

**PLUS** Challenges of the 'High-Risk' Foods List ■ Seek and Destroy Best Practices ■ Hygiene Monitoring in the Lab

Volume 26 Number 4  
AUGUST / SEPTEMBER 2019

# Food Quality & Safety

FARM TO FORK SAFETY

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in the U.S.: An Industry  
in Transition**

**Integrating FSMA require-  
ments into existing food safety  
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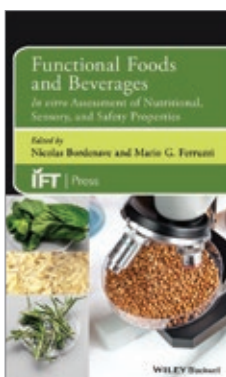
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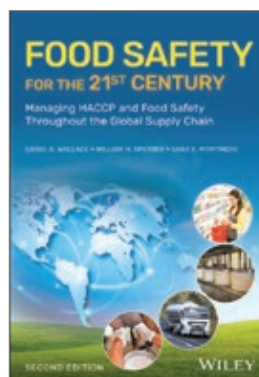
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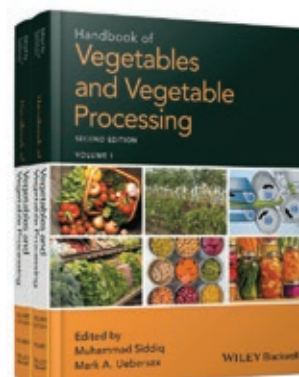
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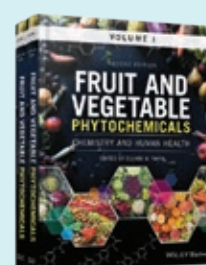
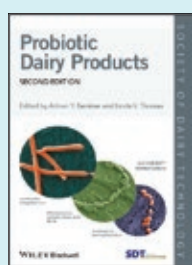
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- Food Safety Technology Prevents Recalls BY MICHAEL KOERIS, PHD
- Sustainable Breweries: How to Reduce Your Beverage Supply Chain's Carbon Footprint BY STEFAN GROBER
- Pet Food Safety Is A Shared Responsibility BY STEVE SAYER

**Correction**

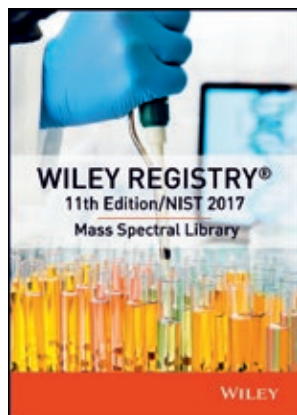
In the June/July 2019 cover story on leafy greens, the incubation period for *Salmonella* and *E. coli* was confused with the period of time it takes for *Cyclospora* to mature outside of humans before it is infectious. As a result, the following quote from Michael T. Osterholm, PhD, MPH, regents professor, University of Minnesota, Minneapolis, and sentence should have been eliminated: "This is much longer than *E. coli* and *Salmonella*." They can take three to four days and six to 72 hours, respectively.



# A Powerful Instrument Needs Powerful Data



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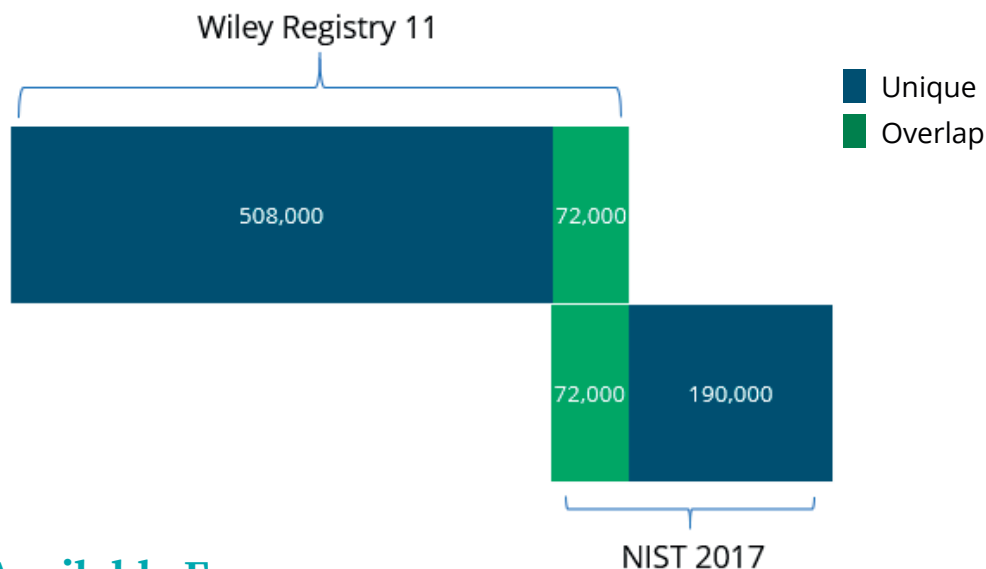


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# From The Editors

One hat I wear is that of a Science Communicator for one of the professional societies to which I belong. I recently received an email from the organization asking that I complete a survey. It was a bit disappointing when I started working on the survey since I expected it would focus on issues facing the food industry and how we might deal with these issues.



Instead, the questions focused exclusively on social media and which media I was actively utilizing. Why was I disappointed? Social media definitely has a place in today's world, but no one has shown me or provided a good explanation as to how we as members of the food industry can properly communicate good science using these tools. How do we manage to tell a good story in 280 characters or less?

Communicating good science—and getting people to listen—is a real challenge for all members of the food industry, whether one is industry, government, or academia. Why? There are many reasons that include, but are not limited to, people being averse to reading long dissertations, an inability to communicate science in terms that non-scientists and/or the general public can understand, and a general distrust of the food industry. Look at how Monsanto has been demonized for GMOs and RoundUp weed killer on social media.

We at Food Quality & Safety are committed to communicating good science to the food industry. Social media is a tool that we undoubtedly utilize, but with great care. We certainly do not want to create a situation where issues may be taken out of context, nor do we want to tell a story that fails to answer questions that are essential to properly understanding the topic being addressed. Partial or incomplete answers can create even greater problems (“What are you trying to hide from us?”). Look at the brouhaha created months ago with the redactions to the Mueller Report—not that we want to dabble in politics. We need to properly communicate the whys, wherefores, whats, and whens, and that simply cannot be done in 280 characters. So, gentle reader, if you take to Twitter or some other form of social media to communicate science or your thoughts and opinions on food science, food safety, or food quality, do tread carefully.

**Richard Stier**  
Co-Industry Editor



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# NEWS & NOTES

## Impossible Foods Receives FDA Approval for 'Bleeding' Plant Burger

FDA approves a key ingredient in plant-based burger patties made by Impossible Foods, a rival to Beyond Meat, clearing the way for direct-to-consumer sales at U.S. grocery stores, according to [Reuters](#). The FDA in a statement said it concluded soy leghemoglobin, a protein-based color additive Impossible Food uses to make its burgers look and "bleed" like real meat, was safe. Soy leghemoglobin, which Impossible Food markets as "heme" as the "magic ingredient" of its burgers, is found in the root nodules of plants. It closely resembles hemoglobin, the iron-containing protein found in red blood cells in humans and mammals. Impossible Foods in a statement said it plans to launch its Impossible Burger in select retail stores in September.



## Produce Safety Assurance Standard

GLOBALG.A.P. launches its the [Produce Safety Assurance Standard](#), a food safety solution that is a subset of the GLOBALG.A.P. Integrated Farm Assurance (IFA) Standard. The GLOBALG.A.P. Produce Safety Assurance Standard V5 covers the certification of food safety and traceability elements throughout a product's entire agricultural production process, from before the plant is in the ground (origin and propagation material control points) to the packaging. Like IFA, the Produce Safety Assurance Standard is an accredited and recognized third-party certification of primary production processes based on ISO/IEC 17065. The Produce Safety Assurance Standard will also undergo the GFSI recognition process.



## New Inventions from USDA Scientists and Researchers

USDA releases its annual [Technology Transfer Report](#), which highlights innovations from scientists and researchers that are solving problems for farmers, ranchers, foresters, and producers. The report reveals 320 new inventions from USDA laboratories in fiscal year 2018, along with 471 licenses, 120 patent applications, and 67 actual patents. Discoveries include a system for removing nitrate from contaminated water and recycling it for re-use as fertilizer; a test strip for major foodborne pathogens that reduces testing time from 24-72 hours to about 30 minutes; a vaccine against *Streptococcus suis* that may markedly improve the health and welfare of pigs while reducing the use of antibiotics; and a treatment for peanut allergies.

## Business Briefs

**The Annex by Ardent Mills partners with Colorado Quinoa, LLC to clean, mill, and market quinoa grown in Colorado's San Luis Valley.**

**FoodLogiQ becomes a contributing partner of the Partnership for Food Safety Education, a public-private collaborative focused on consumer food safety education.**

**USDA designates the Kansas City Region as its relocation for the Economic Research Service and National Institute of Food and Agriculture.**

**Universal Pure Holdings acquires Stay Fresh Foods.**

**DSM and Avril collaborate to bring plant-based protein to food industry.**

**The Food and Agriculture Organization of the United Nations and Korea Telecom agree to work together to create more opportunities for youth to engage in smart farming and other forms of agricultural innovation and entrepreneurship.**

## Decoding the Food Code

FDA makes [Decoding the Food Code: Information to Assist the User](#), an online-based training module developed to engage and educate stakeholders on the foundational policy principles of the Food Code, available through its website. The FDA publishes the Food Code, a model that assists food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry. Local, state, tribal, and federal regulators use the FDA Food Code as a model to develop or update their own food safety rules and to be consistent with national food regulatory policy. The training module was designed to help stakeholders, including all levels of government and industry, understand the structure, nomenclature, and conventions of the Food Code in order to prevent foodborne illness.

# Washington Report



## Risky Business with ‘High-Risk’ Foods

FDA-designated list may give rise to confusion, industry “gaming” | BY TED AGRES

**F**DA has signed a consent decree in federal court agreeing to create a list of high-risk foods and publish a proposed rule establishing industry recordkeeping and traceability requirements by September 2020, with a final rule to be issued by November 2022.

The consent decree, signed in the U.S. District Court for Northern California in June, settled a lawsuit brought in October 2018 against FDA and the Department of Health and Human Services by two consumer advocacy groups. In their complaint, the Center for Food Safety (CFS) and the Center for Environmental Health argued that FDA had violated the Food Safety Modernization Act (FSMA) by failing to publish a high-risk foods list by January 2012 and proposed recordkeeping requirements for facilities that manufacture, process, pack, or hold those foods by January 2013.

The settlement was made without admission or denial of the allegations, with both sides agreeing that “resolution of this matter without further litigation is in the best interest of the parties and the public.”

“This is a major victory for public health,” said Ryan Talbott, CFS staff attorney in a [statement](#). “FDA has sat on its hands for years, neglecting to make these high-risk designations, while outbreaks caused by *Salmonella*, *E. coli*, and other pathogens have sickened and killed people. This settlement ensures FDA will finally take these much-needed actions to reduce the threat of foodborne illness.”

“After years of stalling, FDA can no longer delay enacting the FSMA high-risk food regulations,” added Jaydee Hanson, CFS policy director. “FDA needs to designate what these high-risk foods are and how they should be reported so that we can build a safer food system that prevents as

many of these foodborne illness outbreaks as possible.”

Earlier, in May 2018, nine major consumer and food safety groups urged FDA “to designate produce, including leafy greens, as a high-risk food category and propose regulations that will enhance product tracing for produce in the event of an outbreak.” Among the groups signing the six-page letter were the Center for Science in the Public Interest, Consumers Union, Food & Water Watch, the Pew Charitable Trusts, and the Consumer Federation of America.

Noting that retailers can trace the origin of certain produce shipments in mere seconds using blockchain and other advanced technologies, “it is no longer acceptable that the FDA has no means to swiftly determine where a bag of lettuce was grown or packaged,” the groups wrote.

### Minefield for Industry?

Many food safety experts and consumer groups applauded FDA’s decision to finally move forward on designating a high-risk foods list and proposing rules to mitigate their hazards. But others worry that the effort might have unintended consequences.

“Creating a list of high-risk foods may appear to some to be a great idea, but I am not a big fan of this approach,” explains David Acheson, MD, former associate FDA commissioner for foods and founder and CEO of The Acheson Group.

“Be careful what you ask for in terms of putting industry into compliance for high-risk foods,” Dr. Acheson tells Food Quality & Safety. “In some ways, it could be a minefield for the food industry. As we have learned, any food can become high risk if you don’t grow, produce, transport, or sell it with appropriate food safety controls. I worry that industry will spend too much time trying to navigate from the high-risk to the ‘low-risk’ list,” he wrote in a recent [blog post](#).

