent pests internally and externally and ensure pest issues are resolved promptly.

Every IPM program will have some form of documentation to record pest issues, and many pest management companies offer extensive data tracking to see how pest populations are trending over time to identify areas for improvement. Careful documentation is crucial for demonstrating compliance to an auditor, and it can help trace pest issues back to the source. Talk to partners throughout the supply chain to establish documentation protocols as well, since determining the source of an infestation is an important first step in resolving a pest problem. Make it a point to notify supply chain partners when pest issues are traced back to them, as they might not be aware of these issues at their own facility.

Traceability is a big part of food safety, especially as more global supply chains are formed, but it can be confusing to determine which documents are most important to maintain to create visibility and be prepared for an audit. The following documents are a great place to start.

**Food safety plan.** The food safety plan is the most important piece of documentation. Because this is a larger, overarching document, focus on the pest management portion and what can be done to update and improve it for now. While a food safety plan should cover all aspects of the facility and products, for pest management specifically the plan should include details about all activities done to proactively ensure products are protected from pests. Make sure to incorporate all potential hazards, preventive controls, and corrective actions implemented to reduce risk. It's also important to include monitoring and verification procedures. If possible, include information about

## Proactive Pest Management

Traceable policies help identify what types of pests and how many are lurking behind the scenes to establish approaches in preventing them from returning

BY MICHELLE HARTZER, BCE

**P**icture this: A dad hands his daughter a box of morning cereal, which she rips opens in excitement. While grabbing the toy out of the box, she drops it and screams, spilling cereal all over the floor—there are bugs in the cereal!

It's easy to see how pest problems in a food processing facility can turn into a big problem. Pests can directly hurt your bottom line by contaminating products or equipment, causing you to either throw out and/or replace costly shipments. If products make it all the way to the consumer with pests, it could have a devastating impact on your brand, especially with today's social media connectedness.

Instead of waiting for pest issues to occur, plan ahead. The Food Safety Modernization Act mandates a proactive approach to food safety, so sitting back and waiting for issues to occur is no longer an option. Aside from the legal implications, being proactive will help you protect your facility and bottom line from pests. In today's globalized world, food processing facilities now have to pay attention to their supply chain too.

### The Basics

Every food business should have an Integrated Pest Management (IPM) program to mitigate the risk of pest issues. These programs—which emphasize customized, proactive, integrated solutions whenever

suppliers and their programs. A crucial part of ensuring pest issues are traceable is to show that incoming and outgoing shipments are being inspected, as this will help catch pest issues before they get further down the supply chain.

**List of service changes.** Every IPM program needs to adapt and change as pest pressure does. No two facilities are the same, and pest pressure can shift from year to year depending on a variety of external factors, like nearby construction driving rodents from their homes. Anytime changes are made to the program, note how and why the changes have been made. At a minimum, review the plan at least once per year.

**Monitoring devices/traps.** The best food safety plans include a map noting monitoring equipment, traps, and any other devices used in and around the facility to minimize pest populations. For each device, record the locations and activity levels. The trend report from the collected data will give insight as to what

issues need to be addressed immediately, helping to make management decisions. Pest management professionals should note activity each time they come out, and

Make it a point to notify supply chain partners when pest issues are traced back to them, as they might not be aware of these issues at their own facility.

many already have systems in place that can pull together trend reports. Including this information will show any inquisitive auditor you mean business when it comes to proactive food safety.

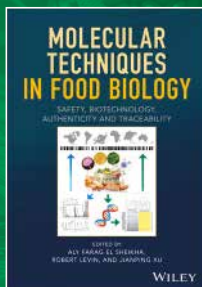
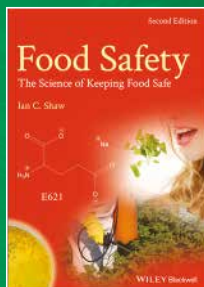
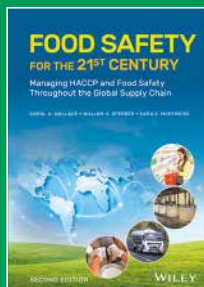
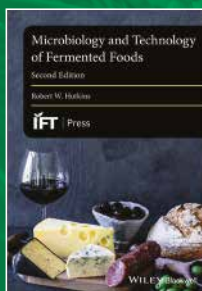
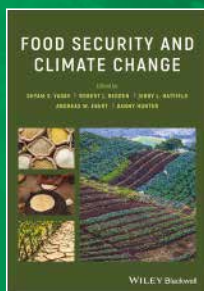
**Annual assessments.** Review your IPM program and how it relates to the food

safety plan every year. Specifically, look at the facility's pest problems and talk through how to resolve and prevent them with a pest management provider. These annual assessments will help uncover recurring problem areas and hot spots around the facility, allowing you to better target the plan to address those concerns. Also, auditors will be looking for these yearly assessments.

**Sighting reports.** Pests and evidence of pests spotted within the facility should be recorded in a logbook. Typically referred to as a "pest sighting log," this will help a pest management professional refine their investigation and better target the areas most plagued. The report should include information about the location of the pest problem within the facility, who found it, and the number of pests spotted. Capturing the pest is ideal, but it's not always feasible to do so. In that case, photo evidence helps with identification, so obtain a close-up picture of the pest(s) if pos-

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Annual assessments will help uncover recurring problem areas and hot spots around the facility to better address concerns.

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sible. Usually, employees will be the first to see pest problems, so make sure they know what to do when it happens!

It takes team effort to have a traceable, proactive IPM program. Typically, it's recommended that employees keep an eye out for pests in areas most relevant to their job title and where they work. Don't make it too difficult for employees to complete assigned inspections or else they won't do it.

These documents can help trace when and where pest issues began so businesses can work on a customized solution to resolve problems. Openly sharing news about documented pest issues with supply chain partners can prevent pests from sneaking into shipments and contaminating product.

### Making It Work

To make this all work in reality, first, hold a training session in partnership with the pest management professional and get as many employees there as possible. Discuss the most common pests around the facility and where they're most likely to be found. Then, arm employees with an action plan they should use when a sighting does occur. Everything should be recorded in the logbook, which will help ensure issues are resolved quickly. Make sure employees know where to find it, and consider having a few logbooks at different, convenient locations around the facility.

Next, give some basic assignments to employees. For example, the forklift op-

erator in charge of moving products into a warehouse could keep an eye out for stored product pests. Meanwhile, the employees working around the assembly line could be tasked with inspecting and wiping down equipment at the end of each day, which will help minimize attractants.

There are a lot of ways to diversify roles and make sure employees keep an eye out for pests. If unsure about how to go about this, talk to the pest management professional. For starters, employees need to know the signs of pests.

**Stored product pests.** Although there are many different species of stored product pests that can affect a food processing facility, all are adept at thriving in and around products undetected. The Indian meal moth, for example, has small, cream-colored larvae that will eat just about anything. Tiny and right at home in product packaging, these pests will wreck a batch of products and then move on to the next. Pheromone traps can help with detection, so make sure employees know what they are and why they are there.

**Rodents.** Rats and mice can carry disease-causing pathogens, which can rub off onto any surface the rodent comes into contact with. Both rats and mice are capable of fitting through tiny gaps (mice can fit through a hole the size of a dime, while rats can fit through a hole the size of a quarter), so any gaps on the exterior of a building serve as a doorway. If rodents are suspected but haven't yet been spotted, look for droppings and yellowish-brown

grease marks around corners and along baseboards. Search for gnaw marks around gaps and openings in walls and on products too. Remember, rodents want to be out of sight. That's why they skitter along walls and stay away from humans as much as possible.

**Cockroaches.** One of the most resilient and persistent pests around, cockroaches can get through minuscule gaps and will feed on just about anything, quickly becoming a terror for food processing facilities. If they're not promptly removed, cockroaches can reproduce rapidly. A few cockroaches can create an infestation in a matter of months, especially with an abundant food supply. If a cockroach is seen during the day, it's a good sign it's time to act quickly. Cockroaches are most active at night, so spotting one during the day likely means others are lurking behind the scenes.

To obtain this trend data and see the hot spots around a facility, monitoring devices are likely necessary. Whether using pheromone traps to reduce stored product pest populations, bait stations to trap rodents, or fly lights to capture flying pests, these tools identify what types of pests and how many are lurking behind the scenes.

Pests are resilient and persistent. They'll do whatever it takes to get to the food, water, and shelter needed to survive.

Pest pressure doesn't just disappear overnight. Consistent improvement and effort are necessary to reduce it. But keeping track of pest population trends around the facility can help you and your pest management professional keep a pulse on the pests plaguing your business.

If your facility is affected by pests and you haven't implemented proactive, traceable policies, you're going to have a tough time finding and removing pests. Protect your brand from negative publicity and your facility from costly shutdowns by keeping tabs on the pest populations and then do everything you can to keep them out.

The best time to implement a proactive approach to food safety was yesterday. The second-best time is now. ■

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## Rodent Control with Remote Monitoring

Understanding how sensors allow pest management professionals to actively screen food facilities 24/7

BY PATRICIA HOTTEL, BCE

**T**he ability to remotely monitor a wide variety of food safety-related processes is not new. Food companies can remotely monitor everything from door closures to food storage temperatures using this technology. There have even been several attempts in recent years to use similar technology for pest management purposes. Current remote monitoring systems primarily focus on rodent monitoring with the hopes of expanding to a variety of non-rodent monitoring devices in the future. Eventually, the industry envisions to be able to utilize these remote monitoring systems for other types of pests, including adaptations for insect light traps and pheromone traps.

These developments will allow pest management professionals (PMPs) to actively control food facilities 24/7 in order to keep all sites free of a variety of pests.

While many food processors are excited for the opportunity to incorporate remote monitoring systems into their facilities, understanding these systems, along with their advantages and disadvantages, is crucial.

### How Do They Work?

Remote monitors provide 24/7 monitoring coverage of rodent control devices. At a minimum, remote monitoring systems will have a sensor to detect the pest, as well as a method of sending a message to the

PMP when a rodent is detected. Although features will vary by manufacturer, all systems will use three electronic devices: a sensor, a hub, and a mobile device. The sensor is placed in or on the rodent device, like a trap or station. The sensor communicates with an onsite hub, which communicates with an off-site data center. In turn, the hub is responsible for communicating the sensor's messages to the PMP via a text or email on a mobile device.

The types of sensors used in pest management programs vary depending on the manufacturer. Sensors currently on the market measure either motion, infrared, or a combination of both. It is important to note that units incorporating motion sensors can be subject to more false positive alerts, especially in high-traffic areas. For this reason, it is vital to consider the impact of human disturbance and vibrations when determining proper placement of remote monitoring systems with motion detectors.

The amount of back-end support offered with remote monitoring systems varies depending on the manufacturer. For example, some manufacturers offer mapping software, which records placements alongside tracking and trending capabilities. Others offer more basic software, which includes only sensor alerting support.

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## Key Terms for Remote Monitoring Systems

False Positive	False Negative
A false positive signal occurs when the remote monitor sends an alert indicating there is rodent activity or capture, but neither rodent activity nor a capture has occurred.	A false negative signal occurs when something has been captured or rodent activity has occurred, but the unit fails to send an alert of the activity.
<b>Impact of a false positive</b>	<b>Impact of a false negative</b>
More of a nuisance factor. It causes inefficiencies as PMPs search for the reasons behind the false alerts. The false positive is not without consequences, but is typically less serious than a false negative event.	If the PMP has not been alerted to the activity, they will fail to respond. The consequences could include failure to control an emerging rodent infestation or failed audits.

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### Sites Most Conducive to Remote Monitoring

Some of the earliest adopters of remote monitoring technology are those performing wildlife removal using live traps. To ensure trapped animals are treated humanely, PMPs are required to visit the sites daily. This process can be labor intensive and costly with no guarantee of a capture. This is where remote monitoring systems are the most beneficial—since some systems utilize motion to signal activity, areas with less human disturbance and vibrations tend to be better locations for these types of sensors. Search for areas less subject to disturbance, as they are often shadowy, protected areas that are more likely to be visited by pests. It is important to avoid areas with the potential for movement-related issues as this can prompt false positive reports due to station or trap movement, and can offset the value of the systems. These false positives can also cause PMPs to monitor an area more frequently, causing an increase in labor costs.

Food processing plants, pharmaceutical plants, and other sensitive facilities are excellent candidates for remote monitoring systems because they can expedite the analysis of a rodent's presence. These types of sites can benefit from niche uses, like monitoring the upper ledges of a processing plant that require assessing for roof rats caused by exterior pressures.

Monitoring systems also hold promise for use in intensive trapping programs where service follow-ups can be determined based on sensor alerts. For example, in facilities with an elusive rat that is not visiting the control devices, remote

monitoring systems can be particularly helpful. The pest management company will still need to assess equipment and strategize but daily visits may no longer be required.

### Advantages and Disadvantages

The main advantages of remote monitoring systems are the ability to have 24/7 coverage and the opportunity to reduce routine inspection of equipment. McCloud Services data reveals that on average 3 percent of interior rodent equipment is showing activity in any one month, which requires weekly inspections to maintain those monitors. Additionally, 24/7 coverage creates an opportunity to gather more data and better understand the cause of the rodent activity. When the sensor sends an alert, a PMP can investigate and determine the “why” behind the capture right away, reviewing potential causes like a door left open, a certain product on the receiving dock, etc.

Through continuous use and tests, McCloud has learned how quickly a trap may become ineffective. In one test, snap traps were triggered within hours of a visit. Once a snap trap is triggered, it is unable to capture additional animals. Learning this information has allowed PMPs to readjust their service visits to increase capture potential.

There are also niche uses where monitoring for rodents in the past was difficult, including trapping rooflines, interstitial areas, false ceilings, safety sensitive areas where access is restricted, chronically blocked sanitation aisles, and roofs. With the advent of remote monitoring systems, these niche areas are now treatable. In fact,

with the use of remote monitoring systems, McCloud used a sensor equipped multi-catch trap to prop open an exterior door on a site. When the trap caught a mouse, a service specialist was dispatched and uncovered certain employee behaviors that contributed to a potential pest problem.

While the benefits of remote monitoring systems outweigh the detriments, the disadvantages include continuous technological advancements, as the development and launch of these systems have come with challenges. This may explain the reasons why it has taken so long to establish systems on the commercial market. Even manufacturers with products currently on the market continue to tweak their systems to perfect the devices. It is like the regular changes seen in other areas of technology, such as mobile phones.



Today's remote monitoring systems are able to treat niche areas that were previously difficult to monitor.

In addition to the systems themselves, costs associated with employee training need to be considered before implementing a system into a facility.

Remote monitoring systems provide a host of opportunities to learn more about rodents and increase the ability to effectively respond to pest intrusions in food facilities. Professionals should become skilled in sensor placement in order to protect from damage, false positives, and inaccurate detecting activity. And be prepared for the time required to manage and analyze the data each trap receives. This includes further analysis of trends and root causes. ■

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# Quality

FSMS



## 10 Resolutions to Enhance Quality and Safety Programs

Ideas to start the New Year right and improve upon food safety management systems | BY RICHARD STIER

**W**e are beginning a new year, which often means it's time for New Year's Resolutions. For individuals, this often entails things like exercise regularly, lose 10 pounds, or get something fixed around the house. For food, beverage, and ingredient processors, the new year may involve implementation of new programs based on the previous year's performance. Allow me to present 10 points (or resolutions) that might be considered as part of continually improving your food quality, safety, and sanitation programs.

### 1. A Commitment from Management

Management commitment is an essential element for ensuring the production of high quality, safe, and wholesome foods. Personally, I always felt it should have been included as one of the preliminary

steps to Hazard Analysis and Critical Control Points (HACCP) as highlighted in the Codex HACCP document and those mandating the adoption of HACCP for seafood and juice. Management responsibility was also a key element of the ISO 22000:2005 standard and remains so in the updated 22000:2018 standard. All food, beverage, and ingredient processors should seriously consider incorporating the communication element into their food safety management system. Far too many operations do not establish formal, *documented* protocols for communication.

The importance of management taking an active and all-encompassing role in a food safety program may be demonstrated by looking at what happened to the top guy at Peanut Corp. of America. He is now behind bars for what may be the remainder of his life.

It is very obvious when management has a positive attitude toward food safety. That attitude echoes through the company as employees at all levels buy off on food safety. These operations are a pleasure to work with and the term "food safety culture" is simply part of everyday life, whether they call it that or not.



### 2. Welcome Third-Party Audits

Most operators are not overly thrilled about third-party audits. Many years ago, the National Food Processors Association safety audit was supposed to be the be-all and end-all for audits—an audit that would satisfy everyone. Today, the Global Food Safety Initiative (GFSI) audits are supposed to fill that role, yet many buyers do their own audits, so operators might end up having 10 or more audits over the course of a year.

Audits may be distasteful to some, but they should be treated as a learning tool and a means of improving operations. When I perform audits and am asked the question, "What do I need to pass?" my sense is that the company is not quite clear on the concept. Audits are supposed to be a check on how an operation is performing, that is, "Do you do what you say and say what you do?" Ideally, the auditor needs to look at what the company is doing and have the knowledge and experience to determine whether that is effective. Hopefully, your auditor is not simply filling out a checklist but digging down and looking at whether programs are both comprehensive and effective. Auditors are not supposed to consult, but there is nothing wrong with picking their brains when on site. The auditor may have observed things elsewhere that can benefit you.

### 3. Appoint a Document Control Officer

With the emphasis on documentation in the GFSI audit schemes, ISO 22000, and the Preventive Controls for Human Food regulation in the U.S., documentation is

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an absolute must to pass audits and ensure regulatory compliance. Documentation must include procedures, work instructions, and development of forms for record maintenance. The company must develop the protocols, properly document them utilizing a standard format, implement the protocols including proper use of any recordkeeping forms, and maintain programs—that is, make sure the system is working.

**Data need to be compiled and turned into usable information that can aid in making decisions.**

An integral part of implementation is training and education: making sure the persons responsible for doing a task know how to do it. The company must document each of these two elements. Development and implementation are the responsibility of the different operating groups within the company, but someone needs to manage all the necessary documents, and that person should be a document control officer. This individual must ensure documents are prepared using a standard format, that they are signed off by developers when they are newly developed or revised, that they are distributed to the proper individuals, and that old documents and forms are collected and destroyed. The document control officer does not necessarily have to be part of the quality group, but they must have computer skills and understand organization. If you don't already have a document control officer, consider establishing such a position.

**4. Use Your Data**

It bothers me to see companies with piles of data that have simply sat in file cabinets and collected dust. Data need to be compiled and turned into usable information that can aid in making decisions.

In today's food industry, buyers often mandate that each lot of ingredients, raw materials, or finished goods they receive be accompanied by a Certificate of Analysis (COA). The data generated when preparing a COA may be utilized in the food

safety management system as a verification activity. It should also be compiled electronically so the company can easily look at how products perform historically. If you are one of those operations that has piles of data sitting in old file cabinets, consider doing something with them. Hire someone who can compile the information and then follow your recordkeeping mandate to get rid of anything that should be disposed of.

**5. Read Labels During Production**

The most common cause of allergen recalls is the use of the wrong label or package. You would think processors would get the message that putting the right label on a package is an absolute necessity. Recalls cost money, time, and can damage a company's reputation.

According to Amy Philpott, senior director, Watson & Green, LLC, "A 2011 joint industry study by the Food Marketing Institute and Grocery Manufacturers Association estimated the average cost of a recall for food companies to be \$10 million in direct costs, plus brand damage and lost sales. Although this is old data, it still seems to be the most commonly referenced in the food industry."

Philpott also observes that recall costs depend on a wide range of variables.

So, processors, I urge you to develop, document, and implement programs to ensure the right label on the right package. Look at the different scanning technologies; develop and implement programs to verify that new labels match the masters when they arrive; do what you can to minimize the potential that the wrong label is applied by clearly segregating labels in storage and when used; and make sure any old or discontinued labels are destroyed so they cannot possibly be used.



**6. Risk-Based Sanitation Programs**

Properly developed and implemented sanitation is one of the best means the food

industry has for ensuring the production of safe food. Obviously, FDA believes sanitation to be important as it has specifically defined it as one of the preventive controls within the Preventive Controls for Human Food regulation. Sanitation preventive controls will be required for many ready-to-eat products and for products containing food allergens.

During hazard analysis, the processor must determine whether there are hazards that require sanitation preventive controls. Ideally, the processor will then develop, document, and implement the necessary programs to ensure the hazards determined to require a preventive control are in fact controlled. The operator should then validate the cleaning and sanitation protocols and ensure the validated program is followed. Validation is not required in the regulation, but it is a best practice.

Processors should take a close look at each cleaning and sanitizing procedure they develop. This would encompass all equipment, utensils, floors, walls, ceilings, drains, overheads, and more. They should also conduct a risk assessment on each procedure to make a clear determination not only whether that area poses a risk, but also whether the procedures that have been established are adequate to control the risk.

**7. Validate Processes and Products**

Validation is defined as obtaining evidence that the elements of the HACCP plan are effective. The Preventive Controls for Human Food regulation mandates all process preventive controls, that is, the critical control points from HACCP, be validated. The GFSI audit schemes, especially FSSC 22000, which is based on ISO 22000, mandate that prerequisite programs used to control hazards must be validated. In reality, this can pose a challenge since some controls simply don't lend themselves to being easily validated.