If that were to happen, it would likely be driven to some extent by the degree of “demonization” of high-risk foods. “I hope



that consumer groups and others providing opinions do not lose sight that any food, if not grown/manufactured/transported/sold with appropriate food safety controls, can be high risk,” Dr. Acheson emphasizes.

Enacted in January 2011, FSMA requires a range of preventive measures to reduce foodborne hazards, including the designation of high-risk foods that are more susceptible to being a source for foodborne illness outbreaks and additional reporting requirements for them.

FSMA Section 204(d)(2) gave the agency one year to compile the list and two years to propose enhanced recordkeeping requirements. FDA has been working on the matter even while grappling with new challenges, such as implementing the produce safety rule, particularly the inspection of farms and other facilities that grow, harvest, pack, and hold fruits and vegetables for human consumption.

FDA delayed routine farm inspections until spring 2019 to allow more time for guidance, training, technical assistance, and planning. The agency continues to methodically work through such contentious issues as agricultural water testing and the safe use of raw manure on crops, especially in light of recent *E. coli* O157:H7 contamination of romaine lettuce linked to untreated on-farm reservoirs and runoff from concentrated animal feeding operations.

Despite missing the two high-risk food designation deadlines, FDA in 2014 did publish a draft methodology for identifying such foods and opened a docket for public comments. And as required by FSMA, FDA completed two product tracing pilot projects in conjunction with the nonprofit Institute of Food Technologists.

Currently, the Bioterrorism Act of 2002 requires businesses in the food supply chain to maintain rudimentary one step forward, one step back traceability records. But farms are exempt from that rule. And while the produce safety rule imposes certain recordkeeping requirements on covered farms, traceability coding is not one of them. Any new high-risk food recordkeeping rules that FDA develops will be in addition to these requirements.

### Growing Burden of Illness

An estimated 48 million people in the U.S. become ill from foodborne diseases each year, according to CDC. Approximately

128,000 are hospitalized and 3,000 die every year based on exposure to pathogens present in the food supply. The annual cost to the U.S. economy in medical bills and productivity losses is more than \$93 billion, according to a [2015 study](#).

The incidence of foodborne infections increased in 2018 compared to 2015-17, according to CDC’s Foodborne Diseases Active Surveillance Network ([FoodNet](#)) report, released in April. Surveillance from labs in 10 states confirmed that more than 25,600 infections, nearly 5,900 hospitalizations, and 120 deaths were caused by eight enteric pathogens commonly transmitted through food.

As in previous years, *Campylobacter* was the most prevalent, being responsible for 9,723 illnesses, 1,811 hospitalizations, and 30 deaths. This was followed by *Salmonella* with 9,084 illnesses, 2,416 hospitalizations, and 36 deaths. *Campylobacter* is commonly associated with consumption of raw or undercooked poultry and meat, while *Salmonella* is an issue in many types of food, including eggs, meat, poultry, fruits, vegetables, spices, and nuts.

Nationwide, the actual number of cases is much greater. This is because FoodNet collects data from public health departments in only 10 states, covering just 15 percent of the U.S. population.

### Making a List

FDA’s draft methodology for designating high-risk foods lists several factors the agency might consider. These include the food’s known safety risks, including its history and severity of illnesses; its potential risk for microbial or chemical contamination given its nature or production processes; the point in manufacturing where contamination is most likely to occur, and steps needed to reduce it; and the food’s likely or known severity, including health and economic impacts.

Dr. Acheson draws particular attention to the fact that, for the high-risk designation, FDA might consider not only the food but the manufacturing process points at which contamination is most likely to occur. He urges FDA to consider feedback it received from its proposed 2014 designation of high-risk foods.

The Produce Marketing Association (PMA) noted in its comments that it would be “patently unfair that [food companies]

that have implemented robust preventive controls be burdened with additional tracing requirements due to the industry segment as a whole being designated a ‘high-risk’ food category.”

For example, FDA should evaluate facilities that manufacture, process, pack, or hold raw agricultural commodities in a manner different from low-acid canned food facilities, wrote James R. Gorny, PhD, vice president, PMA. “A one-size-fits-all approach to evaluating food risk will likely prove difficult, overestimating risk for some foods while underestimating risk for other food categories,” he said.

In its comments, United Fresh argued that “high risk” and the need for traceability are not connected.

“The need to trace implicated foods back to the source of contamination and forward to all other potentially contaminated foods can occur in any commodity, regardless of prior linkage to foodborne outbreaks,” wrote David Gombas, PhD, senior vice president, United Fresh.

“Further, requiring enhanced recordkeeping will not make ‘high-risk’ foods safe, only potentially better assure their traceability in the event of a recall or outbreak, as would be necessary for any food regardless of calculated risk,” Dr. Gombas added. Accordingly, “it is unnecessary for FDA to designate a food as ‘high risk’ in order to require adequate and accurate recordkeeping to enable traceability.”

According to the consent decree, FDA can extend the court-imposed deadlines only if the plaintiffs (the Center for Food Safety and the Center for Environmental Health) agree. If agreement cannot be reached, FDA can petition the court for extension of time but it needs to demonstrate “good cause and/or exceptional circumstances,” with the burden resting on FDA.

“FDA has a large and complex job in front of it, which is most likely why it has taken so long” to compile a list of high-risk foods, Dr. Acheson says. “I also suspect that FDA has not seen this as a great public health tool and so has not given it priority. But I hope that FDA is able to leverage this for the minor gains it will give us and not create a two tier structure for food that will create potential complacency in the low-risk category.” ■

Agres is an award-winning writer based in Laurel, Md. Reach him at [tedagres@yahoo.com](mailto:tedagres@yahoo.com).

# Market Initiatives



## Poultry Particulars

Innovations are enhancing the new king of protein from farm to fork | BY LINDA L. LEAKE, MS

**N**ewsflash for royal watchers: Poultry has captured the coveted crown!

With great fanfare, industry insiders are calling poultry the new king of protein, as it is surpassing global pork production in 2019.

Poultry's rise is due to African swine fever, which is expected to result in a 15 percent drop in pork production worldwide in 2019, according to Paul Aho, PhD, principal of Poultry Perspective, a consulting firm based in Storrs, Conn.

"Poultry has already surpassed pork in total production this year and it's doubtful it will ever again relinquish its place at the top," Dr. Aho predicts.

### Production and Consumption by the Numbers

In 2018, more than 9 billion broiler chickens, weighing 56.5 billion pounds (liveweight), were produced in the U.S.,

according to the National Chicken Council. More than 42.1 billion pounds of chicken product was marketed in the U.S. in 2018, measured on a ready-to-cook basis.

The U.S. produced 5.878 billion pounds of turkey meat in 2018, according to USDA. The U.S. is the world's largest turkey producer and largest exporter of turkey products.

Currently, annual per capita consumption of poultry in the U.S. is 109 pounds, (93 pounds of chicken and 16 pounds of turkey combined), basically tied with red meat (52 pounds of pork and 57 pounds of beef), USDA reports.

"Forty years ago, red meat companies produced and sold only red meat products, and poultry did the same," says John Butts, PhD, president of FoodSafetyByDesign, LLC. "Today we have meat processing companies that are selling both red and poultry meat protein. We now have beef hot dogs, all-meat hot dogs, poultry hot dogs, and

hot dogs made of both meat and poultry. The same goes for how a consumer uses ground meat. Ground turkey and chicken have become very popular for their perceived nutritional and health qualities and are used instead of or in the place of ground beef or pork."

### Industry Support and Training

Calling itself the "All Feather Association," the U.S. Poultry and Egg Association (USPOULTRY) touts itself as the world's largest and most active poultry organization. Membership includes producers and processors of broilers, turkeys, ducks, eggs, and breeding stock, as well as allied companies. Founded in 1947, the association has affiliations in 26 states and member companies worldwide.

Among its services, USPOULTRY provides technical assistance and education to its 470-plus members, according to Rafael Rivera, MS, the organization's manager of food safety and production programs.

For the poultry meat sector in particular, USPOULTRY has developed reference documents explaining whole genome sequencing use for foodborne illness detection and source traceback. "Members get an introduction to what whole genome sequencing is and how can it be used as a meat quality and food safety tool," Rivera relates. "The documents provide guidance into what type of equipment they should think about acquiring if they wish to use this technology in areas beyond regulatory compliance.

"In addition, we have developed training in the area of carcass sorting for those companies that are transitioning to the voluntary USDA Food Safety and Inspection Service New Poultry Inspection System," Rivera says.

### Prebiotics: Updates from Arkansas

University of Arkansas (UARK) researchers have been reviewing the effect of prebiotics on foodborne pathogens in poultry.

"We noticed that there has been increased commercial interest in recent



years for giving feed additives to chickens that limit foodborne *Salmonella* and *Campylobacter* establishment in the gastrointestinal tract (GIT)," says Steven Ricke, PhD, director of the UARK Center for Food Safety.

"Prebiotics have been examined as potential candidates," Dr. Ricke relates. "They are generally oligosaccharide polymers that are not available to the chicken but can be utilized by the native bacteria of the chicken's GIT."

According to Dr. Ricke, prebiotics are effective against pathogens because they are fermented by the "good" bacteria of the GIT to produce short chain organic acids such as lactate, acetate, propionate, and butyrate. The presence of these organic acids, along with other inhibitory mechanisms, prevents pathogens from colonizing and becoming established in the chicken's GIT.

"While current prebiotics offer considerable promise as feed additives for poultry production, more research needs to be done to identify additional prebiotic candidates and elucidate mechanisms that make them effective against pathogens," Dr. Ricke emphasizes.

### **Campylobacter Research**

A University of Georgia (UGA) study published in March 2019 demonstrates the effects on the prevalence and antimicrobial resistance of *Campylobacter* of chickens raised without antibiotics and with organic methods.

Results show that organic birds had a lower prevalence of *Campylobacter* and lower populations of presumptive *Campylobacter* during early processing steps, according to Manpreet Singh, PhD, professor of food safety and processing in the UGA Department of Poultry Science. "However, no differences between organic and conventional birds were seen post-chill, with the exception of a lower prevalence in post-water-chill organic birds," Dr. Singh reports.

"These observations show that organic methods can be associated with lower initial *Campylobacter* levels than can conventional methods, although appropriate processing interventions result in similar *Campylobacter* populations post-chill, regardless of processing method," Dr. Singh explains. "Prevalence of antimicro-

bial-resistant *Campylobacter* in chickens at slaughter suggests that raising birds without the use of antimicrobials may not be effective in reducing the incidence of antimicrobial-resistant *Campylobacter* in chicken meat."

### **Ice Slurry Chilling Medium**

Researchers at the Georgia Tech Research Institute (GTRI) recently completed a feasibility study using ice slurry (a mixture

of tiny ice crystals and liquid water) as an alternative chilling medium for poultry carcasses.

"We looked at ice slurry both for its increased cooling capacity and antimicrobial properties," says Comas Haynes, PhD, GTRI principal research engineer and project director, who supervised the study.

"We hypothesized that the ice slurry's grain acts as a scrub on the external

*(Continued on p. 14)*

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(Continued from p. 13)

surface of the poultry carcass, dislodging or eroding skin-attached pathogens and releasing them directly into the chiller's water," Dr. Haynes relates. "This direct abrasion could possibly reduce bacterial loads and lower the amount of antimicrobials needed."

Using different combinations of experimental factors, including peracetic acid (PAA) concentration, salt concentration, and immersion time, the researchers found that, on average, the ice slurry provided a greater reduction in pathogens than chilled water. Of note, Dr. Haynes says, slurry demonstrated the same antimicrobial effect with reduced amounts of PAA compared to chilled water and PAA.



"Our results support the hypothesis that ice slurry has a thermomechanical advantage over chilled water with regard to antimicrobial efficacy," Dr. Haynes says. "We believe ice slurry holds promise for commercial use as a natural sanitizing aid for poultry chilling."

### Bird Housing Comfort Tool

On May 19, 2019, FarmLab Innovations, Chattanooga, Tenn., launched SWASH<sub>COOL-CELL</sub>, a liquid sanitation product designed to maintain the longevity and effectiveness of evaporative cooling systems for the poultry (and swine) industries.

Common issues with such systems include mineral and algae buildup, deterioration of cool-cell pads from continual cleaning, and increased utility costs due to inefficient airflow, according to Eric Spell, business development director for FarmLab Innovations. "The high pH level of groundwater, combined with dust and high mineral concentrations, compound algae and mineral buildup on cool-cell pads and within evaporative cooling systems," Spell relates. "SWASH<sub>COOL-CELL</sub> is added to the water in the sump to regulate and control water quality at the source."