Food processors should also take a close look at their products to determine whether they are bacteriostatic (inhibitory to pathogens) or bactericidal (lethal to pathogens). There are a wide variety of products on the market such as carbonated soft drinks, soy sauce, syrups, and condiments that are lethal to pathogenic bacteria. If a company allocates resources

to conduct a challenge study that shows their products are lethal to pathogens, they should not only sleep easier knowing their products are safe, but they would not have to do environmental monitoring since the Preventive Controls regulation in 21 CFR Part 117.130(c)(2) states the following:

(ii) *The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.*



## 8. Get Back to the Basics of Food Microbiology

Sometimes I wonder whether the food industry has forgotten the basics from food microbiology 101. The rapid methods and new tools for testing and analysis are extremely powerful additions to the food safety toolbox, but our goal is to produce safe, wholesome, and high-quality foods. This should be accomplished through formulation, and there are ingredients and processes that, when utilized properly, can create products that may be inhibitory and/or lethal to pathogens.

One product characteristic often ignored and definitely under-utilized is total acidity. Processors and regulators have become overly infatuated with pH and seem to forget that some foods have greater buffering capacity. Mayonnaise is routinely blamed for outbreaks associated with products like chicken or egg salad, but it is not the mayonnaise that is the culprit. Mayonnaise has a very high total acidity, which makes it a very safe product. Don't forget to look at the ingredients and finished product characteristics and relate those how pathogens and spoilage organisms may be inhibited.

## 9. 5S Adoption

5S may be defined as a program to reduce operational steps and improve the overall cleanliness of a work area, making it safer and more productive. This definition can be expanded to say that development and implementation of the program can also enhance overall food safety and quality. If one wishes to summarize the 5S program, it can be described simply as "Everything has a place and everything in its place." The program was first developed in Japan with the five "S"s as *seiri*, *seiton*, *seiso*, *seiketsu*, and *shitsuke*. These translate to sort, set location, shine and sweep, standardize, and sustain.

I encourage processors to consider the 5S method. It can, as noted above, enhance food safety, quality, and sanitation simply by better organizing overall operations. Companies that have implemented the program are generally amazed when they discover how much junk they got rid of with the first step of "sort." This frees up space in the warehouses, production area, and other locations. Think about it: How much stuff do you have in your facility that simply collects dust? Employees in the shop never want to get rid of things as they "might" use it someday. If you ask how long something has been here, you'll often get an answer like, "Before I joined the company, which was 10 years ago."



## 10. Educate, Educate, Educate

A company can never devote too many resources toward educating its workforce. Education starts as soon as a worker joins the company. He or she will undergo an orientation that should address food safety, sanitation, allergen control, personal hygiene, food defense, worker safety, and other topics. Workers need to be trained on each task they perform, and those sessions must be properly documented. It is not simply a question of making sure that a person knows how to do a task properly; it is, unfortunately, also a

liability issue. To ensure foods are safe, workers must follow the documented procedures, so training must be based on those procedures. Refresher sessions are recommended on a yearly basis.

**Don't forget to look at the ingredients and finished product characteristics and relate those how pathogens and spoilage organisms may be inhibited.**

Part of the education process is addressing the potential worker safety issues and making sure they understand that phase of the job. Are they handling chemicals? Then they must be taught about safe chemical handling and proper use of personal protective equipment. This needs to be documented. If a worker is injured on the job as a result of a chemical, the company will be liable for the injuries. If there is no record that the person was properly trained, then the company can be deemed negligent and may pay penalties.

It is imperative that training materials be applicable to the job and the plant. Utilize group exercises, take pictures of operations in the facility so it is more germane to the tasks at hand, and encourage participation. Make the learning enjoyable. Many workers look at training as a pleasant break from their day-to-day job, so consider this aspect in developing and scheduling educational programs.

Another potential benefit of such programs is they may help a company keep its workers. With reduced turnover, a company has a stronger and more knowledgeable workforce and educational costs may be reduced since it takes more time and effort to work with a new employee.

If you're already doing some or all of these, I say "Bravo!" If not, there's no time like the present to get started. Good luck in 2019! ■

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References Provided By Request



# Testing

SEAFOOD



## Targeting Shellfish Toxins

Stringent testing programs stop unique threats in seafood

BY ALLISON HAMMERLY

Seafood products present unique food safety concerns beyond the usual pathogens and other risks—the marine environment from which they are harvested creates conditions that can threaten consumer health in different ways from the most common forms of food poisoning. Shellfish can be contaminated with a number of marine biotoxins, and certain species of fish are prone to building up damaging levels of histamine toxin in their systems as they decompose. Proper sanitation and traditional kill-steps cannot prevent these food safety threats, so testing becomes the key way for producers to protect consumer health.

### Shellfish Toxins

The principal way for shellfish producers to safeguard consumers from the damag-

ing effects of shellfish toxins, and to meet regulatory limits for those toxins, is a stringent testing program. Shellfish toxins are heat stable, meaning there is no cooking kill-step to eliminate them in food. They are also invisible to the naked eye, making scientific testing the only way to identify their presence.

Shellfish toxins are produced naturally by marine microalgae, and they reach problematic numbers only when large algal blooms form in the water. Bivalve shellfish such as mussels and oysters are filter feeders, feeding on small particles in the water including toxin-containing microalgae. The toxins from the algae can bioaccumulate to levels that can harm any organism that consumes the shellfish, in-

cluding humans; the toxins do not harm the shellfish themselves, however.

“Because these blooms tend to form in warmer waters, shellfish producers often ramp up their testing in summer months,” says Neogen’s Kevin Mullholland. “However, in the face of gradually warming ocean temperatures, blooms have been popping up more frequently during the rest of the year in traditionally cooler waters around the globe. Experts have noted the possibility of more frequent algal bloom events in the future, requiring toxin testing more often across a wider area.”

### Well-Known Types of Poisoning

#### **Amnesic shellfish poisoning (ASP).**

This condition is caused by domoic acid, which is produced by *Pseudo-nitzschia* spp. diatoms (a type of microscopic algae). Razor clams are most commonly associated with ASP, but mussels, crabs, and oysters can also be contaminated with domoic acid. In addition to nausea, vomiting, cramps, and diarrhea, ASP can cause neurological symptoms: confusion, dizziness, headaches, seizures, cardiac arrhythmia, and short-term memory loss that can become permanent. Symptoms usually occur within a day, and neurological symptoms take closer to 48 hours. Severe cases can lead to death.

#### **Diarrhetic shellfish poisoning (DSP).**

Okadaic acid produced by the dinoflagellate *Dinophysis* causes DSP. The symptoms of DSP are generally more mild than other forms of shellfish poisoning, and include abdominal cramps, nausea, vomiting, and diarrhea.

#### **Neurotoxin shellfish poisoning (NSP).**

Breve-toxins or their analogs cause NSP, which can trigger nausea, vomiting, and slurred speech when consumed.



#### **Paralytic shellfish poisoning (PSP).**

An unusually high mortality rate is associated with PSP. The condition is caused by any of about 20 toxins derived from the neurotoxin saxitoxin. It is most often associated with molluscan shellfish, gastropods like moon snails, and

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crabs that feed on other shellfish. It takes usually under two hours for symptoms to appear in an infected person. Symptoms include tingling mouth, fingers, and toes, followed by a loss of motor control in the arms and legs. If enough toxin is consumed, a person might experience difficulty breathing or even paralysis of respiratory and chest muscles, causing suffocation. For these reasons, PSP can quickly become deadly.

“The issue producers face, then, is finding a consistent, accurate, and easy-to-use method for testing their shellfish for the toxins that produce these conditions,” says Neogen’s Brooke Roman. “Testing methods can be qualitative, meaning they simply screen for the presence of any given toxin, or they can be quantitative, meaning they provide a precise value that can be used to determine where a product’s toxin level is at relative to regulatory limits.”

### Toxin Testing Methods

There are multiple ways to test for shellfish toxins, and the method a producer uses depends on their capabilities and needs.

A more recent technological development in the field of shellfish testing is the lateral flow immunoassay. Often compared to home pregnancy tests, these test strips screen for the presence of specific marine biotoxins and offer results in just minutes.

An example of how these tests work is as follows: A shellfish sample, prepared for testing by a simple extraction process, is absorbed into a test strip, and travels upwards toward a reagent (a substance that provokes chemical reactions). This reagent zone contains antibodies specific for the targeted toxin. If the toxin is present in the shellfish extract, a chemical reaction will occur, resulting in lines being displayed on the test strip that indicate a negative or positive result—no toxin is present, or toxin is present above a predetermined level. Most tests take under 10 minutes to complete from start to finish.

Some test strips can be read visually. However, visual interpretation of the results between different people can vary. Problems can arise when differentiating between low positives and high negatives. In light of this, some companies now offer electronic readers that re-



For testers processing a large number of samples, immunoassays are available in microwell formats, which allow the testing of up to 96 samples at the same time.

move user subjectivity when reading the test strips. The electronic readers can be networked and can also store test data, making recordkeeping easier for the user.

“These tests are easy for anybody to conduct, and don’t require specialist training,” says Roman. “They’re portable, making them easy to use right on the boat or elsewhere onsite or in the field. They’ve made testing easier and more affordable for operations that use them.”

For testers processing a large number of samples, immunoassays are available in microwell formats, which allow the testing of up to 96 samples at the same time. These formats are often known as ELISAs (enzyme-linked immunosorbent assays) or EIAs (enzyme immunoassays).

“For those unable to test onsite, sending samples to independent laboratories is another method,” says Mulholland. “These methods are highly scientific and are run by experienced chemists. Most lab tests for shellfish toxins are liquid chromatography methods, including liquid chromatography-mass spectrometry (LC-MS) and high-performance liquid chromatography (HPLC). These are quantitative methods that can identify toxins in a wide range of shellfish from around the world.”

Both HPLC and LC-MS work by deconstructing the compounds that make up shellfish toxins. The sample and a sol-

vent are pumped through a column with packing material that makes molecules with certain properties travel faster, while others travel more slowly. A reader analyzes the separated compounds to determine the substances that made up the original sample.

### Histamine

A chemical compound, histamine is released by cells when damaged (or as part of an allergic reaction). High levels of histamine may develop in a variety of fish species as they decompose, especially when they are not kept at suitably cold temperatures. These species include tuna, mahi-mahi, marlin, bluefish, sardines, anchovy, bonito, herring, and mackerel. Histamine poisoning is also sometimes known as “scombroid poisoning” because some of the earliest fish associated with the condition were members of the suborder *Scombridae*.