Specifically, Spell says, the product's three-step solution to mineral buildup includes buffers to balance the pH level of the water, chelating agents to keep minerals soluble, and dispersants that cause dust and dirt to disperse in the water rather than build up on the cooling pad.

Within 15 to 20 minutes of adding SWASH<sub>COOL-CELL</sub> to the water source, pH neutralization begins, sequestering non-soluble minerals and dispersing them to inhibit buildup, Spell notes.

"The natural cooling effect of evaporation is important for maintaining proper temperatures for poultry (and livestock) facilities, particularly during months when the temperature exceeds 80 degrees Fahrenheit," Spell explains. "Thus,

SWASH<sub>COOL-CELL</sub> contributes to creature comfort, an animal welfare issue of importance to consumers."

### Food Quality Diagnostic Tool

On May 6, 2019, PerkinElmer, Inc., Waltham, Mass., a purveyor of diagnostic technology, launched a new food testing tool, the DA 6200 NIR analyzer.

Part of the company's Perten portfolio of analytical instruments, the DA 6200 is based on next-generation diode array near-infrared transmission spectroscopy (NIR) technology, according to Per Lidén, PerkinElmer's product manager for benchtop DA instruments.

"The DA 6200 is particularly geared for meat, including poultry," Lidén says. "In 30 seconds, it provides accurate test results of fat, moisture, and protein levels in a sample, as well as collagen, salt, and ash content. In particular, the collagen content reveals the presence of connective tissue, and the ash content demonstrates if there is bone ground into the product. This accuracy and speed translate to quality and process control as readily in very large, inhomogeneous samples as they do in small samples."

Lidén notes that its compact size and battery power option make the DA 6200 analyzer fully portable and the instrument sports an intuitive touchpad screen.

With bones removed first, chicken or turkey samples need to be homogenized (typically using a benchtop mixer) before they can be measured with the DA 6200, he adds.

"If it is mechanically separated poultry already mixed in process, the grab samples from production can typically be analyzed without extra homogenization," Lidén elaborates. "The DA 6200 can also analyze final products, such as a chicken sausage, burgers, or entrees."

### Peracetic Acid

The use of PAA as an antimicrobial sanitizer is expanding in poultry processing, according to Joe-Ben Mattos, director for Biosan LLC, Saratoga Springs, N.Y.

The company's two key offerings for poultry intervention that contain PAA are BIOSAN 1510 MPS and BIOSAN 2205 MPS. "These products are environmentally friendly antimicrobial agents approved for a multitude of intervention points, including both online and offline reprocessing in federally inspected processing facilities," Mattos says.

"BIOSAN 1510 MPS and BIOSAN 2205 MPS exhibit a high level of efficacy against *Campylobacter*, *Escherichia coli*, *Salmonella enterica*, *Listeria*, and other pathogens," he relates. "These products are chlorine free and generate no harmful byproducts."

If used as directed, the BIOSAN products will help reduce contamination and cross-contamination of edible food products, Mattos says. "They are acceptable for direct or indirect contact in or on food, including poultry. They can be used as an acidifier in scald tanks and as an antimicrobial agent on poultry carcasses and poultry parts," he elaborates. "They are permitted for use on poultry products labeled as "organic." ■

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**For bonus content** on the poultry industry, go to the August/September 2019 issue at [www.FoodQualityandSafety.com/issue/august-september-2019/](http://www.FoodQualityandSafety.com/issue/august-september-2019/).



# Legal Update



## What Is Adulteration?

It's 1,200 words and a century of American food safety law

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

**W**hat does it mean for a food to be “adulterated”? From a lay standpoint, it is a simple question. But from a legal standpoint, the answer is surprisingly complex.

The section of the U.S. Code (21 U.S. Code § 342) that governs adulterated food begins innocuously, with the words “A food shall be deemed to be adulterated...” That simple directive, however, is followed by more than 1,200 words of dense legalese, an extraordinary amount of information to define something as seemingly straightforward as whether a food is adulterated.

By contrast, the First Amendment to the Constitution, which grants freedom of speech, freedom of religion, freedom of the press, and the right of the people to peaceably assemble is 45 words in length. The entire Bill of Rights is fewer than 500 words. Likewise, Merriam Webster’s definition of “adulterate” is only 17 words. Why then, does the statute need an additional 1,200 words?

In short, the statute is exhaustive because it must be. To serve its intended purpose, the federal adulteration statute must address a complicated nexus of enormously important (and often competing)

societal concerns. Broadly speaking, food safety brings into play social, political, demographic, and economic interests. Effective adulteration laws, in turn, must anticipate and address all possible risks—microbiological, manufacturing, and, perhaps most difficult, risks associated with human greed and ingenuity. That is to say, adulteration standards must simultaneously cast a wide enough net to capture all foreseeable risks while avoiding loopholes that would defeat the purpose of the law.

The safety and plentitude of food in the United States is truly extraordinary. In fact, never in human history has any society had access to such a wide variety of safe and wholesome products. On the contrary, historically most people have lacked access to safe and healthy food. Even today, an estimated 800 million people are going hungry globally. Most Americans, however, take for granted that the food they eat is safe. We trust, for the most part, that our food is free of contamination (microbiological, chemical, or otherwise), that ingredient statements are accurate, and that the food we consume will not be injurious to ourselves or our loved ones. That is a truly remarkable, albeit largely overlooked, reality.

## The History of U.S. Food Safety Laws

Currently, there are 15 federal agencies responsible for administering dozens of federal food safety laws. This may seem excessive but given the importance of safe and wholesome food to our collective national health, security, economy, etc., it is in fact unremarkable. Put differently, food touches every aspect of our society, and as a result, the laws pertaining to its safety must necessarily do so as well.

Congress enacted the first food adulteration laws in the 1880s, but most experts regard the early 1900s, when Congress enacted sweeping food safety laws, as the de facto advent of American food safety regulation. The timing was due to a confluence of factors, including the emergence of transnational food shipments (made possible by the rapid expansion of railroads), the application of electricity, the invention of refrigeration (which allowed perishable food to be shipped nationally) and, most importantly, a series of scandals that shocked and enraged the nation.

One scandal, which appeared on the cover of *The New York Times*, involved Chicago meat producers who shipped chemically and economically adulterated beef—so-called “embalmed meat”—to American soldiers fighting in the Spanish-American War. The contaminated meat is believed to have caused thousands of illnesses and deaths among American soldiers. At the time, most Americans were unaware of the widespread economic and chemical adulteration practices being employed by American food manufacturers.

The tipping point came six years later, in 1905, with the publication of *The Jungle* by Upton Sinclair. The novel, which detailed the atrocious and insanitary meatpacking practices in the Chicago Stockyards—enraged Americans and led to the 1906 enactment of the Federal Meat Inspection Act (FMIA) and the Pure Food and Drug Act.

The FMIA created sanitary standards applicable to the meatpacking industry and mandated the first continuous governmental inspection oversight of food production. Perhaps most importantly, the FMIA granted USDA enforcement authority over food safety regulatory viola-

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tions. The FMIA also bifurcated oversight responsibilities between meat products and other types of food. That regulatory fragmentation has continued ever since.

The next piece of landmark food safety legislation was the 1938 Federal Food, Drug, and Cosmetic Act (FDCA). The FDCA granted FDA authority to oversee the safety of food, drugs, medical devices, and cosmetics. When the FDCA was enacted, FDA and USDA's Food Safety and Inspection Service were both part of USDA. In 1940, however, President Roosevelt reassigned FDA to the Federal Security Agency (currently HHS) due to concerns about perceived conflicts between USDA's and FDA's respective missions.

For 70 years after the passage of the FDCA, food safety regulations remained largely unchanged. Then, in 2011, Congress passed the Food Safety Modernization Act (FSMA), vastly expanding FDA's food safety oversight authority and ushering in the modern era of food safety.

### Adulteration Today

For all that has changed in the century since the FMIA became law, it is surprising how much has remained the same.

Although the definition of adulteration has undergone many revisions and is now more comprehensive, it remains materially the same. Generally, a food is adulterated if it contains any poisonous or deleterious substances that may render it injurious to health. This could include chemicals, drugs, pesticides, and certain pathogens. Likewise, food that has been prepared, packed, or held under insanitary conditions such that it may have been rendered injurious to health or otherwise contaminated is adulterated. So are foods comprised in whole or in part of any filthy, putrid, or decomposed substance, or are otherwise unfit for food. Any food derived from an animal that has died by means other than slaughter, such as from disease, is deemed adulterated.

These are all relatively straightforward examples that ostensibly capture the ambit of adulteration. Yet, they collectively cover less than the first paragraph of the statute. In addition to the foregoing, products that have been intentionally subjected to radiation are adulterated. That's pragmatic, but what about products *unintentionally*

exposed to radiation? Shouldn't any product exposed to radiation be adulterated? Perhaps. But then, sunlight is a form of radiation. Does that mean all sundried tomatoes are adulterated? Presumably not. This intellectual exercise, and countless others like it, illustrate how difficult it can be to define a seemingly simple concept, like adulteration.

There is also economic adulteration. Economic adulteration—also referred to as food fraud—refers to the practice of intentionally adulterating food for economic

**Evidence of food fraud dates back thousands of years, and has afflicted manufacturers, importers, retailers, and consumers alike.**

gain. Food fraud is among the most intractable problems facing the food industry. It isn't a new problem, either. Evidence of food fraud dates back thousands of years, and has afflicted manufacturers, importers, retailers, and consumers alike. Nobody, as the old adage goes, is immune from human greed.

In some respects, food fraud presents a more formidable challenge than any other type of adulteration, including pathogens. This is because food fraud involves deliberate concealment. Moreover, successful perpetrators of food fraud seek to avoid inflicting discernible harm, meaning their crimes often go undetected—in fact, experts almost unanimously agree that most instances of food fraud go undetected.

That does not mean, however, that food fraud is a harmless crime. It is not. Food fraud causes profound economic and physical harm. For example, the Grocery Manufacturers Association estimates that food fraud results in \$10- to \$15 billion of direct losses annually. Further, food fraud impedes competition, rendering responsible, honest purveyors of food products unable to compete against fraudsters.

As noted, 21 U.S.C. § 342 is comprehensive. Food fraud features prominently. The statute prohibits the undeclared omission

or abstraction of any valuable constituent. Recall the embalmed meat scandal of the early 1900s: One manufacturing practice involved extracting all the nutritional components from the beef and selling it as beef extract. After the nutrients were extracted, the pulp was treated with chemical preservatives, canned, labeled as roast beef, and shipped to unwitting soldiers. Of course, we have come a long way since 1900. Today, Americans enjoy the safest and most plentiful food in the world. Yet, acts of food fraud still abound.

As the food industry continues to globalize, food fraud will likely become more widespread. This is due to lack of oversight in other nations as well as diminishing resources. Consequently, oversight of suppliers will become both increasingly important and difficult. Given the intrinsic difficulties associated with detecting food fraud, and the substantial losses that companies and consumers suffer because of it, it will be increasingly important for companies to address the threat directly and unilaterally.

It may be that future technologies will effectively eradicate foodborne pathogens and better prevent contamination that, today, would otherwise render food adulterated. However, it is less likely that technology will be able to eradicate food fraud because doing so would require technology capable of outsmarting human beings.

Consequently, companies should develop and implement comprehensive multi-faceted strategies that incorporate testing, auditing, and oversight of suppliers, including certification by trustworthy organizations. Already, genetic testing, where applicable to prevent food fraud, is both economical and effective. Other testing methodologies are effective in identifying food fraud in situations where DNA testing is not feasible.

Employing a comprehensive and proactive approach to prevent all types of adulteration will help to minimize the risk to food businesses and their customers. Put another way, sometimes it is better to use 1,200 words to describe something, even if others use only 17. ■

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# Global Interests



## Farmers Markets: Popular, But Safe?

While cottage foods are defined and regulated in different ways around the world, food safety remains the foremost issue

BY **AURORA A. SAULO, PHD**

**I**n 2017, the USDA Agricultural Marketing Service reported farmers markets in the U.S. are increasing in popularity since it began tracking them in 1994. USDA's Local Food Directories listed 8,687 farmers markets in 2017, an increase of approximately 42 percent from 2010. USDA estimates farmers markets in the U.S. contribute annual sales of around \$1 billion.

In the U.S., foods made in the home and other venues not considered a regulated commercial kitchen (also called a "food establishment") go by different

names such as cottage foods, farmers market foods, homestead foods, home processed products, home foods, home caterer products, or homemade foods. For purposes of this article, "cottage foods" is used to denote those foods not prepared in a regulated commercial facility. As of this writing, all states, except New Jersey, legalized the production and sale of foods produced in the home.

### American Cottage Food Laws

Cottage food laws in the U.S. are not all the same. Although states have sovereign

power on all matters affecting the public health and safety of their residents as well as commerce, the federal government provides guidance to the states through the Food Code (also called the Model Food Code). It is the best advice of FDA on the safety and protection of food at retail and in food service.

Some states have stand-alone cottage food laws to make the rules convenient and clear to cottage food producers. Although the state or local statutes, regulations, and ordinances are different in scope, design, specificity, and degree of completeness, U.S. food safety laws look similar to one another because of the Food Code.

For food safety purposes, the Food Code categorizes operations as "low risk" and "high risk," where the latter refers to the handling of TCS foods (where TCS means time/temperature control for safety, formerly called potentially hazardous foods), including sensitive raw ingredients, cooking, hot and cold holding, and

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reheating. The Food Code further defines food as TCS due to its ability to limit pathogen growth or toxin formation, by evaluating its pH,  $a_w$ , pH- $a_w$  interaction, heat treatment, and packaging.

To date, almost half of the states allow cottage foods to comprise only low-risk foods or “non-potentially hazardous foods,” and some states qualify this definition with a list that explicitly includes or excludes certain foods. Almost an equal number of states and the District of Columbia allow the sale only of the cottage foods defined in their provided lists. Some of the lists allow thermally processed acidified foods that, if acidification to pH<4.6 is incomplete, may result in high-risk products. Some states have tiered cottage food systems that further differentiate cottage foods from other similarly prepared foods, complicating the definition of a low-risk food.

There are states requiring registrations, permits, or licenses for the premises, while others do not. Other states insist on the completion of a food safety or food handler course by the operator. Some states require only a food safety training course.

Although cottage food laws in the U.S. are intentionally crafted to be not as stringent as those for food establishments, a few states enacted even broader food freedom laws. Through these laws, the preparation and sale of almost any food and beverage is allowed within the state without licensing or food safety inspection. Wyoming, for example, allows any low- or high-risk food or beverage, including animal products, fish, and rabbit. It does not require licensing, permitting, certification, packaging, or food labeling when sold directly to an “informed end consumer” at a farmers market, or a producer’s ranch, farm, or home, as long as the sold foods are for home consumption only.

Maine authorized its local governments to develop their own ordinances that would exempt producers of any food directly sold to consumers from food safety regulations (except for meat and poultry operations that remain under federal inspection and licensing).

### Cottage Foods Outside the U.S.

**Europe.** In Europe, farmers markets are also increasing in popularity and for some of the same reasons as in the U.S. About

71 percent of farmers market shoppers in Italy *perceived* the products are of “high quality” and offer “guarantees of safety.” Consumers are focused on health, their well-being, and the environment. For the shoppers, buying cottage foods eliminates the middle salespeople, making prices attractive, supporting the local business economy, and allowing them to provide instant product feedback through this direct relationship with the farmer or product manufacturer.

Italy is the European country with the largest network of farmers markets. According to the leading farmer organi-

To align the food safety issues and continue supporting cottage foods, some limitations to cottage food manufacturing need to be considered.

zation, Campagna Amica, Italian farmers markets contribute an estimated sale of €6 billion. Campagna Amica represents about 500,000 farmers and has 130,000 farm members selling directly to consumers, in addition to other direct-to-consumer markets in many other cities. In Sicily, a regional law authorized municipalities to define the locations and methods of direct sales. Farmers are encouraged to inform shoppers of the direct link with the terroir where the produce or animal was grown and the product was manufactured. The link establishes the specificity of each farmers market, a feature likely to be adopted by other farmers markets in Italy.

Farmers markets in Italy, Spain, and France offer direct-to-consumer sales of regional products prepared under established traditions. In Portugal and Greece, farmers markets further inject industrial conventions to their regional and traditionally made products. Although farmers markets in Sweden, the Netherlands, and Germany are more “modern” and commercial, they also sell directly to consumers and address environmental sustainability and animal welfare.

In post-Communist countries such as Russia, Croatia, Latvia, Slovakia, Hungary, Poland, and the Czech Republic, the farmers market, or “villagers market” as it is called in Albania, remains as the traditional channel for local food. Supermarkets are a newer food channel in Albania, being introduced in 2005, and are perceived as “trusted sources of food” but not as the primary sources of organic and good-quality fruits and vegetables. In both the industrialized and post-Communist countries, farmers or producers sell their locally grown or manufactured products directly to consumers.

**U.K.** Farmers markets address U.K. shoppers’ growing interest in locally produced foods they perceive offer better taste and connect them to a “rural heritage” and “culinary traditions,” resulting in a 30 percent sales increase from 2011-2015.

Although supermarkets are commonplace in the U.K., they are seen negatively by some Green consumers. As a result, many shoppers turn to farmers markets to buy locally produced goods that they assume are organic, natural, and Green, and that also align with their social, environmental, ethical, and moral values such as fair trade, animal welfare, support and trust in local producers, small-scale agriculture, health, and food safety. Thus, sales of organic food in farmers markets in the U.K. increased by 3.5 percent in 2013 compared to an increase of only 1.2 percent in supermarkets during the same time period. To farmers market shoppers, organic fruits and vegetables are “tastier,” “local, healthy, and environmentally friendly,” and “free of pesticides and hormones,” making them “Greener” consumers.

**Asia.** Although farmers markets around the world aim toward a similar goal of supporting local food production and the health and well-being of the community, the proliferation of markets seems to be related to the demand for organic foods. Most of the information on farmers markets are from studies from North America and Western Europe, and there is little organized information on farmers markets in Asia, Latin America, and Africa.

Although agriculture is especially important to Central Asia economies, their shares of agriculture exports to China, Russia, and the European Union remain limited. These economies believe most of



the food eaten in the world is produced by “small-scale food producers and family farmers” who sell their products in local and territorial markets. They further believe that they can meet their sustainable development goals at direct-to-consumer markets, such as community-supported agriculture, community-supported fisheries, and farmers markets. But a key factor responsible for the slow increase in exports to China, Russia, and the European Union is the slow use of food safety standards.

In 2014, the China Environmental Ministry reported that 20 percent of its farming area was alarmingly polluted. China is a country where small-scale agriculture still dominates, and industrialized agriculture comprises only 5 percent of all agriculture. In addition, recent major food scandals such as melamine found in dairy products and cadmium found in rice caused about 72 percent of its residents to be suspicious of the food grown, harvested, and prepared in their country. As a result, its residents searched for food with no pesticides and other “chemicals,” catapulting the organic food market in China to grow 30-fold over the past decade.

In China, as well as in Eastern and Western Europe, short supply chains such as farmers markets are developing fast. Younger farmers using agro-ecological methods bring fresh, “healthy” local produce directly to consumers. Farmers markets in China are seen as building trust-based, direct-to-consumer relations between sustainable family farms and consumers. But many issues remain to be addressed. The organic certification process to verify that food was grown, harvested, and prepared following their strict organic standards must be implemented, and legislation defining how to keep the foods safe must be developed.

**Australia.** Farmers markets in Australia are also growing in popularity. The Australia New Zealand Food Standards Code—also called The Code—refers to such foods simply as “food” and does not use the term “cottage foods.” The Code focuses on the operation that produces these foods (called a “food business”) and the food produced. A food business in Australia is almost the same as a temporary food establishment in the U.S. Anyone who sells food, including offering free food samples



or food prizes and giveaways, is defined as a food business.

The Code defines the national requirements that a food business must meet, including those selling cottage foods. But just as in the U.S. and other parts of the world, the states (or local governments) may have specific exemptions to the national requirements to ease compliance of certain businesses when preparing cottage foods. Exemptions are also not the same and may have different specificity for each state.

### Food for Thought

Cottage foods are defined in many different ways and the laws regulating their production and sales, if any, are just as varied anywhere in the world. But food safety remains the first and foremost issue to protect public health since many of the cottage foods are prepared in facilities seldom inspected by a recognized public health agency, and often are not prepared under the same strict guidelines. For example:

- Preparation of high-risk foods to be sold commercially mandates the use of commercial processing equipment that meets regulatory specifications, while most cottage food manufacturers use equipment for home use, such as home pressure cookers;
- Waters used for commercial processing are required to be tested, but are not when used for cottage food preparation (although some cottage food manufacturers use private water wells);
- Commercially prepared food producers in the U.S. are mandated to have a working food safety plan that demon-

strates the safety of their food’s ingredients, qualification of facilities and personnel, and conditions of the environment (cottage food manufacturers are not); and

- Proper food labeling, including the declaration of allergens, is a standard requirement on commercially packaged products but is not for all cottage foods.

Since cottage foods are not subject to these requirements, there is likely no history of the hazards in the finished product (including pathogens), the sanitary conditions of the home kitchen, or food safety training of the food handlers. Although many cottage food manufacturers start with low-risk foods, it is not unusual to see line extensions with high-risk foods, such as smoked seafood and meats, beef/turkey jerky, sometimes in hermetically sealed and reduced oxygen packages, and without knowledge of proper processing, refrigeration requirements, and transportation conditions to maintain food safety. And as in many other areas, political and legislative influences could also override food safety issues, consequently limiting regulatory authority.

The underlying rationale for the sale of cottage foods is reasonable, understandable, and addresses contemporary concerns of consumers, farmers, and manufacturers. To align the food safety issues and continue supporting cottage foods, some limitations to cottage food manufacturing need to be considered. It is recommended that cottage laws permit the sale only of low-risk foods and not include thermally processed acidified foods in hermetically sealed containers, unless a waiver is obtained from the local regulator. In addition, and as much as possible, a list of low-risk foods should be provided to guide farmers and cottage food manufacturers in this business. High-risk foods may be prepared, but their public sale should be prohibited and limited to home-use only. Food safety comes before sales—if a food is not safe, it is not a food. ■

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To read this month’s column on farmers markets in its entirety, go to the August/September 2019 issue at [www.FoodQualityandSafety.com](http://www.FoodQualityandSafety.com).





# Food Safety Auditing in the U.S.: An Industry in Transition

Attempting to efficiently integrate FSMA requirements into existing food safety management systems with a shortage of qualified auditors

BY **AMANDA MCCORQUODALE**





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**W**ith the passage of the Food Safety Modernization Act (FSMA) in 2011, the food industry overseen by FDA experienced the most extensive regulatory overhaul in the last 70 years. In the years since, auditing, which is used to both evaluate whether a food safety system is appropriate and effective, and to verify whether it is in compliance with certain industry or government standards, is also in a whirlwind of transition.

For instance, in 2010, the year before FSMA was signed into law, a cut green bean processor in the U.S. would have undergone regulatory inspections as well as several customer audits, either via first-party audits performed by the customer's staff or third-party audits conducted by an outside company. As a condition of supplying a major retailer such as Walmart, the processor would also have been required to participate in a third-party audit for one of the Global Food Safety Initiative (GFSI) certifications, which is a food safety auditing platform that established a standardized level of global food safety requirements almost two decades ago.

However, in 2019 under new FSMA regulations, the farm supplying green beans to that processor is now also experiencing its first round of regulatory inspections on the federal level. What's more, certain segments of its supply chain that were somewhat overlooked in the past (e.g., harvesters, packing facilities, etc.) are now also subject to regulatory inspections and may opt to seek out third-party auditing to confirm that their food safety management systems address all FSMA requirements.

In the current food safety auditing climate, that means that more than half of U.S. food facilities have five or fewer audits a year while a third have anywhere from six to 20 audits annually, according to a spring 2019 poll of U.S. food businesses by Lloyd's Register.

"It remains to be seen if the volume of customer audits and request or requirements for GFSI third-party audits will decrease as FSMA implementation and regulatory inspections ramp up over in the coming years," says Willette Crawford, principal, Food Safety and Regulatory Compliance at Katalyst Consulting. Yet regardless of what's coming in the future, the food safety auditing industry is currently straddling two approaches as it attempts to efficiently integrate FSMA requirements into existing food safety management systems.

### What's Changed

Prior to FSMA, although FDA required Hazard Analysis and Critical Control Points (HACCP) for seafood and juices, it was not required for the bulk of FDA-regulated products. In fact, the Federal

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Food, Drug, and Cosmetic Act of 1938 was the last major federal legislation passed to improve food safety for FDA-regulated facilities in the U.S.

To fill this gap in regulation and streamline auditing, a group of major retailers came together in 2005 to create GFSI, an auditing platform that made HACCP a fundamental food safety requirement for a scheme to be recognized by GFSI, setting the baseline above FDA's regulatory requirements at that time. Individual GFSI schemes include FSSC 2200, SQF, and BRC, all of which have been widely used by industry and executed by third-party auditors internationally for the last 15 years.