When it affects humans, histamine poisoning can cause red blotches to appear on the skin, nausea, a burning sensation in the mouth, headaches, muscle weakness, abdominal pain, diarrhea, wheezing, and swelling of the face and mouth. Symptoms can appear within a half-hour of consumption and usually last a few hours.

“In rare cases, histamine poisoning has been deadly, and so histamine testing of fish products is generally considered an important part of a Hazard Analysis and Critical Control Point plan for certain fish species,” says Roman.



Both lateral flow and microwell tests are available for histamine testing and are just as easy to run as similar tests for shellfish toxins. Laboratory testing methods, such as HPLC and LC-MS, can also be used to determine histamine levels. ■

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# In The Lab

PATHOGEN CONTROL

## Aim High When Detecting Pathogens in Low Moisture Foods

From validated and verified cleaning regimens to automated pathogen testing practices, detailed workflows are helping processors deliver safe products

BY RAJ RAJAGOPAL, PHD



**L**ow moisture foods (LMFs)—foods that are naturally low in moisture or made through processes such as drying or dehydration from higher moisture foods—include but are not limited to cereals and grains, flours, milk powder, powdered infant formula, spices, chocolate, dried fruits and vegetables, nuts and nut products, dried protein items, coffees and teas, pet food, and animal feed. LMFs have low water activity, a measure of free water that is an important factor in food safety because it determines the amount of water available to help microorganisms grow.

For many years, it was thought that LMFs were safe from microbial contamination. After all, LMFs are defined as having water activity levels less than 0.85 and most bacteria (including pathogens like

*Salmonella* and *E. coli* O157) need water activities of 0.91 or higher to grow.

However, just because these bacteria have growth challenges doesn't mean they can't survive. Numerous outbreaks of foodborne illnesses have been linked to LMFs contaminated with *Salmonella* spp. (peanut butter, chocolate, milk powder, crackers, almonds, infant cereals, spices), *Bacillus cereus* (rice, nuts, herbs, spices), *Cronobacter sakazakii* (powdered infant formula), *Clostridium* spp. (herbs, spices, dried tofu), Shiga toxin-producing *E. coli* (STEC) strains (flour, walnuts, almonds, rice, seeds), and *Staphylococcus aureus* (rice, seeds, nuts, almonds). It is generally agreed that pathogenic bacteria can remain viable in these foods for long periods of time and, given the opportunity and right conditions, can grow and cause

illness. Several studies have documented long-term survival of pathogens in LMFs, and *Salmonella* spp., STEC, and *Cronobacter* survive from days to years in low moisture conditions. In addition, the pathogens show increased resistance to heat treatment in LMFs and exposure to low water activity confers cross-tolerance to other stresses, including low pH, bile salt tolerance, resistance to disinfectants, UV irradiation, and heat. The pathogens in LMFs have also been shown to have a low infectious dose (10 to 100 CFU) to cause illness. This is well documented from several studies of *Salmonella* outbreaks from LMFs (chocolate, peanut, paprika powder, and others), where very low numbers of cells were present in the contaminated product (about 13 CFU/g) in contrast with the high infectious dose ( $>10^5$  CFU) for other contaminated foods.

Consequently, there is a global recognition that these foods need to be monitored and managed for microbiological hazards, and many regulatory agencies including FDA, USDA, Health Canada, European Food Safety Authority, and Codex have developed guidelines for managing these foods. FDA has developed the Preventive Controls rule for human food and animal food that can come in contact with humans. Similarly, the Codex Alimentarius Commission has developed a [Codex Code of Hygienic Practice for Low Moisture Foods](#). Increased surveillance of LMFs has been implemented under the Food Safety Modernization Act (FSMA), Canadian Food Inspection Agency's Food Safety Action Plan, and Codex guidelines. In addition, several industry guidelines describe methods to limit or reduce *Salmonella* and other pathogens in nuts, spices, and other foods (see Table 1).

Pathogens are most often introduced in LMFs via contaminated ingredients or cross-contamination during processing. Regulatory agencies such as FDA therefore recommend conducting hazard analyses for preventive controls for human food, and manufacturers need to consider the potential for biological, chemical, and physical hazards relating to their raw materials and other ingredients (ingredient-related hazards), processes (process-related hazards), and the food-production environment (facility-related hazards). Regulatory guidelines



Table 1: LMF industry guidance for pathogen reduction

Source	Guidance	Link
GMA (2009a)	The Grocery Manufacturers Association (GMA) <i>Salmonella</i> control guidance	<a href="http://www.gmaonline.org/downloads/technical-guidance-and-tools/Salmonella-ControlGuidance.pdf">www.gmaonline.org/downloads/technical-guidance-and-tools/Salmonella-ControlGuidance.pdf</a>
GMA (2009b)	GMA's annex to control of <i>Salmonella</i> in LMF	<a href="http://www.gmaonline.org/downloads/wygwam/Salmonellaguidanceannex.pdf">www.gmaonline.org/downloads/wygwam/Salmonellaguidanceannex.pdf</a>
GMA (2010)	GMA's industry handbook for safe processing of nuts	<a href="http://www.gmaonline.org/downloads/technical-guidance-and-tools/Industry-Handbook-for-Safe-Processing-of-Nuts-1st-Edition-22Feb10.pdf">www.gmaonline.org/downloads/technical-guidance-and-tools/Industry-Handbook-for-Safe-Processing-of-Nuts-1st-Edition-22Feb10.pdf</a>
ASTA (2017)	The American Spice Trade Association's clean safe spices	<a href="http://www.astaspice.org/download/129">www.astaspice.org/download/129</a>
AFIA (2010)	The American Feed Industry Association's <i>Salmonella</i> control guidelines	<a href="http://www.ucfoodsafety.ucdavis.edu/files/172958.pdf">www.ucfoodsafety.ucdavis.edu/files/172958.pdf</a>
Anderson, DG, Lucore, LA (2012)	Validating the reduction of <i>Salmonella</i> and other pathogens in heat processed LMF, by the OpX product safety solutions group	<a href="http://www.opxleadershipnetwork.org/food-safety-plan-validation/download/validating-reduction-salmonella-and-other-pathogens-heat">www.opxleadershipnetwork.org/food-safety-plan-validation/download/validating-reduction-salmonella-and-other-pathogens-heat</a>

also recommend good hygienic practices, hygienic design of equipment, proactive maintenance programs, control of incoming materials, and effective ingredient control in the LMF establishment to prevent contamination. The Codex advises that special attention be paid to those products exposed to the processing environment following a pathogen reduction step (such as almonds and pistachios), products that are not subjected to a pathogen reduction step (such as flour and dry mixes), and products for which ingredients are added after a pathogen reduction step (such as herbs and spices).

### Beyond Finished Foods: Production Environments

In contrast to the historical focus on testing finished products for pathogens just prior to release with little or no attention given to the processing operation and environment, new guidelines and regulations place more attention on environmental monitoring and entire process operation as means to prevent pathogen contamination.

The FSMA Preventive Controls rule, for example, focuses both on environmental monitoring and finished product testing for human food. In addition to recommending that raw materials, ingredients, and end products be tested, FSMA highly recommends environmental monitoring of pathogens in LMF and ready-to-eat (RTE) food processing environments. According

to FSMA, “Foods such as peanut butter, soft cheeses, dried dairy products for use in RTE foods, and roasted nuts are among the products for which manufacturing operations would need to have an environmental monitoring program when such foods are exposed to the environment.”

In addition, when environmental monitoring results are gathered both prior to and following cleaning, manufacturers gain a good sense of the overall effectiveness of their hygiene controls and sanitation program. Armed with strong before and after data, they can make the necessary adjustments to improve cleaning strategies, practices, and training.

Carefully designed and implemented sampling programs also bring the benefit of detecting sites potentially harboring pathogens. To that end, LMF manufacturers are advised to perform environmental swabbing and analysis using a hygienic zoning system based on food safety risk. An example would be Zones 1 through 4, with Zone 1 being product contact surfaces, Zone 2 being surfaces immediately over or next to the product, then moving to Zones 3 and 4, with Zone 4 being furthest from the product.

### Pathogen Control in LMFs

Every step of the LMF production chain—from sourcing of raw commodities and ingredients, preventing cross-contamination from harvest, to post-process, employing effective dry cleaning and san-

itation processes, and implementing and monitoring validated lethal processes—is critical to ensure safer LMFs. Although today's thermal (heat) processes coupled with continuous monitoring are probably adequate, there is significant room for improvement.

Thermal processes for nuts include oil roasting, dry roasting, and blanching as more traditional practices, but heat can also be applied through steam, infrared heat, and other means. Pasteurization has been successfully applied to raw almonds to reduce the presence of *Salmonella*. Some emerging technologies for LMFs include radio frequency and microwave heating, nonthermal plasma, pulsed light, UV light, irradiation, propylene oxide, ozone, and novel drying technologies such as microwave drying, vacuum drying, super-heated steam drying, infrared drying, and freeze drying. Although high-pressure processing has been successfully applied to high moisture foods, efficacy in LMFs is not well understood. Additional research is needed to understand these technologies' application to LMFs.

### Pathogen Detection Technologies and LMFs

Eliminating or preventing pathogens entering the production process through raw material screening and finished product testing are key to ensuring safe product is delivered. Unfortunately, processes that rely on inadequate or incorrectly used technologies can thwart a lot of well-meaning work.

High-performing pathogen testing technologies are able to identify intact pathogens, as well as pathogen cells that may have been damaged by freezing, drying, antimicrobial treatments, or other processing conditions. Pathogen detection methods typically require an enrichment step to allow bacteria to grow to detectable levels, and this nourishment and recovery step is especially critical for LMFs. Pathogens in these foods can be severely dehydrated due to the low water activity, and recovery and detection of desiccated bacteria from dry matrices and environments is critical.

Manufacturers of food—LMFs or otherwise—mostly utilize one of two test tools for detecting the bacteria in their low mois-

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ture products: culture-based tests and rapid methods. Traditional culture-based tests rely upon growth of pathogens in a selective media followed by counting of visible colonies based on certain traits, such as their ability to grow in the presence of a particular chemical (e.g., salts, bile) or their ability to utilize particular chemicals or nutrients. Rapid methods for foodborne pathogen detection have evolved over the last several years with fundamental advances in immunology and molecular biology and applications of these advances to testing methods. The accuracy of these rapid methods is generally validated against the same standard methods used in culture methods—FDA BAM, ISO, or USDA MLG, for example. However, compared to traditional culture tests, these rapid methods not only offer enhanced accuracy but drastically reduce the time-to-result of food testing (next day findings rather than three days to a week) and provide greater ease of use.