A series of high-profile and deadly foodborne illness outbreaks, many tied to imported foods, prompted Congressional action. Signed into law in 2011, FSMA directed FDA to develop U.S. food safety regulations focused on prevention across the entire supply chain. Under one of FSMA's seven rules, the Preventive Controls Rule for Human Food, FDA's regulations now require that domestic food facilities and those importing to the U.S. develop, document, implement, validate, and keep records of a food safety plan. This food safety plan must identify food safety hazards and adulteration risks associated with the specific foods and processes involved, assess the level of risk involved, and implement controls to minimize those risks. The plan must verify that the controls used are effective, and define the corrective actions necessary to address deviations from applied controls. FSMA includes a similar rule for animal foods, and a Produce Safety Rule that addresses farm food safety.

FSMA's Preventive Controls rules also require that food companies verify their supply chain for raw materials and ingredients, and require an audit of any supplier that controls a serious hazard not otherwise controlled downstream in the supply chain. FSMA dictates that the audit must cover the applicable regulations, be performed by a "qualified auditor," and verify that the suppliers' controls for the hazard identified are effective and used consistently. This also applies to imported foods under FSMA's Foreign Supplier Verification Program (FSVP) rule. As supplier verifica-

## But it isn't just auditor capacity that's a challenge—it's auditor competency as well.

tion audits must cover all regulations applicable to the suppliers' products, this process can involve using more than one type of audit document.

"A great deal of confusion seems to persist regarding the difference between HACCP and Preventive Controls despite FDA's education and outreach efforts," says Crawford. While FSMA's preventive controls approach to controlling hazards incorporates the use of risk-based HACCP principles in its development, it goes further in many regards such as requiring a recall plan for each product for which a hazard requiring a preventive control has been identified.

Crawford also stresses that by this September, most of the FSMA compliance deadlines, which were staggered over a series of years based on risk and operation size, will have passed. And while she says FDA has used its discretion on what to enforce while the industry becomes more familiar with the new requirements, inspections and enforcement of FSMA rules such as preventive controls, FSVP, and produce safety have already begun.

"At this point, industry should already be complying and analyzing their food safety program and documentation for gaps in compliance, as well as identifying and mitigating weak points in their supply chain," says Crawford.

### Auditing Gets a New Role

While auditing has always served to assist food companies with identifying and correcting gaps in their safety practices, third-party auditing now has a new role. Designed to help FDA expand its regulatory reach on imported foods, FSMA's Accredited Third-Party Certification rule outlines that third-party certification bodies that meet FDA's accreditation criteria can conduct audits and issue certifications on foreign suppliers of FDA-designated high-risk foods.

These third-party certification audits fall into two categories: consultative and regulatory. Consultative audits can serve as readiness audits that assist foreign companies in understanding gaps in practice that need to be addressed to become compliant with the appropriate FSMA regulations. A regulatory audit of foreign facilities is required for FDA certification, and can also be used for verifying compliance of a company's supply chain under FSVP. These certification audits are the basis for participating in FSMA's Voluntary Qualified Importer Program (VQIP), which offers importers expedited review and entry of food into the U.S.

In addition to the new auditing opportunities that FSMA presents, third-party auditors continue to audit food facilities against safety program schemes such as GFSI, which are still recognized internationally and are required by some retailers. "It isn't that GFSI audits weren't comprehensive, in fact they have made tremendous strides in improving food safety, but they lack a required reporting feature that documents the detail that FDA wants to see," says Patricia "Trish" A. Wester, CEO, The Association for Food Safety Auditing Professionals (AFSAP).



In fact many in the industry recommend companies striving to be FSMA compliant make sure they are GFSI certified, which will get their operation 80 percent of the way there. “Regulators all over the world, not just in the U.S., are struggling with implementation of regulation,” says Véronique Discours-Buhot, the director of GFSI. “We are all short on resources and an organization like GFSI can be part of the solution.”

In the meantime, FSMA compliance is creeping its way into the existing GFSI food safety standards. “What we’re seeing as a certification body is that when, for instance, FSSC 2200 was last updated, it now encompasses many of the FSMA requirements,” says Jennifer Lott, senior food safety auditor at SGS. “So in the new version of FSSC, you now have to look at vulnerability assessments, food defense, and how you’re meeting all those extra requirements of the FSMA law and all of its regulations.”

While existing food safety plans may encompass some of FSMA, they are not interchangeable as an FDA certification audit goes beyond the traditional food safety elements and focuses on compliance with specific regulations. “Food safety auditors are currently in a transition from these bigger, broader, every-question-you-can-think-of-food-safety-event type of audits such as GFSI,” says Wester, “to very specific FSMA audits that say, ‘Look at this cook step and this regulation. Are they doing it right?’ We are not accustomed to reporting that level of detail on a specific hazard or regulation.”

### An Increasing Number of Audits

While FSMA is, at least for the time being, increasing the number of third-party audits, SGS’s Lott says she’s noticed another reason for the growing number of audits. “Walmart tells a supplier, ‘If you want to sell your product in our store, you have to be GFSI certified,’ a company gets that certification, then looks at all their raw material suppliers and says, ‘Why don’t we get all them GFSI

**Whether an audit is being done for internal assessment, toward certification, or to comply with regulation, those in the field say food companies often have an unrealistic expectation of what an audit can accomplish.**

certified as well?” she says. This trickle-down effect has even reached packagers in a supply chain as their product includes a surface that has contact with food, she says, which buyers want to get GFSI certified as well.

In addition, the journey from farm to fork has become increasingly complex, says Stuart Kelly, head of Commercial at Lloyd’s

*(Continued on p. 24)*

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Register. “Fifty years ago, the average supermarket stocked 200 items, 70 percent of which were processed within 100 miles,” he says. “Today, supermarkets stock around 39,000 items, and on average these items have travelled 1,500 miles before they’re consumed.” He adds that the more complex the supply chain, the higher the risk of foodborne illness hazards. “This complicates auditing but also makes it more important than ever to ensure safe, sustainable, and responsibly sourced food,” he says.

## Guidelines for the Fresh Tomato Supply Chain

United Fresh Produce Association recently released the updated version of the Food Safety Programs & Auditing Protocol for the Fresh Tomato Supply Chain, commonly known as the “Tomato Metrics.” These metrics were initially developed in 2009, endeavoring to harmonize food safety audit standards for the fresh tomato supply chain. It was this original effort that led to the development of the Produce GAPs Harmonized Standard.

The Tomato Working Group recommended a new structure for the Tomato Metrics in which tomato operations will use the Harmonized Standard (or other similar GAP audit) as the base food safety protocol, with the Tomato Metrics added as an industry-specific addendum. With the revision, the Tomato Metrics are limited to areas that are either unique to the tomato industry, or not necessarily unique, but not currently in the Harmonized Standards.

This update of the Tomato Metrics corresponds with the September 2018 publication of the Tomato Guidelines, 3rd ed. Together, these resources provide in-depth information and auditing protocols for the recommended food safety practices intended to minimize the microbiological hazards associated with fresh and fresh-cut tomato products.

“We hope that the new format of these metrics will encourage continued use of these standards, achieving our ultimate goal of food safety standard harmonization, and reduced audit fatigue among produce growing and handling operations,” says Emily Griep, manager of food safety, United Fresh.

The Tomato Guidelines can be downloaded for free by visiting [www.unitedfresh.org](http://www.unitedfresh.org). —FQ&S



## Personnel Challenge

As FDA increases regulatory inspections under FSMA and third-party auditors are beginning to issue FDA certifications, the food safety auditing industry is going to be under a lot of pressure. “This industry is going to grow tremendously,” says SGS’s Lott. “And auditors are an aging population. We need to focus on how we can get young people qualified faster to answer that demand.”

Lack of qualified auditors has always plagued the industry, even before FSMA and the recent uptick of audits. “Auditors are typically independent contractors who often do two or three audits a week, spending Monday to Friday on the road,” says Wester. “How does one maintain a life or a family—let alone write their audit reports—with that kind of schedule? We don’t have enough auditors, and the ones we do have burn out too quickly.”

What’s more, many job postings for auditors require so many years of auditing experience or specialized knowledge in a specific food sector or certification scheme that it filters out most new job seekers. “We need to work out entry-level positions for auditors,” says Wester, who helped start an association to represent those in the auditing industry. “Let them start at low-risk foods and then climb up to high-risk and reward them with pay increases.”

Meanwhile Martin Fowell, director of Auditing Operations at Mérieux NutriSciences, says that they have been working with the U.S. Department of Labor on an apprenticeship program to help alleviate some of the pressures they’re seeing on auditor capacity.

But it isn’t just auditor capacity that’s a challenge—it’s auditor competency as well. GFSI recently created “knowledge exams,” also known as GFSI Auditor Exams, to offer a consistent method to assess auditor knowledge across a range of relevant skills for all GFSI-recognized programs, as well as cover HACCP and Good Manufacturing Practice (GMP) requirements, and standard auditing skills such as sampling and evidence gathering.

While this exam will help ensure a baseline of expertise, GFSI’s Discours-Buhot also says that the challenge of auditor competence stems from the fact that a good auditor does a lot more than check off boxes. “We need auditors who have not just technical but human skills,” she says, “to be able to investigate, but also be able to chat with the employees in their own language.”

## Aligning Expectations

Whether an audit is being done for internal assessment, toward certification, or to comply with regulation, those in the field say food companies often have an unrealistic expectation of what an audit can accomplish. “Some view these certification audits as a kind of zero-risk insurance when in fact, the auditor is taking only a snapshot of one moment in time,” says Discours-Buhot. “As an industry, we need to better communicate that the certificate is only one of the tools used to mitigate risk when it comes to foodborne illness.”

Food safety is everyone’s business, according to Wester, not just the auditor. “Every person on every line plays a critical role in producing safe food,” she says. “They are the ones who see everything and should be empowered to act when necessary. Because even the best auditor is in a facility for only a couple of days.” ■

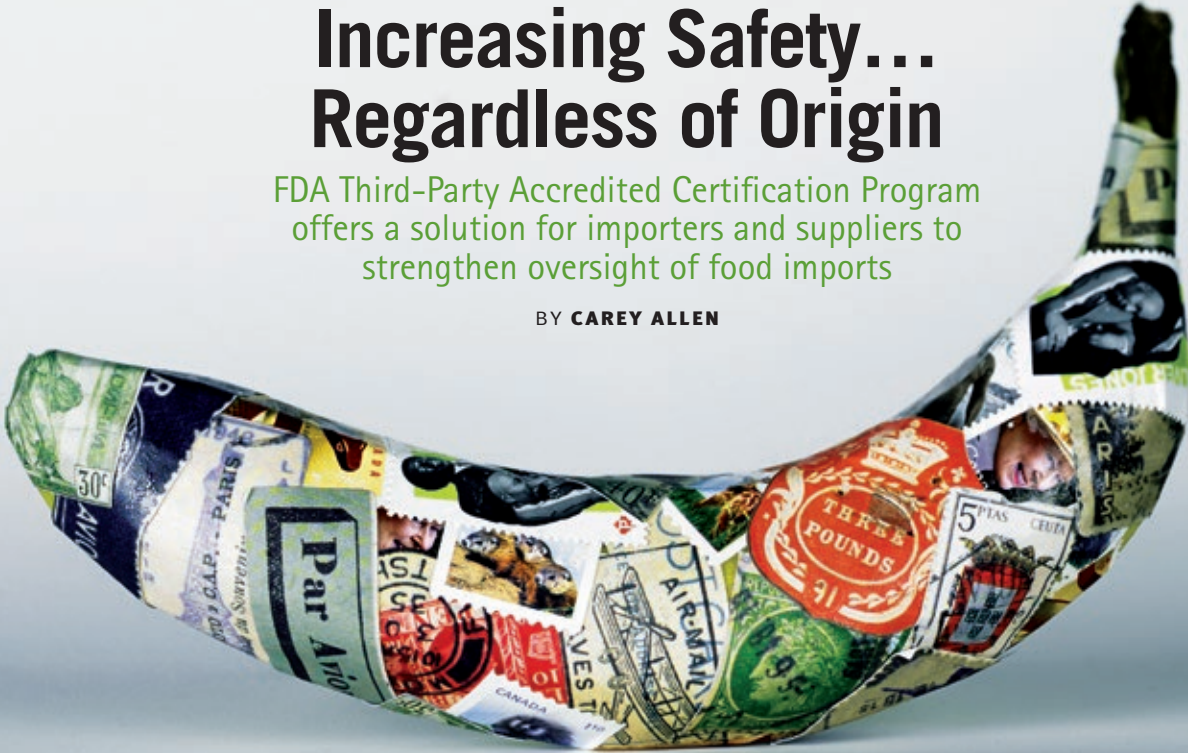
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# Increasing Safety... Regardless of Origin

FDA Third-Party Accredited Certification Program offers a solution for importers and suppliers to strengthen oversight of food imports

BY CAREY ALLEN



According to FDA, approximately one in six Americans experiences a foodborne illness each year, with about 128,000 of those cases resulting in hospitalization. Nearly 3,000 people die each year from foodborne diseases, which most frequently include older adults, young children, and individuals with compromised immune systems.

Signed into law in 2011, the Food Safety Modernization Act (FSMA) enables FDA to better protect public health by strengthening food safety and increasing focus on food safety prevention rather than just reacting to problems. The law and the rules that followed were designed to put more accountability on food and ingredients producers to understand and control the risks associated with the foods they make or import into the U.S. from other suppliers. Under the rule, imported foods must be assured of food safety compliance equivalent to that of foods produced in the U.S.

Finalized in November 2015, FDA's Accredited Third-Party Certification Program was created to ensure increased safety of imported food products. Third-party certification bodies can become accredited to perform FDA regulatory audits and issue certificates to facilities outside the U.S. The certificate is required for eligibility to supply products to an importer participating in the Voluntary Qualified Importer Program (VQIP) and for FDA-mandated import certification. An importer verifying supplier food safety may also use this certification audit to comply with the supplier verification activity requirements of the Foreign Supplier Verification Program (FSVP) rule of FSMA.

The supplier's scope of certification is determined by the product and process employed in manufacturing and production of the food—preventive controls for human food, the produce safety rule, seafood HACCP, or juice HACCP. The audit also verifies compliance with any additional applicable food safety regulations that apply for sites exempt from the preventive controls rules for food, such as thermally processed low-acid canned foods, acidified foods, and others. The regulations regarding sanitary transport also apply for those activities under the control of the certified site.

The Accredited Third-Party Certification Program was designed to:

- Establish eligibility for participation in VQIP, which offers expedited review and entry of food at the U.S. border;
- Assist food importers in identifying and addressing potential safety issues before food reaches the U.S.; and
- Help ensure imported foods are produced in accordance with the same safety standards required of U.S. foods.

## Foreign Supplier Verification Program

Under FSMA, importers are responsible for ensuring the safety of food products they bring into the U.S. for distribution and sale for public consumption. FSVP requires importers to verify that food imported into the U.S. is not adulterated or misbranded with respect to allergen labeling and it complies with U.S. product safety standards.

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Food hazards can be biological, chemical, or physical and can be intentionally or unintentionally introduced. Importers must conduct a documented review of the imported food, as well as the supplier's performance, every three years. The importers must identify and evaluate reasonably foreseeable hazards for each type of food imported to determine whether there are any that require control and, if so, document them. The hazards evaluated must also include an assessment of vulnerability of the materials or products to food fraud, or to economically motivated adulteration.

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## Importers must conduct a documented review of the imported food, as well as the supplier's performance, every three years.

Importers are responsible for determining the appropriate activity to verify that any identified hazards have been controlled. The verification activity most appropriate is dependent on many factors, including the nature of the hazard and the severity of the risk associated with failure to control it, any additional processing the food may receive further along in the value chain that may reduce the hazard or its severity, and the intended consumer market for the food. Appropriate verification activity by a qualified individual may include annual onsite audits of the supplier's facility, sampling, and testing, and a review of relevant food safety records is a requirement.

A qualified individual is someone hired on a full-time basis or sought through an external resource to help you:

- Document and implement the hazard analysis, verification activities, and corrective actions;
- Conduct performance evaluation of foreign suppliers;
- Approve suppliers;
- Reevaluate FSVP and documentation;
- Perform on-site supplier verification activities; and
- Maintain up-to-date records.

Certification audits conducted according to the program may be used to satisfy the onsite audit activity requirement for supplier verification. Supplier certificates must be maintained as records to demonstrate compliance with FSVP.

When the FDA Third-Party Accredited Certification is used to satisfy FSVP requirements, it provides the opportunity to reduce audit burden and conserves human and financial resources related to repetitive or redundant customer audits. The audit against the applicable FDA regulations for the product scope may be conducted in conjunction with a current certification program, such as a Global Food Safety Initiative (GFSI) benchmarked food safety program, to ensure any gaps between the existing program and the FDA requirements are fully evaluated.

## Voluntary Qualified Importer Program

VQIP, a voluntary fee-based program, provides expedited review and import entry of food brought into the U.S. for participating importers. Participating importers benefit from increased speed and predictability at U.S. points-of-entry. Consumers benefit from increased safety and security of imported foods.

VQIP suppliers must be certified by a certification body accredited under the FDA Third-Party Accredited Certification Program. A supplier site may choose to have a third-party consultative audit prior to the certification audit to help the site prepare. Consultative audits are not available from accredited certification bodies and may not be used for certification.

VQIP benefits for importers include:

- Quicker, easier market entry for imported goods;
- Limited examination and sampling;
- FDA sampling at importer's preferred location; and
- Faster test results.

## FDA High-Risk Import Certification

FDA may determine a foreign supplier or food product is high risk and mandate import certification (IC) by a Certification Body accredited under the FDA Third-Party Accredited Certification Program. FDA does not maintain a register or list of high-risk products, but may designate this status in the event of an ongoing food safety incident, as a result of field sampling, or in response to elevated risk to food safety due to geopolitical or natural events.

If FDA designates a product as high risk requiring import certification, the supplier would be notified by FDA and the site would choose the accredited certification body to perform the certification in order to qualify for import. The imported product must be accompanied by the certificate and be listed by the certification body on its public listing of certified sites.

Regardless of the reason for the certification, foreign suppliers and importers should remember:


- All accredited certification audits for VQIP suppliers and FDA high-risk imports are unannounced;
- FDA may mandate an import certification for high-risk products as a condition of import, unrelated to VQIP or FSVP;
- If a supplier undertakes a VQIP or IC audit by an accredited certifier, its audit information is shared with FDA, and it is listed publicly for its certification status and authorized products for import;
- Audit information for VQIP suppliers and FDA IC imports is subject to public disclosure under the Freedom of Information Act;
- If a VQIP or IC supplier is involved in a recall, the certification is immediately suspended pending further investigation;
- If a certification body observes a critical food safety hazard at the certified site, FDA is immediately notified, the certification audit is stopped, and certification is suspended;
- Importers and suppliers must maintain clean food safety records for the three years immediately preceding certification; and
- Mixed loads of certified and non-certified products for VQIP imports will be detained in order to separate the load.

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# Safety & Sanitation

HYGIENE MONITORING



## 5 Things Not to Do With ATP Monitoring

While ATP monitoring is considered easy to use and interpret, there are a number of cautions of how the instruments and monitoring systems should not be used

BY ANDREW PORTERFIELD

According to the World Health Organization, 1 in 10 people in the world (about 600 million) falls victim to illness from contaminated food each year. Of that, about 420,000 die. Unsafe food not only causes disease—it also strains healthcare facilities and can hurt economics, trade, and tourism.

It's estimated that food contamination costs the industry about \$55 billion a year in the U.S. alone. For individual businesses, it can range from a few thousand to millions of dollars. Those numbers do not necessarily reflect other costs, including reputation to a facility and industry, and the ability to regain trust from suppliers and consumers.

Complicated international food supply chains help distribute more food around the globe, but also call for more vigilant food safety precautions at every step of the supply chain. The outbreak of *E. coli* O157:H7 in several states from romaine lettuce is an example of how the complexity of the produce supply can create significant challenges to maintaining food safety.

Quickly identifying potential contamination sources is a key part of protecting the food supply chain. Since its introduction, adenosine triphosphate (ATP) bioluminescence-based monitor-

ing of surfaces and even some products has been invaluable to identifying possible sources of contamination. Within seconds, food processor professionals can now monitor safety levels, identify contaminant areas, and more effectively set up and fine-tune Hazard Analysis and Critical Control Points (HACCPs).

While ATP monitoring is considered easy to use and interpret, there are a number of cautions of how the instruments and monitoring systems should not be used. The following are five warnings about how not to work with ATP monitoring.

### Don't Confuse ATP with Direct Bacteria or Viral Detection

ATP is the energy-containing molecule that is found in every living cell. Therefore, it is a useful indicator that contamination may exist on a surface or other part of the food supply chain, from irrigation water to farm to processor, transporter, handler, or retail market. But since all cells contain ATP, a positive reading in relative light units (RLU) will indicate any cell, and not just bacterial cells. Furthermore, not all bacterial cells cause disease. And viruses, which are not technically living cells, usually do not contain any ATP at all.

Nevertheless, ATP monitoring is valuable because it points to areas where bacteria (and, to a more limited degree, viruses) may lurk. After all, bacteria are cells, and areas that record very low RLUs have fewer cells and are far less likely to harbor pathogenic microorganisms. Other tests, such as enzyme-based or bioluminescent devices based on specialized substrates, can determine the presence of specific bacteria, including *E. coli*, *Enterobacter*, *Coliform*, or total bacteria counts, within hours. Still more sophisticated tests, like those using the polymerase chain reaction, can identify specific bacteria or viruses, sometimes within a day. Traditional methods like cell culture may take days to generate results, but commonly can verify species of bacteria.

### Don't Use on Soiled or Pre-Cleaned Surfaces

Many users of ATP monitoring can fall into the trap of measuring environmental surfaces before cleaning, hoping that those readings can be compared to readings taken after cleaning and/or sanitization steps. While those readings should be significantly different (hopefully!), ATP luminometers and mostly importantly the testing devices were never meant to be used on uncleaned surfaces. This is because it is easy to overload the swab part of the testing device with microorganisms, which can significantly impact results.

As the universal energy molecule, ATP is found in all animal, plant, bacterial, yeast, and mold cells. Product residues, particularly food residues, contain large amounts of ATP. Microbial contamination contains ATP, but in smaller amounts. After cleaning, all sources of ATP should be significantly reduced.

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The test is designed to detect invisible or trace amounts of product residue. When performing sample collections, it is important to make sure not to overload the swab bud with too much sample. Some products in very high concentration can inhibit the bioluminescence reaction.

This also means that when collecting a sample, make sure to use aseptic techniques. Do not touch the swab or the inside of the sampling device with your fingers.

### Don't Assume a High Reading Indicates Supply Chain Failure

ATP monitoring is a valuable tool for determining the potential for contamination and can help improve processes at every step in the food supply chain. Too often, a reading with high RLUs, indicating potential contaminants and possibly even pathogens, is interpreted as a failure of personnel to keep things clean. To counteract this misperception, ATP monitoring can be used as a staff or contractor training tool.

Any successful cleaning efforts require a plan, including setting up an HACCP process. ATP can provide nearly instantaneous data to find possible gaps in your processes that can be quickly and efficiently closed by changing cleaning methods, protocols, or locations. Far better to identify potential issues at an early stage than later when pathogens can cause costly shutdowns. Furthermore, a high RLU indicates that intervention and cleaning steps need to be taken, and re-testing the same area can determine the effectiveness of those efforts.

Training should include the use of ATP monitoring and the efficient use of data storage and tracking, which relies on software packages (such as Hygiena's SureTrend cloud-based software) that can record trends in your facility and point out areas that need improvement. This is also helpful when supply sources, technology, and equipment are changed, which will alter how you monitor and clean your facility. Training efforts and a quest for continuous improvement should be an integral part of your facility's culture, and the data that comes from ATP monitoring can form a solid foundation for creating that culture.

### Don't Under Sample

A cleanliness monitoring system needs to be thorough enough to sample every potential area where contamination could possibly occur. Food contact areas (direct and indirect) and hard-to-clean areas should be the main focus of your swabbing program. Direct contact areas are surfaces where the presence of any contaminant will taint the final product. Indirect contact areas are those where splashed product, dust, or liquid has the potential to be dropped, drained, or transferred onto the product. Hard-to-clean areas may include filler heads, O-rings, nozzles, and areas with irregularly-shaped surfaces, corners, grooves, and cracks.

A recent study showed that some amount of over-sampling (overlapping some areas at times) can be an effective way to get

robust ATP results and prevent possible contamination. While Hygiena advises structured, repeated cleaning schedules on key environmental surfaces and a sampling area of 4 x 4 inches, certain intricate surfaces in food contact areas may benefit from using smaller sampling areas, such as 2 x 2 inches. Re-testing is still a vital part of maintaining facility cleanliness, too.

### Don't Test Inconsistently

Hygiena advocates for the development of a comprehensive cleaning schedule and map of environmental surfaces, including the sampling of "high touch" areas in facilities. The schedule should include multiple sampling sites on a surface and reliable recordkeeping on online reporting tools to track cleanliness and

re-testing of areas, especially those areas that result in higher RLUs. A number of researchers claim that ATP measurements suffer from too much variability in results partly because of inadequate cleaning and monitoring strategies.