When it comes to rapid methods, antigen/antibody-based assays such as ELISA or lateral flow have been in use for many years, but a growing concern with these methods is the cross-reactivity with non-target organisms. DNA-based methods are generally considered to be more accurate, as they target a specific and unique DNA sequence of the bacteria.

Among the several kinds of DNA-based rapid methods, polymerase chain reaction (PCR) has been widely used for foodborne pathogen detection, and there are multiple vendors offering validated PCR methods to detect *Salmonella*, STEC (O157 and non-O157), *Listeria* spp., *L. monocytogenes*, *Cronobacter*, and other organisms. PCR uses *Taq* polymerase and repeated cycling (heating and cooling) to



The 3M Molecular Detection System offers a sample preparation process without DNA extraction and purification steps.

Table 2: LAMP vs. PCR comparison

LAMP	PCR
Isothermal reaction (60°C to 65°C)	Thermal cycling reaction (repeated heating and cooling at 95°C and 60°C to 72°C)
Uses four to six primers based on the six distinct regions of the target gene	Uses only two primers
Loop primers accelerate the reaction and increase sensitivity (two additional recognition site)	Use of probes in real-time PCR add additional specificity and enable ease of detection
Simple, inexpensive instrument	Needs thermocycler (heating and cooling) and expensive instrumentation for fluorescence detection
LAMP bioluminescent technology enables real-time detection	Results available at the end of the run (>1 hour)
Tolerant to sample matrix inhibitors	Sensitive to sample matrix inhibitors
Streamlined protocols (similar for all targets), with minimal steps	Varied protocols and run conditions (depending on target)

amplify DNA, relying on instrumentation capable of rapidly heating and cooling. In addition, PCR methods typically require multiple steps for processing enriched food samples and amplify target DNA for detection of pathogens.

Newer DNA-based methods such as the LAMP (loop mediated isothermal amplification) technology that 3M commercialized offer an alternative to PCR (see Table 2). These tests are also globally validated for their ability to detect the *Salmonella*, *E. coli* O157, *Cronobacter*, and other key pathogens implicated in LMFs, but with fewer steps and simpler instrumentation. LAMP uses *Bst* polymerase that has strand displacement activity, allowing amplification at a single temperature without the need for cycling through series of temperatures. In addition, *Bst* polymerase has been shown to be more resistant to inhibitors from media or food matrices that may compromise PCR results. The 3M Molecular Detection System based on LAMP integrates a proprietary bioluminescence solution for detection that offers a sample preparation process with only two transfer steps and no need for DNA extraction and purification steps.

The PCR and LAMP assays have been validated for various LMFs. Manufacturers need to select an appropriate method to fit their purpose and need based on comparative benefits such as cost, ease of use, and validations.

Lastly, whole genome sequencing (WGS) provides the complete DNA makeup of a test subject, allowing organisms to be differentiated with precision not possible

with other technologies. WGS is an emerging technology for food safety applications, but it is mainly being used by regulatory agencies such as FDA and USDA to pinpoint sources of contamination during outbreaks. Its wide use for routine food safety testing is debatable given the cost and complexity of the method.

### LMF, High Economic Pressure Businesses

The LMF industry is focusing on major changes to produce the highest food quality. New requirements are being enacted in supply chain controls, environmental monitoring programs, training, and recordkeeping. Greater enforcement of food safety laws and regulations is pushing LMF manufacturers to place safety at the forefront.

LMF processors are forced to balance countless procedural, competitive, and economic pressures alongside needs to cut testing time and release products to market faster. But as recent outbreaks and recalls attest, it's imperative that they not take their eye off the ball when it comes to food safety. With goals of mitigating risk at every step and improving operational efficiencies and productivity, thoughtful workflows—from expertly designed, validated, and verified cleaning regimens to more automated pathogen testing practices to safe storage approaches—can help LMF products safely and sufficiently reach consumers. ■

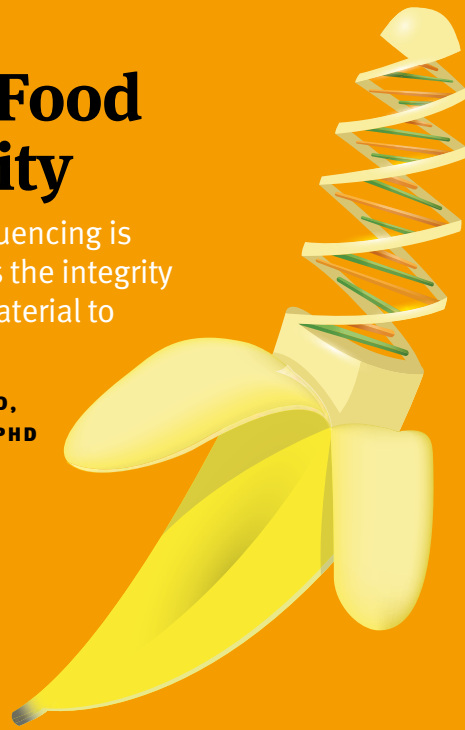
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References Provided Upon Request

IMAGE CREDIT: 3M FOOD SAFETY

# DNA and Food Traceability

Next-generation sequencing is being used to assess the integrity of food from a raw material to a final product

BY **MÁRIO GADANHO, PHD,**  
AND **FRANCK PANDIANI, PHD**



**T**oday's food industry is truly global, involving producers and manufacturers from around the world. Consumers are increasingly demanding transparency about food composition. However, ensuring traceability along the entire supply chain, from primary production to the end-consumer product, is challenging. The number of intermediaries and geographical locations involved in manufacturing processes creates a network that requires the most advanced traceability systems.

On the analytical side, food traceability remains a challenging topic. The aim of the traceability system is to guarantee the integrity of food from a raw material to a final product for the end consumer. Many methods have been proposed to track ingredient composition and identification along the supply chain. However, until now, very few methods have been identified that can really tackle this complex problem. These include DNA-based methods more focused on species identification and chemical methods, like stable isotopic analysis, which is a very powerful tool for origin and wild/farmed ingredient tracking.

Within food traceability, one of the hot topics is food authenticity to guarantee the correct composition of a product according to the description of that product and what is expected to be included in it.

Today we are seeing food authenticity being introduced to the routine testing and regulatory arena. Recent food fraud scandals mean it is imperative that the industry be able to identify the food ingredients that compose each food product, whether meat-, fish-, or plant-based. However, ready-to-eat products that are generally composed of several ingredients are more complex, particularly if those ingredients are sourced from different geographical origins, each with its own requirements. This means that the global food industry needs to adapt to the challenges presented by a dynamic and rapidly growing food market.

## Popularity of NGS

The introduction of DNA-based tracing methods brings new and very powerful tools for identification of many ingredients in processed food products. One of the most recent DNA-based methods introduced for food analysis is next-

generation sequencing (NGS). This method is dramatically changing the analytical approach, moving from the detection of one or a set of species to determining all species in a sample.

Currently, NGS is the only method that ensures the correct identification of species in complex foods. Its use by all major laboratories for food authenticity analysis is increasing.

The NGS method is based on DNA analysis through DNA sequencing and produces millions of individual DNA sequences all grouped in a single file. With NGS, different sequences can be produced from the various DNAs composing the food product. This means that the method is appropriate to use in products containing many ingredients visually not identifiable and mixed. Basically, since each different ingredient contains a unique DNA sequence (its own fingerprint), NGS will virtually sequence each one of the DNA molecules present in a sample to produce individual DNA sequences for each. Therefore, unlike the Sanger DNA sequencing method that originates only one DNA sequence from a food sample, NGS is the method of choice for DNA sequencing identification of products containing multiple ingredients.

Using appropriate software, the scope of NGS is virtually unlimited and it can be used on any kind of sample DNA, whether it contains different DNA sequences or not. This means that any kind of species can be detected, as the analytical method is no longer focused on detection of a limited number of species. Despite different NGS platforms available in the market, all of them are used to obtain sequences of defined regions in the DNA molecules and produce huge text files containing millions of individual sequences.

Specific genes are well known for species identification and include nuclear (e.g., ribosomal RNA genes), mitochondrial (e.g., COI), and chloroplast (e.g., rbcL). When a sample is analyzed the question is no longer: "Are species X, Y, or Z present in the sample?" Using NGS the question is: "Which species are present in the sample?"

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Since all sequences obtained can be compared with a specific DNA database, each match between the obtained NGS sequences and the database originate a species ID result, producing a list of species instead of a presence/absence result for targeted species. Additionally, using appropriate software, a ratio of DNA sequences obtained for each species can be created. Due to the untargeted nature of this method even exotic species can be identified.

### The Challenge of Fragmented DNA

DNA-based methods are limited by the need to obtain DNA fragments with the necessary integrity to perform the analysis. In some products, specifically those that have been highly processed, ingredient DNA can be highly fragmented or even absent. When DNA is highly fragmented, it is essential to guarantee that the DNA-based method used will allow the detection of DNA fragments as small as 100 base pairs, or even lower.

The smaller the DNA fragment to be analyzed, the more difficult it is to differentiate between closely related species. The best strategy is to use a DNA sequencing method that obtains the full nucleotide (A, T, G, C) sequence of the target region to be analyzed. Real-time polymerase chain reaction's (PCR's) fluorescent signal is a limitation for the detection of cross species reactivity, and may produce false positive results, especially in complex food products containing multiple ingredients.

### DNA Barcoding Strategy

Probably the most well-known use of DNA sequencing for food authenticity is the DNA barcoding strategy that is already in use by many regulatory entities in the sector. Perhaps one of the most widely used barcoding methods is the one for fish-based products, enabling fish species identification by regulatory bodies in the U.S. and Europe. However, this method is not suitable for processed samples that contain multiple ingredients (species) as it only enables the identification of a unique species. Food products containing multiple species cannot be analyzed with this approach.

With NGS a similar barcoding approach can be used by sequencing defined

DNA regions and comparing the results with the same DNA/species databases used for the classic Sanger DNA sequencing approach.

### The DNA Sequence Database

One of the key points when using a DNA-sequence producing method like NGS is the reliability of the databases that are used for species identification. Many efforts have been made in recent years to try to ensure the reliability of the DNA sequences contained in the databases, including using reference material that is



Recent food fraud scandals mean it is imperative that the industry be able to identify the food ingredients that compose each food product, whether meat-, fish-, or plant-based

sequenced and included on the database. Using bioinformatic tools to analyze public data is also valuable work so long as the DNA sequence analysis tools are used correctly. The use of multiple DNA alignments and phylogenetic analyses is crucial for ensuring the reliability of the sequence included on the databases. Because NGS is highly customizable, it makes it possible for any lab to produce its own DNA database to ensure its quality.