Consistent testing starts with a solid plan and means to evaluate it:

- Set up all the locations, users, and test plans before testing so that running reports is easy and accurate;
- There's no need to create reports from scratch—preprogrammed reports can be modified and saved;

- Graphs can be quickly converted to line, bar, or pie charts depending on preference;
- Sharing reports with team members in regular meetings initiates a conversation on improvement opportunities and positively reinforces successes;
- Share these reports with executives and quality committee members to demonstrate how ATP cleaning verification helped improve cleanliness; and
- Compare these reports to any existing contamination/bacterial infection data to correlate cleaning improvements with infection rate reductions.

Consistency isn't just about sampling locations, however. For consistent readings, surfaces should be swabbed in the same conditions (always wet or always dry). This will make it easier to compare data and look for trends that might need attention.

A successful contamination prevention effort will involve some amount of planning, training, and evaluation for effectiveness. As the world's food supply chain gets more complex and global in scope, an adaptable yet robust monitoring plan will be essential to maintaining a safe food supply. Reducing foodborne illness by just 1 percent would keep approximately 500,000 people from getting sick each year in the U.S. Reducing foodborne illness by 10 percent would prevent 5 million people from getting sick annually.

ATP-based testing is now a worldwide standard method as a first step toward rapidly identifying potential reservoirs of pathogens, so problems can be corrected—and prevented—before they become serious, or even deadly. ■

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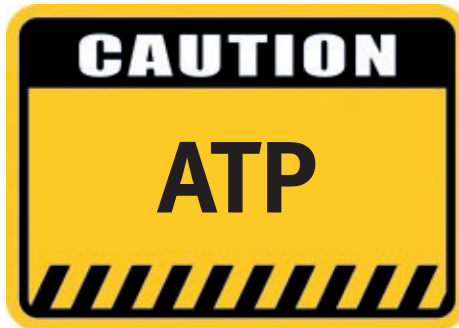
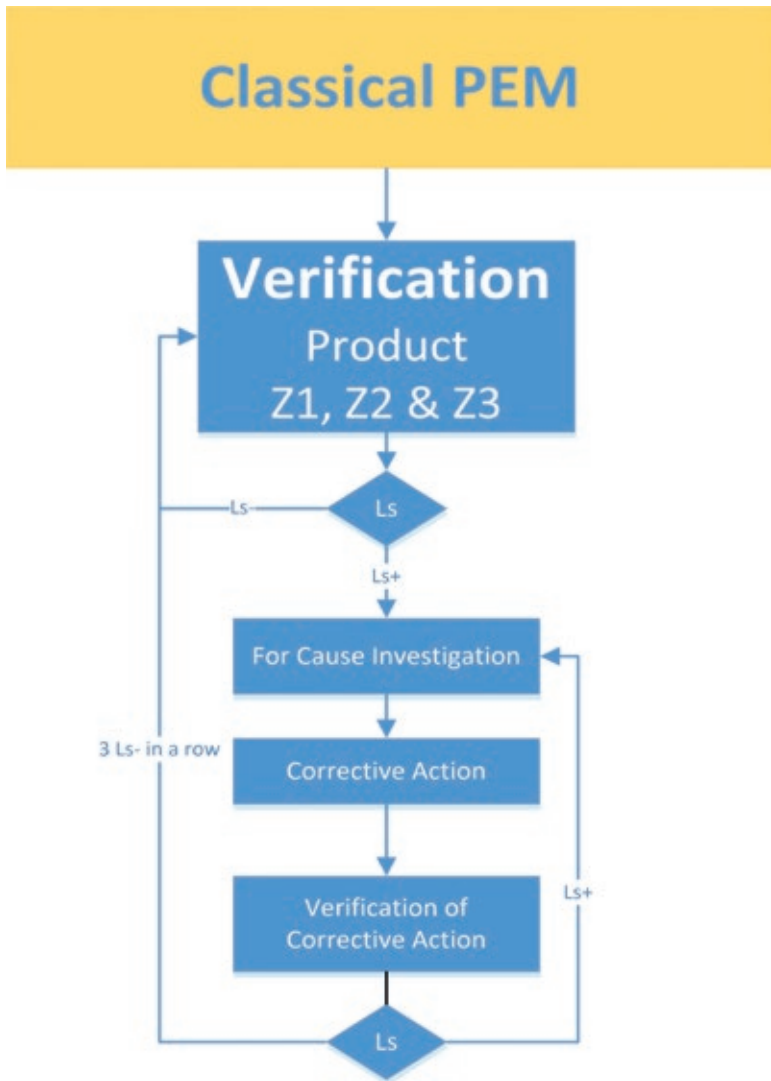




Figure 1: Classical pathogen environmental monitoring



ing environments can be attained. Every plant is different because the inherent microbiological risks are different even though equipment, procedures, processes, and products may be the same.

**A Basis for Process Control**

The theory of food safety process control has its basis in risk identification, science, and management. The challenges of environmental microbiological process control are daunting because there is no kill step to intervene. Root cause analysis produces three primary results:

**Pillars of Control**

1. Eliminate harborage sites in exposed product areas.
2. Control transfer of the organism.
3. Deploy process management techniques to control the environment.

Persistent resident pathogen strains must be removed from the exposed product production process even if there is not a kill step in the product production process. The Seek and Destroy Process started as an investigative method to assess the sanitation of and locate harborage sites in equipment. Today, it represents the totality of establishments' overall microbiological sanitation process control efforts. This includes verification of control as well as measurements of process control. Most companies producing ready-to-eat (RTE) products deploy a pathogen environmental monitoring (PEM) program. Typically, sampling occurs during production with the intent to verify the absence of the organism. The PEM is an effect measure and trailing indicator of risk.

**Verification monitoring program.**

This is a routine program to verify the effectiveness of the sanitation process control program that includes sampling of Zone 1, 2, and 3 environmental sites in the RTE area. This program is used for regulatory compliance.

Monitoring of verification sites detects the organism as it is being moved from its harborage location to a contact surface or the product. Verification sites are surfaces that are exposed during the normal operating conditions and are likely to serve as transfer points (i.e., they are located in transfer pathways). If an exposed surface is suspected to be a har-

*(Continued on p. 30)*

# The Seek and Destroy Process

An in-depth look at best practices for environmental pathogen control | BY JOHN N. BUTTS, PHD

*"If you cannot define what you are doing as a process, you do not understand what you are doing."*—W. Edwards Deming

The purpose of this article is to share over 30 years of best practices developed in the area of environmental pathogen control.

The focus is *Listeria*, but the practices and principles apply broadly to organisms harbored in our environment.

Many of these best practices were learned at some expense, many failures, and just plain tenacity. There are no silver bullets, but experience has shown that microbiological control of food process-

(Continued from p. 29)

borage site, then preoperative sampling should be used to measure the effectiveness of the sanitation process. Sanitation effectiveness of exposed surfaces needs to be validated with preoperative sampling then monitoring (APC) to verify effectiveness. Verification type sampling is used by USDA Food Safety Inspection Service in its RLM events as well as FDA in its “Swabathons” sampling events.

The S&D Process is a method for not only verifying the effectiveness of the sanitation process control program, but also sampling to measure preventive controls such as investigative (not-for-cause) sampling to define levels of disassembly, identification of indicator sites, qualification of new equipment, measure effectiveness of hurdles and barriers, and measurement of potential risk from Zone 4 areas.

**Engage Your Employees**

The development and sustained deployment of best practices requires employee engagement—teamwork is the pathway to success. I strongly encourage the development of a team to be the responsible and accountable force to implement and deploy environmental control best practices at each plant site (see Figure 1).

Our team is called the “Seek & Destroy” Team. Below are our model team charters using the elements of purpose, methods, and the results expected.

**Team meetings.** These meetings are not committee meetings to discuss why GMPs are not working. Lengthy notes are not expected nor wanted. Instead the focus is on action taken to accomplish the results expected.

Task team leaders report progress and identify any roadblocks to success,

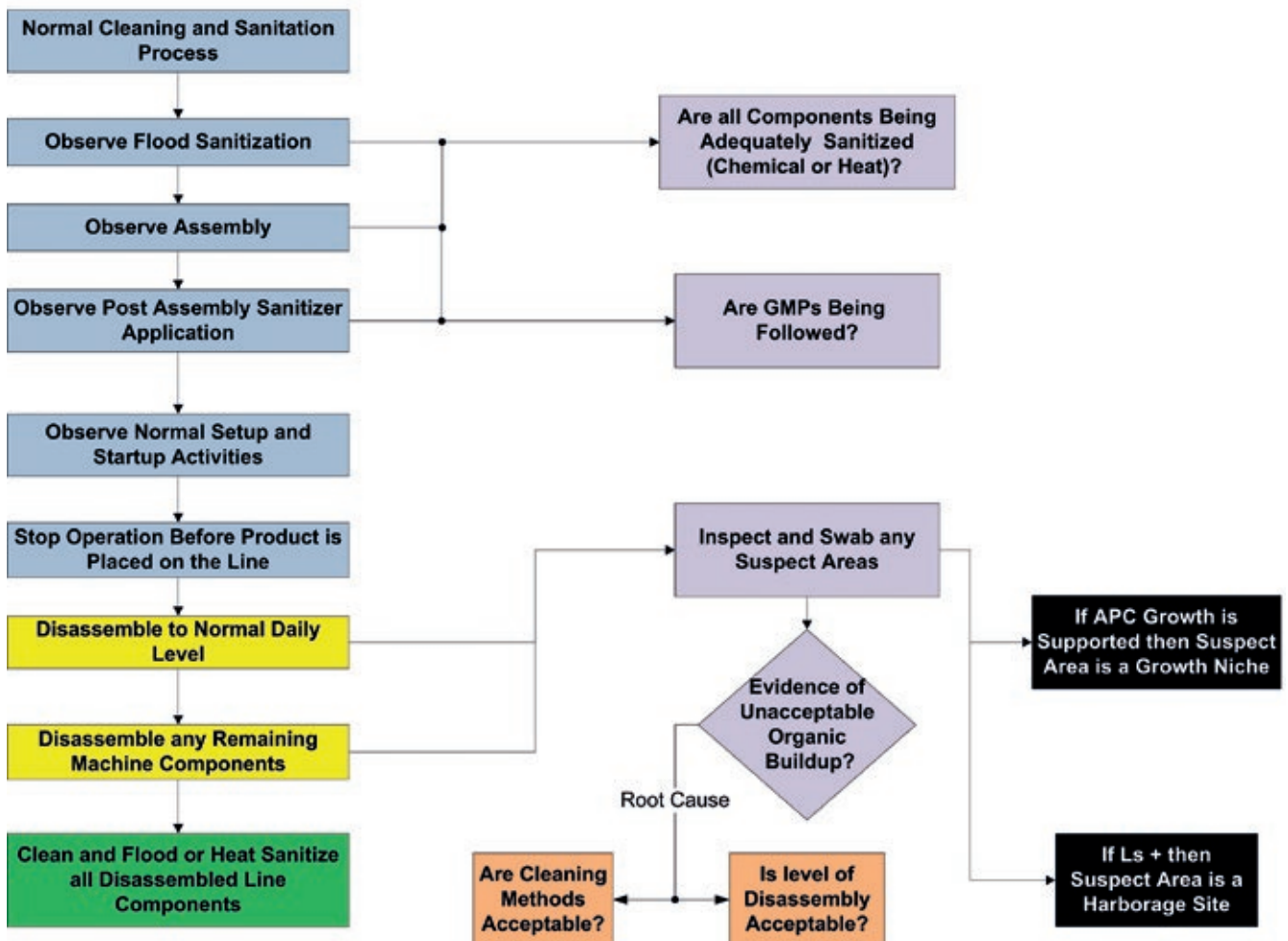
which become key issues for resolution. These may be solvable within the team (vested authority to make change is a critical component of each team member’s responsibility); those that cannot must be addressed by team leadership, or plant and/or corporate management.

Action taken on roadblocks is reported in the team’s action log or action register. Transparency and communication of solutions to roadblocks and best practices implemented are needed to reinforce the preventive mindset of the organization.

Management, quality, and maintenance must all hold one another accountable for timely action on roadblocks, and each has a specific role to fill.

1. Management’s role: Management must support team training and provide facilitation when needed. Team members’ time must be allocated appropriately—this

Figure 2: Seek and Destroy Mission





is another reason to keep the scope very narrow and address the most significant risks. The management systems of SOP, SSOP, operational procedures, and work instructions must support the documentation, training, and implementation of changes made by the team. In addition, management must not let the team “boil the ocean”—focus and execution are keys to success.

2. Quality’s role: Audits are designed by quality management to recognize changes made and to hold gains.

3. Maintenance’s role: The maintenance PM system is most often the ideal way of managing simple changes. The team leader and maintenance/engineering members can input and create work orders to address the types of problems that are encountered. Periodic infrastructure cleaning (PIC) and periodic equipment cleaning (PEC) are often best managed with the maintenance PM system.