### Wider Availability of NGS

Given the recognition of NGS as a powerful tool, the first workflow for using NGS for species identification on food was announced for the market in November 2018, making the method available to any

laboratory working in food production. Additionally, NGS has been introduced into standardization, namely at the ISO level, to start to define the minimum requirements related with all pre- and post-bioinformatic analyses required during NGS analysis. This includes not only the DNA sequence itself that depends on the NGS platform used, but also the definition of the DNA regions to be analyzed and the DNA databases used for species identification.

The availability and use of an untargeted approach is of great importance. Experience tells us that when authenticity issues are involved, a targeted approach is not suitable, as it will only deliver a result for the species targeted. If a product contains any additional species besides those targeted by PCR analysis, no information will be available.

### A Changing Regulatory Landscape

Along with issues of authenticity, local regulators respond to increased concern about anything that can impact human health. This adds more layers of regulation to food markets.

Furthermore, today's consumers are much more concerned about a product's ingredients. There is often a financial concern that they are paying for something that is not as labeled, or is not what they paid for. Additional consumer concerns relate to allergens, food intolerances, species protection, and species sustainability, amongst others. Nutritional content is highly dependent on a product's ingredients, and the full or partial substitution of any specific ingredient can impact this. Any of these concerns can be highly damaging to a food brand as consumers can rapidly lose confidence.

One of the biggest advantages of NGS testing is its untargeted nature that enables full knowledge of the DNA content of a food sample. In addition, virtually any kind of DNA sequence can be identified using the appropriate bioinformatic tools available. The use of NGS can have a huge impact on all matters related to food integrity including authenticity, safety, and traceability. ■

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# Manufacturing & Distribution

TRACKING & TRACEABILITY



advancements in produce safety systems are needed to provide the unseen but accessible data and documentation layers behind the lot coding transaction ledgers.

## Why Trace?

Traceability is a key component in any modern food safety program and can be an important companion tool in quality management and improvement efforts. Adopting a sound- and scale-appropriate traceability system isn't just good business practice—your operation may be covered by federal regulations under the Food Safety Modernization Act (FSMA). These regulations require a recall program, which minimally dictates having a rudimentary track and trace system in place. The basic requirement is to be able to determine one step back and one step forward in all aspects of product handling and distribution to the end-consumer. This necessitates the ability to determine what product was received, who it came from, and what was done with it. For raw agricultural commodities, current market standards may require product receivers and handlers to have in place a routinely tested and verifiable traceability system to rapidly get back to a harvest date, a harvest crew, a mobile or mechanized harvesting unit, and even a field location.

Businesses meeting the current definition of a farm that are growing, harvesting, handling, or holding covered crops subject to the FSMA Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Standards, or PSS) are not required to have a formal food safety plan or traceability system. Regardless, many handlers, market-standards, and “approved-supplier” audit requirements from buyers mandate at least the one-step-back-one-step-forward tracking capability, including clear and defensible lot coding practices. Sprout growers are similarly covered under the PSS but have additional testing, recordkeeping, and

*(Continued on p. 40)*

## Fitting Traceability into Produce Safety: Keeping it Real

A traceability program is like insurance coverage that is activated during recalls and foodborne illness outbreaks

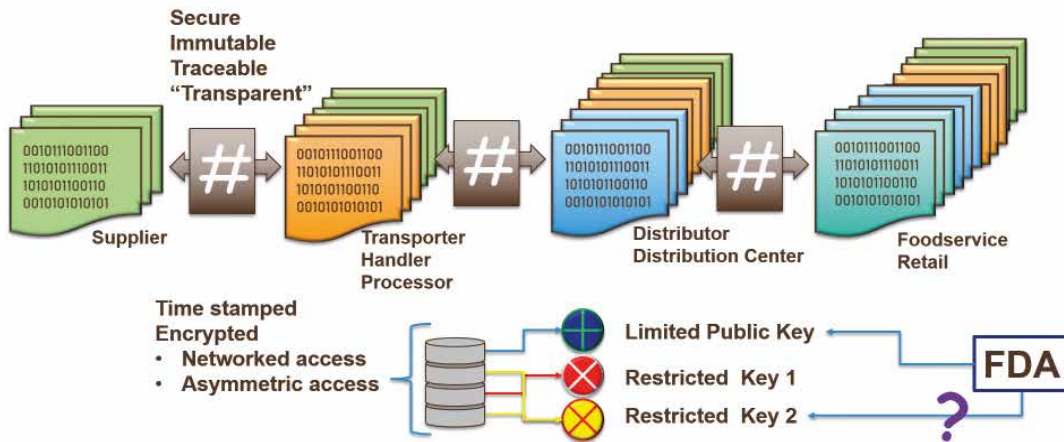
BY TREVOR SUSLOW, PHD, ED TREACY, JOHNNA HEPNER, AND VONNIE ESTES

**T**he first step on the road to preventing the next multistate foodborne illness outbreak is honesty and openness throughout the supply chain, and broader adoption and participation in existing and emerging supply chain traceability tools is an important part of this. The hard work ahead to advance public health protection is much more than instantaneous lot tracking based on distributed ledger technologies (now often and more generically referred to as blockchain) or alternative open-participation traceability platforms. Clearly this is an important investigative tool needed to serve the food industry by

assisting public health agencies during an emerging outbreak.

However, it is also a largely retrospective tool as far as illness prevention is concerned. It is activated several steps after an outbreak is recognized and the hypothesis generation and epidemiological process has begun to focus in on a common, implicated food vehicle.

Having an unbroken and timely traceability chain may prevent further exposure and illnesses by removing contaminated product from distribution, inventory, food establishments, and consumer kitchens, refrigerators, and freezers. Significant enhancements in training and foundational



(Continued from p. 39)  
recall-motivated tracking requirement expectations.

Traceability and recall programs are mandated for registered facility businesses that are subject to the FSMA Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. They must encompass the potential need, based on the hazard analysis, for supply chain controls and oversight management related to the FSMA Foreign Supplier Verification Program.

The ability to trace product into and out of an organization is like taking out an insurance policy: Most times it is not needed, but when it is, it proves highly beneficial. A well-designed and managed track-and-trace program will prove its value in times of crisis and in preserving your organization’s credibility. Recent experiences during the 2018 romaine lettuce outbreaks have, once again, graphically underscored the high potential for substantial collective economic losses and erosion of consumer confidence resulting from lapses and gaps in step-wise, hand-off-to-handoff supply chain traceability.

Such a system can also be used defensively or offensively in a product quality claim or dispute, in conjunction with an internally or externally activated stock recovery, market withdrawal, recall, or related to an outbreak investigation. One of the key benefits of a good traceability system is that it expedites removing your company from the implicated pool of suppliers in the event of a recall or outbreak. Another benefit is that it can rapidly

and efficiently provide implicated lot information for public health investigators as they conduct a traceback effort based on epidemiological evidence. Equally, rapid and definitive tracking allows you to communicate clearly and in a timely manner with your customers and, ultimately, your customer’s customers along the supply chain.

**The Required Elements**

The requirements of a good traceability system are capturing and recording the key data elements at the critical tracking events.

Critical tracking events are those instances where product is moved between premises, is transformed, or any instance that is determined to be a point where data capture is necessary for effective tracing.

Specifically, the critical tracking events are:

1. Transformation input (used to create another product or item);
2. Transformation output (product creation or manipulation);
3. Shipment;
4. Receipt;
5. Disposal; and
6. Consumption.

The ability to query and extract key data elements in a seamless manner is critical. The key data elements that should be digitally captured, stored, and electronically retrievable are:

- Item number or Global Trade Item Number (GTIN) and uniquely identifiable product description\*;
- Quantity on hand;

- Physical location at which the product was last handled, whether at the packer, processor, or another location;
- Incoming lot number(s) of product received;
- Amount of product created, packed, shipped, consumed, or eliminated from lot association;
- Continuity of an incoming lot or record of lots included—for example, following comingling or repacking to create a new lot code;
- All physical locations to which cases were shipped;
- Lot number(s) shipped to each location;
- Date(s) and time(s) product was received and/or shipped to all locations;
- Date(s) and time(s) each lot was packed, processed, or harvested; and
- If applicable, all ingredients used in product, with lot numbers, facility at which they were manufactured, and date(s) and time(s) they were received.

There are many system applications that record the key data elements at all critical tracking events in use in the fresh produce industry today. Some of these applications are utilizing the blockchain data sharing protocol while others run on proprietary databases. These applications are designed to provide supply chain transparency while also providing traceability. The value of these visibility platforms is to gain a supply chain-wide view of the products from harvest through to point of sale to the consumer to identify when there are delays, unnecessary steps, or less-than-ideal conditions. It is reason-



able to anticipate that transparency in time temperature controls for food safety, alluded to briefly below, would also be captured and visible in modern traceability systems.

Complete “mass balance” of each lot is an attainable goal of sound traceability systems. Ability to account for 100 percent of product received or created is a must. It is equally as imperative for lot number and manufacturing facility to appear on each case of product, and lot number(s), quantity, and shipping location to appear on invoices and bills of lading as well.

A fresh produce industry best practice capable of executing case-level tracking is the Produce Traceability Initiative (PTI)

## Ability to account for 100 percent of product received or created is a must.

label, which is foundational in functioning as the bridge between the physical goods and any of the tracked information that would be contained within blockchain’s virtual ledger—composed of blocks of linked and sequential data. All traceability systems should be regularly audited, and effectiveness of recall implementation tested to ensure the procedures and training are current and effective.

One of the mandates of FSMA is that FDA work with industry and both assess and conduct pilot traceability programs to improve public health protection. PTI is currently working in conjunction with FDA for evaluating the fidelity and sufficiency of traceback data for these audits and tests, as well as functionality, as in the event of a product recall.

### Standardized and Interchangeable Platforms

Data tracking and collection will be imperative in the coming years. Data stand to become the next most used natural resource. Of the 2.5 quintillion bytes of data created each day across all industries, only 1 percent is collected, analyzed, and used. There is a large opportunity for blockchain

and other technologies to collect data and turn the resultant data mining and analysis into insights and quick actions. This capability will benefit traceability as well as other key aspects including the design, implementation, and oversight of produce safety systems.

Clearly, these digital platforms will be helpful in that they do allow investigators to trace data digitally all the way back to harvest, and beyond into crop management inputs, upon request. This is a significant advancement over the basic requirement of bi-directional one-step increments already in place within many traceability programs, and not just among the larger producers. A diversity of data capture and software solutions are available, but, unfortunately, not all inter-compatible.

It is predicted that these digital platforms will be able to link a valid food safety audit to each transaction. This will validate that there is a credible, basic snapshot verification of practices and all supporting required and additional documentation and records are in place from each participant in the supply chain.

Produce Marketing Association (PMA) recently led an effort to enable this process by developing the Trellis Data Framework for digitally sharing audit data. There are also alerts that can and are being set up to flag when there is a discrepancy or violation of time, temperature, humidity, etc. that will complement supply chain visibility applications/platforms in using blockchain technology to supplement food safety systems.

There are many examples of where blockchain technology is being used with PTI and the Trellis framework to record and share relevant audit data across the supply chain. Perhaps the most well-known of these examples is Walmart’s use of IBM’s blockchain technology to monitor and track the data of its fresh produce supply and distribution. Other instances include the Dole Food Co. working with Centricity, a grower-owned partner, to leverage the Trellis framework to connect audit data to the blockchain. These types of pilot programs and collaborative efforts help provide the produce industry with mechanisms to standardize data sharing for more efficient and timelier traceback.

As it stands, the too-common experience is that the “last mile” to the point of purchase or point of consumption is the weakest link in the currently complex and too often gap-plagued supply chain trace-forward-trace-back sequence. This means that the lack of lot numbers and clearly identifiable product information being recorded by buyers or distributors/wholesalers creates a broken link and barrier to establishing clear supply chain convergence in traceback investigations. This invariably slows down or stalls the investigation, limits uncovering the full scope of implicated product distribution, or results in failure to identify a minor, but widely distributed and consumed commodity or ingredient.

While blockchain technologies and traceability systems will help close this gap, traceability itself is unequivocally incapable to fundamentally improve the foundation of food safety programs, and the prevention and mitigation of contamination. Traceability programs, in reality, are the insurance coverage activated only for recalls and foodborne illness outbreaks.

People have a deep, emotional connection with their food. When they hear that there is a problem, they want to know what it is and that the information they are getting about their food is accurate. We often speak about the “race to disclosure.” Speed matters; the faster we can get accurate information to the consumers, the better the outcome for all parties. Traceability can help create strong food safety programs and help build consumer confidence. We as an industry need all participants in the supply chain to do their part in order to have effective whole-chain traceability. ■

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*\* For specialty crops, a uniquely identifiable product description should provide more detail than a category, such as sweet cherry, and should provide a recognized varietal name. Variety differences have proved to be important in projections of defining shelf-life expectations during outbreak investigations and in developing public advisory notifications.*

## Go Fish! *(Continued from p. 13)*

manufacturers have begun to utilize fish meal and fish oil as ingredients, our treats stand out because we are specifically incorporating fish skins into our product to take advantage of the unique functional properties of fish collagen found in fish skins,” he explains.

“These properties give our pet treat product some unique characteristics and nutritional benefits that we believe make them very appealing to dogs and their owners.” ■

**Leake**, doing business as Food Safety Ink, is a food safety consultant, registered SQF contract auditor, and award-win-

ning freelance journalist based in Wilmington, N.C. Reach her at [LLLeake@aol.com](mailto:LLLeake@aol.com).

**For bonus content on the seafood market, go to the February/March 2019 issue at [www.FoodQualityandSafety.com/issue/february-march-2019/](http://www.FoodQualityandSafety.com/issue/february-march-2019/).**

## To BE or Not To BE *(Continued from p. 15)* Enforcement

Failure to comply with the BE food disclosure requirements is prohibited, but the consequences are relatively feeble. The AMS enforcement authority is limited to enforcing compliance through records audits and examinations, hearings, and public disclosure of the results of audits, examinations, and hearings. The Final Rule does not authorize civil penalties or recall authority for violations.

During the rule-making process, some argued that accountability is a

key aspect of a meaningful labeling claim, and that rigorous enforcement provisions were necessary to effectuate the rule. AMS asserted that the enforcement process, which again includes a complaint process, investigations, audits, hearings of limited scope, and resulting notifications to both regulated entity and the public, sufficiently meets the requisite enforcement needs.

Time will tell whether and how these regulations may need to be altered, added to, refined, or repealed. While

the Final Rule will not be perfect for every consumer every time, we are pleased that the Final Rule, whatever its faults, will provide consumers with additional information from which to answer that age-old question: To BE or not to BE. ■

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## Food Defense Is Good ... *(Continued from p. 17)*

- Food defense monitoring procedures (21 CFR 121.140(a));
- Food defense corrective actions procedures (21 CFR 121.145(a)(1)); and
- Food defense verification procedures (21 CFR 121.150(b)).

2. Food defense training and qualifications of supervisors and personnel working at actionable process steps. (21 CFR 121.4)

IA Rule records that must be prepared and kept include:

- The vulnerability assessment—for each point, step, or procedure in the facility's operation, it must evaluate the severity and scale of the potential impact on public health if a contaminant were to be added, and the degree of physical access to the product;
- The ability of an attacker (from outside or inside the facility) to contaminate the product (21 CFR 121.130);
- The mitigation strategies applied at each actionable process step to significantly minimize vulnerabilities—the facility must include a written explanation of how each strategy minimizes the vulnerability (21 CFR 121.135);
- Food defense monitoring of the mitigation strategies with adequate frequency to provide assurances that

they are being consistently performed (21 CFR 121.140);

- Records of food defense corrective actions to be taken if mitigation strategies are not properly implemented (21 CFR 121.145); and
- Food defense verification that monitoring is being conducted, that appropriate decisions about corrective actions are being made, that mitigation strategies are being properly implemented, and that a reanalysis of the food defense plan has been conducted, as appropriate, according to 21 CFR 121.157. (21 CFR 121.150).

### Maintaining Trustworthiness

So, why is food defense good for business?

As a food-related facility covered under the requirements of the IA Rule, trustworthiness must be earned by partnering with others occupying space in the global supply chain. This is done by making a management commitment and resource investment to ensure cooperative understanding and sharing of responsibility to mitigate international product security risks. Even if a food-related facility is not covered by regulatory statute under applicable FSMA rules, including the IA Rule,

commercial agreements between supply chain parties may still contain language that requires FSMA compliance to specific FSMA rules and their provisions prior to engaging in the purchasing, manufacturing, and sale of goods. A relationship in food defense requires honest and effective communication of clear expectations among all stakeholders.

With the exception of an opportunistic intentional terrorist attack using toxic agents, most perpetrators, in their deceit, have no intent of harming life. Sadly, akin to a food safety incident that occasionally escapes detection and control, supply chain food defense breaches that the IA Rule now addresses can have serious adverse health consequences or death for human or animals. Everything possible must be done to intercept these product security issues before they become public health concerns. The chain of food protection and product security custody and trustworthiness, once broken, has already been proven to be both difficult and costly to regain. ■

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## Simplifying Complex World of ... (Continued from p. 19)

be transferred to that product especially on the initial amount of product made after changeover. However, depending upon the amount of residue remaining of the equipment surface and the volume of the next product that passes over that equipment surface, the residues may not always be detectable in that next product. The testing of finished product is the only way to determine if detectable residues are present.

For obvious reasons, food companies are reluctant to test finished food products for undeclared allergens because the presence of such residues means that the product cannot be sold. However, the ultimate validation of an allergen cleaning procedure involves ensuring that no detectable residues are present in the finished product. If a robust swabbing strategy has been used and no allergen residues have been

detected by swab with LFD, then it is very unlikely that allergen residues will be detected in the finished product. In those circumstances, testing of the finished product does serve as the ultimate validation. ■

**Dr. Taylor** is the co-founder and co-director of the Food Allergy Research and Resource Program (FARRP) at the University of Nebraska, Lincoln. Reach him at [staylor2@unl.edu](mailto:staylor2@unl.edu). **Dr. Baumert** is the co-director at FARRP. Reach him at [jbaumert2@unl.edu](mailto:jbaumert2@unl.edu).

## Events



### FEBRUARY

25-28

#### Global Food Safety Conference

Nice, France

Visit <https://www.theconsumergoodsforum.com/events/gfsi-conference>.

### MARCH

6-8

#### Consumer Food Safety Education Conference

Lake Buena Vista, Fla.

Visit <https://cfsec2019.fightbac.org> or call 202-220-0651.

17-21

#### Pittcon 2019

Philadelphia, Pa.

Visit <https://pittcon.org/pittcon-2019>, email [info@pittcon.org](mailto:info@pittcon.org), or call 800-825-3221.

### APRIL

8-11

#### High Pressure Processing Short Course and Workshop

Bedford Park, Ill.

Visit <https://www.eventbrite.com/e/high-pressure-processing-short-course-and-workshop-registration-46418095774>.

### MAY

6-9

#### Food Safety Summit

Rosemont, Ill.

Visit <https://www.foodsafetystrategies.com/food-safety-summit>.

21-23

#### Food Microbiology Short Course

University Park, Pa.

Visit <http://agsci.psu.edu/foodmicro> or call 877-778-2937.

### JUNE

2-5

#### IFT19

New Orleans

Visit <https://www.ift.org/>.

11-13

#### Food and Airborne Fungi & Mycotoxin Short Course

University Park, Pa.

Visit <https://bit.ly/2FNgSZ7> or call 814-865-8301.

17-18

#### 22nd World Congress on Nutrition and Food Sciences

Brisbane, Australia

Visit [www.nutritionalconference.com](http://www.nutritionalconference.com).

18-20

#### 53rd Annual Microwave Power Symposium (IMPI 53)

Las Vegas

Visit <http://impi.org/symposium-short-courses/>, call 804-836-7125, or email [molly.poisant@impi.org](mailto:molly.poisant@impi.org).

### OCTOBER

30-31

#### China International Food Safety & Quality Conference

Beijing City, China

Visit [www.chinafoodsafety.com](http://www.chinafoodsafety.com).

#### Have an Upcoming Event to Promote?

If you have an upcoming industry event that you would like considered for inclusion in our online and print listings, go to [www.foodqualityandsafety.com/events/](http://www.foodqualityandsafety.com/events/) for info or contact Ken Potuznik at [kpotuzni@wiley.com](mailto:kpotuzni@wiley.com).



# NEW PRODUCTS



## Food Processing Sanitation

Elite 360 with Precision Application Technology electrostatically applies an antimicrobial intervention to cover a product, using the least amount of antimicrobial possible, while still being as effective as possible. The Precision Application Technology not only reduces chemical and water usage by as much as 95% and has shown up to a 2.0+ log reduction and 360° product coverage, as well as reducing wastewater treatment costs. Elite 360 is currently on the market for red meat processors and will be available for use in the produce and poultry industries in the second half of 2019. **Birko**, 800-525-0476, [www.birkocorp.com](http://www.birkocorp.com).

## Cloud-Based Label Management System

Label Cloud is a software-as-a-service solution built on the NiceLabel Label Management System. It allows users to centrally manage label design, product data, and quality control, with branches, suppliers, and partners able to access that information in the cloud and print their own labels locally. IT is not needed for design and deployment of labels. Quality assurance is digitalized, eliminating manual quality control processes, reducing labor requirements and costs, and minimizing risk and error. The system is ideal for use in manufacturing labeling, allergen and nutrition labeling, localized re-labeling, and supplier labeling. Label Cloud requires no installation. **NiceLabel**, 262-784-2456, [sales.americas@nicelabel.com](mailto:sales.americas@nicelabel.com), [www.nicelabel.com](http://www.nicelabel.com).

## Supply Chain Quality Management

The Version 8 of SupplyChainMetrix (SMX) includes several advancements in technology and features for the supply chain quality management solution. Updates to SMX include enhanced partner onboarding and maintenance, automated payment processing, and a new option for document-based specification management. Customers can now choose between managing specifications using data-driven forms or as document attachments, expanded ingredients and sourcing functionality, and enhanced configuration management. In addition, there are new features and reports for automating the resolution of product- and guest-related incidents between restaurants/retail locations, distributors, and suppliers. **ComplianceMetrix, LLC**, 858-866-8888, [sales@compliancemetrix.com](mailto:sales@compliancemetrix.com), [compliancemetrix.com](http://compliancemetrix.com).

## Air to Air Heat Exchangers

Lightweight and easy to install, the PKS (Pfannenberg's Kinetic System) Series Air to Air Heat Exchangers take advantage of a cooler ambient environment when closed-loop cooling is required, sealing against gas, humidity, and dust. Designed for indoor, outdoor, remote, and washdown applications that require a closed-loop system to protect electronics, systems are ideal for protecting against corrosion and contamination in the food and beverage industry. Available in five configurations: 22, 45, 64, 100, 150, and 180 watts per °C. **Pfannenberg**, 866-689-0085, [www.pfannenbergusa.com](http://www.pfannenbergusa.com).



## Detectable Food Temperature Probe

Made from Detectamet's detectable polymer, the company's new temperature probes are both metal detectable and X-ray visible. This digital food temperature probe features a smooth, durable surface and its wide measuring range makes it suitable for all food, storage, and equipment checks. It can also be stored in a wall-mountable, detectable holder for easy access at each crucial stage in the food production and storage process. **Detectamet Ltd.**, [sales@detectamet.com](mailto:sales@detectamet.com), [www.detectamet.co.uk](http://www.detectamet.co.uk).



## Business Briefs

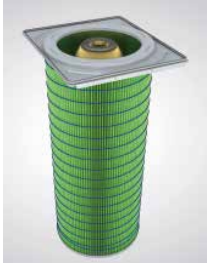
**Fapas** launches proficiency tests for polycyclic aromatic hydrocarbons in shellfish and perfluoroalkylated substances in sea fish. It also releases two tests to identify and quantify ergot alkaloids in multigrain baby food products and tropane alkaloids in cereals.

**3M Food Safety's** Molecular Detection Assay 2—*Campylobacter* earns Performance Tested Methods Certificate number 111803 from the AOAC Research Institute.

**AIB International** releases the new Baking Process Kill Step Calculator for fruit-filled pastry.

**Testo North America** achieves certification for its Testo 104 family of food thermometers according to NSF/ANSI Standard 2—Food Equipment.

**Registrar** releases version 2.0 of the FDA Compliance Monitor to facilitate industry compliance with the FSMA compliance tool.



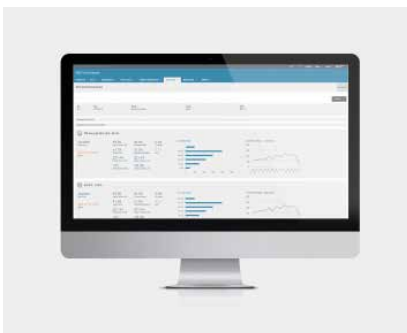
### Filter Cartridge

Gold Cone X-Flo (GCX) filter cartridge for high-efficiency industrial dust collection uses a proprietary inner pleat pack with an open-bottomed inner cone of media that expands the usable surface area of the cartridge. Because the HemiPleat design exposes more media to the airstream, more dust is loaded on the filter and released during pulse cleaning. The cone is configured so that pulsed air is evenly distributed top to bottom along the outer pack of the filter and down through the inner cone pack. That means with each pulse, the GCX

cone cartridge ejects more dust out of the collector, straight down to the hopper. These filters are available in a selection of regular or nanofiber media and meet EPA particle emission requirements. GCX filters were designed specifically for Camfil APC's Gold Series X-Flo dust collector. **Camfil APC, 800-479-6801, filterman@camfil.com, www.camfilapc.com.**

### Statistical Process Control

The new Statistical Process Control (SPC) feature in Safefood 360°'s Food Safety Management Software system is an industry-standard methodology for measuring and controlling food safety and quality during the manufacturing process. Data in the form of product or process measurements are obtained in real time and analyzed to determine the capability of the operation to meet requirements. This is particularly helpful when it comes to controlling CCPs and operation PRPs. SPC automatically crunches monitoring data to produce process control charts, distribution curves, and calculate Cp and Cpk values to provide a clear picture of process capability. **Safefood 360°, 855-3663-360, team@safefood360.com, www.safefood360.com.**



### Dual Canister Water Filtering System

The Dual Canister Water Filtering System found on the new Sanitary Zero Maintenance Screen from Lyco Manufacturing works by automatically purging and switching filters without manually changing or isolating valves. These actions eliminate the need to have one or more employees monitor and service their water filtration system. The system can filter between 50 to 400 gallons per minute, and captures particulates as small as 200 microns, making the water clean enough to be used a second time. CIP systems stop blinding, rotating nozzles for sanitation. The Sanitary Zero Maintenance Screen is designed for water reuse as it filters wastewater from food-based applications such as inside/outside bird washers, and reclaims it for re-use back in the processing lines. **Lyco Manufacturing, 920-623-4152, sales@lycomfg.com, www.lycomfg.com.**



### Surface Sanitation System

BioSpray-10 is a portable option for surface sanitation that is designed to limit the growth of bacteria and other pathogens that can be missed with other methods of sanitation. It has many of the same features as its predecessor, BioSpray-20, but in a smaller, lightweight system. BioSpray-10 is safe for use around water-sensitive equipment and machinery. The system is non-electric, with no power source required. **Goodway Technologies, 800-333-7467, www.goodway.com.**

### AI Label and Date Code Verification

APRIL Eye is an artificial intelligence-based vision system for date code verification. The system removes the operator from the date code verification process, achieving full automation to reduce the risk of product recalls and emergency product withdrawals caused by human error on packaging lines. By taking photos of each date code, the system can read them back using scanners to ensure they match the programmed date code for that product run, allowing manufacturers to achieve unmanned full traceability. Running at speeds of over 300 packs a minute, it also allows them to increase throughput. The production line comes to a complete stop if a date code doesn't match, ensuring that no incorrect labels can be released into the supply chain. **OAL, sales@oalgroup.com, www.oalgroup.com.**

## Advertiser Directory

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Food Safety Summit	Insert, 7	IAFP	48
Hygiena	3	Wiley	4, 25

# SCIENTIFIC FINDINGS

For access to complete journal articles mentioned below, go to “Food Science Research” in the February/March 2019 issue at [www.foodqualityandsafety.com/issue/february-march-2019/](http://www.foodqualityandsafety.com/issue/february-march-2019/), or type the headline of requested article in website’s search box.



## **ARTICLE: [Irrigation-Induced Salinity Affects Olive Oil Quality and Health-Promoting Properties](#)**

Olive oil, a functional food, is increasingly produced from trees irrigated with water containing high concentrations of salts. This review studies the effects of irrigation-induced salinity on quality and health-related compounds in olive oil. Trees were grown in lysimeters with continuous control and monitoring of root-zone salinity. Salinity in the root zone was altered by changing irrigation solution salinity or by changing the extent of leaching. Extracted oil was analyzed for quality parameters including free fatty acid content, polyphenol, tocopherol, sterol and carotenoid levels, fatty acid profile, and antioxidative capacity. **Journal of the Science of Food and Agriculture, Volume 99, Issue 3, February 2019, Pages 1180-1189.**

## **ARTICLE: [Microwave Processing—Current Background and Effects on the Physicochemical and Microbiological Aspects of Dairy Products](#)**

Overheating is still a major problem in the use of conventional heating for milk and various dairy products because it leads to the lowering of quality and sensory and nutritional values. Microwave (MW) heating has been credited with providing superior-quality dairy-based products with extended shelf life, representing a good alternative to conventional heat treatment. The main drawback of MW heating refers to nonuniform temperature distribution, resulting in hot and cold spots mainly in solid and semisolid products; however, MW heating has been shown to be suitable for liquid foods, especially in a continuous fluid system. This review describes the main factors and parameters necessary for MW heating technology in dairy processing, considering the theoretical fundamentals and its effects on quality and safety aspects. MW heating has demonstrated the ability to destruct pathogenic/spoilage microorganisms and their spores, and also inactivate enzymes, thereby preserving fresh characteristics of dairy products. **Comprehensive Reviews in Food Science and Food Safety, Volume 18, Issue 1, January 2019, Pages 67-83.**



## **ARTICLE: [Cold Plasma for Effective Fungal and Mycotoxin Control in Foods](#)**

Cold plasma treatment is a promising intervention in food processing to boost product safety and extend shelf life. The activated chemical species of cold plasma can act rapidly against microorganisms at ambient temperatures without leaving any known chemical residues. This review presents an overview of the action of cold plasma against molds and mycotoxins, the underlying mechanisms, and applications for ensuring food safety and quality. The cold plasma species act on multiple sites of a fungal cell resulting in loss of function and structure, and ultimately cell death. Likewise, the species cause chemical breakdown of mycotoxins through various pathways resulting in degradation products that are known to be less toxic. **Comprehensive Reviews in Food Science and Food Safety, Volume 18, Issue 1, January 2019, Pages 106-120.**



## **ARTICLE: [A Review of the Use of Biostimulants in the Vineyard for Improved Grape and Wine Quality](#)**

Foliar application of biostimulants (including resistance inducers or elicitors) in the vineyard has become a strategy to prevent plant diseases and improve grape quality on the grapevine. This also represents a partial alternative to soil fertilization, avoiding some of the negative effects to the environment from leaching of nutrients into the groundwater. The foliar applications that most promote the synthesis of

secondary metabolites in grape berries are treatments with nitrogen, elicitors, other biostimulants, and waste from the agricultural industry. However, the impact of their use in the vineyard depends on a number of conditions, including mainly the type of compound, application rate, timing and number of applications, and cultivar. This article summarizes the influence of biostimulants as foliar applications to grapevines on grape amino acids and their phenolic and volatile concentrations to define the most important factors in their effectiveness. **Journal of the Science of Food and Agriculture, Volume 99, Issue 3, February 2019, Pages 1001-1009.**



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