### **Teams and teamwork best practices.**

It’s a good idea to rotate team leader and team members to create greater buy-in within the workforce. Take pictures and tell stories to onboard and engage new team members. They will spread and be used as a basis for the normal and accepted behavior.

Be sure to keep the team charter simple—two pages maximum. The charter should identify the team as the accountable body within the facility to define and implement process control measures. Management must support this concept and approach, and provide resources.

The determination of results expected is broken into smaller tasks. Assigned task teams are typically led by an S&D Team member. Task teams are small but employ key affected parties for solutions and implementations. The implementation of recognized best practices eliminates needless research and firefighting.

Teamwork enables the plant organization as a whole to have a much deeper understanding of “why” certain procedures exist as well as how to follow data and to use it to hold gains. “Why” is a driver of the process—a key to sustainability.

### **Eliminate Harborage**

A growth niche is defined as a location that supports microbiological growth and is protected from the sanitation process; it is characterized by high microbial counts after normal cleaning and sanitation. A harborage site is defined as a growth niche that contains the pathogen or its indicator. (For a complete list of Environmental Monitoring Operational Definitions see the [3M Environmental Monitoring Handbook 1st Edition](#).)

Hollow rollers have been and continue to be one of the greater nemeses of the food industry. A classic mode of contamination

*(Continued on p. 32)*



# FOOD SAFETY TOOLS, SERVICE, AND SUPPORT

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(Continued from p. 31)

and recontamination occurs during every cleaning cycle during the initial rinse. The rinse down and removal of product debris unfortunately enables food, water, and microorganisms to penetrate the hollow member, making the bacteria protected from the cleaning and sanitizing chemicals. Further rinsing only provides more water for growth. Land O' Frost and I found the depth and degree of penetration is directly correlated to the force of the rinse water. High pressure used during sanitation is a major cause of sanitary design issues becoming growth niches and harborage sites.

**No Niches.** According to (North) American Meat Institute's (N)AMI's Equipment Design Task Force, "All parts of the equipment shall be free of niches such as pits, cracks, corrosion, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolt rivets and dead ends. All welds must be continuous and fully penetrating."

The method to identify growth niches and harborage sites is the Seek and Destroy investigation, which is used to find pathogenic growth niches, find potential growth niches requiring monitoring and control, define normal level of disassembly, define periodic deep levels of disassembly, define the frequency of periodic deep levels of disassembly, qualify a new piece of equipment (usually, run for 90 days then conduct Seek and Destroy Investigation); validate effectiveness of equipment cleaning protocol; and validate effectiveness of intervention applied to a piece of equipment (heat treatment or other method).

The sanitary design of the equipment during disassembly may be evaluated using the (North) American Meat Institute Equipment Design Task Force Checklist or another method.

In a Seek and Destroy Investigation:

1. Pre-number or pre-code sample collection bags.
2. Take a picture of the bag to indicate the next sample site to be taken.
  - a. Get a distance picture to locate the site within the plant area. Take several more pictures up to a closeup of the site itself.
  - b. Document the name of the site. Typically a maintenance person

is the best resource for properly naming sites.

3. Repeat step 2 with each consecutive site.

### Understanding Movement

The movement of people, equipment, product, and materials during production operations provides motility for organisms—they move along a pathway by vectors from transfer point to transfer point. Movement from a harborage site also occurs deep within equipment or facility to the exposed processing environment. Sampling during production finds the organism moving from its preoperational state to a contact surface, the product, or a

## Indicator sites are the measurement system for a microbiological process control.

drain. The process flow of the vectors dictates the direction of movement.

Disruptive events such as rinse down at breaks even with sanitizer may physically remove many organisms from equipment. However, this activity does not eliminate the organism from the environment. Rinsing does relocate the organism, however, providing more pathways of movement.

Verification sampling during production of Z1, Z2 and Z3 pathways verifies the ability of the sanitation process control to minimize the transfer and movement of the organism.

To prevent or minimize movement, create a torturous pathway that maintains a high concentration of sanitizer on the floor and includes hurdles such as sole scrubbers between hygienic zones. Also consider captive footwear, separation and segregation of transport equipment, and keeping floors dry.

### Implement a Process Control

The final pillar of environmental pathogen control defines how the gains are being held while continuing the risk reduction process. The cost of pathogen sampling has and continues to drop. Pathogen sampling of verification and indicator sites are composited. History and data analysis

have identified those most optimal and risky areas to sample on a regular basis. Not-for-cause investigations continue ensuring any process changes are done without increasing microbial risk. APC testing is fine tuned to recognize any shifts in the environment. Shifts that are found lead to the application of interventions and aggressive sampling.

The visual of the S&D Process as a whole is presented in the Figure 3 flow chart.

**S&D Process best practices—process control (not-for-cause) investigation.** The S&D Process can be conducted in situations where food safety has not been compromised. Examples include when samples are taken to find a new growth niche, find a new transfer vector/pathway, establish or qualify a hurdle or barrier system, establish a monitoring procedure or process, and assess or characterize risk of a control procedure, part of facility or process change.

Investigations can also be triggered by an indicator site positive. This becomes part of the aggressive sampling following an indicator out of control observation. These indicator sites are strategically located in close proximity to a known growth niche, barrier or hurdle. Movement of the organism from the indicator site through a verification site or area would be required before violation of food safety. These indicator sites over time measure the strength of the barrier or hurdle or the effectiveness of the management of growth niches.

In addition, a Seek and Destroy Investigation can be conducted on a new piece of equipment to develop sanitation methods and identify potential areas of risk and on a piece of equipment to define the normal and periodic deep level of disassembly.

Investigative sampling to identify optimal locations for placement of indicator sites in either Z3 or Z4, and measurement of risk in Z4 area are also acceptable.

**Indicator sites.** Indicator sites are the measurement system for a microbiological process control. They are "risk-based" indicators of special causes or process shifts in the environment.

Ideal indicator sites include locations close to the growth niche that can identify an active growth niche, locations that can identify suspect organisms before they

(Continued on p. 34)





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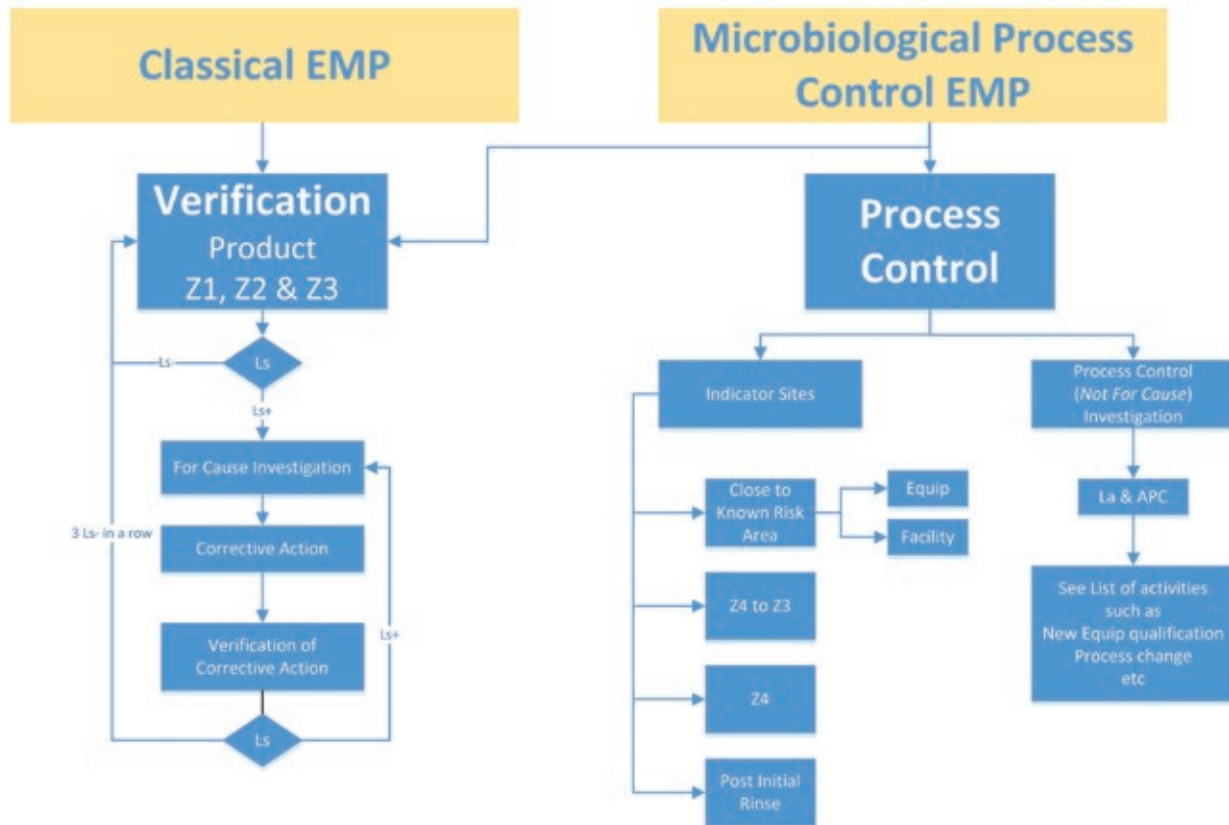
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Figure 3: Seek and Destroy Process



become attached to or imbedded within the equipment, Z4 to Z3 Transfer areas, and Sanitary Facility & Equipment Design issues.

**Post rinse.** Post-rinse sampling is an indicator for potential risk. Positive post-rinse sampling is not an indicator of a food safety hazard, however. Typical sites are below the product line and in areas that tend to collect spatter from the rinsing process (e.g., machine sides, legs, support structure, floor wall juncture). Detection of the organism does not mean there is a harborage site within the scope of the sampled area. Positive post-rinse samples will typically trigger aggressive sampling or not-for-cause investigative sampling. Post rinse 10 days in a row.

Sample large areas that collect “spatter.” Composite sampling is acceptable. Positive results will direct investigation team to a line, pair of lines, or section on a line.

#### **The S&D Process quick tips.**

- Measurement system
  - APC to manage growth niches
  - APC at Preop to measure effectiveness of sanitation

- Expect 99 percent large area swabs (Plant KPI) to be < 100 cfu (total area)
- Continuously seek indicator sites
- Increase percentage of indicator sites to verification sites by adding indicator sites as the process evolves and data is collected
- Reward finding positives
- Seek and Destroy Investigation on a piece of equipment that has been in operation without any linked verification positives to measure the effectiveness of sanitation methods below the normal level of disassembly

#### **Maturity Models**

Maturity models are used in the S&D Process to define the stages or levels of control attained. The stages include Awareness, Enlightenment, Preventive, and Predictive.

Awareness & Enlightenment are characterized by repeated positives in the same general areas: firefighting and a failure to find and eliminate or manage the harborage site(s). Failure to effectively use or deploy preventative practices keeps the establishment in a “firefighting state.” In

this state, management promotes not getting to the root cause and rewards solving the same problem over and over again.

The S&D Process moves the establishment along the journey from the Awareness Stage to the Predictive Stage. The establishment transcends to the Preventive Stage when harborage sites are eliminated through redesign or managed with an intervention capable of eliminating the pathogen from the harborage site. The Predictive Stage evolves as data is used to predict when to apply interventions and other more aggressive preventive controls.

I see the elements of our maturity models changing as technological advances occur in metagenomics, rapid methods, and broader application of whole genome sequencing. These technologies are reducing the time for identification of outbreaks as well as detecting smaller events. Time compression is and will continue to occur at the processor level to identify, eliminate, or manage harborages. ■

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# Testing

FOOD FRAUD



## Taking Adulteration Analysis to the Next Level

Food fraud detection throughout the supply chain with advanced testing and informatics

BY GREG SEARS AND STEFAN TORDENMALM

**C**ombating food fraud has different meanings depending on whom you ask along the supply chain. For growers, it refers to protecting the integrity of the ingredients they introduce into the supply chain. For the regulatory community, it means helping to reinforce and establish the authenticity of the food market so consumers don't have to worry about the safety of the food that they eat. For food retailers or manufacturers, it's about maintaining their brands' integrity and value with consumers and the industry. For everyone involved—from farm to fork—it's about ensuring there is a continued supply of safe food around the globe.

In order to battle food fraud, it is vital to provide a host of robust analytical and informatics solutions that can detect and analyze adulterants throughout the sup-

ply chain. Techniques such as infrared (IR) spectroscopy, liquid chromatography tandem mass spectrometry (LC-MS/MS), and inductively coupled plasma mass spectrometry (ICP-MS) address food quality and safety and help consumers be more confident in the integrity of the food they eat.

### First Line of Defense: UV-Vis and IR Spectroscopy

There are a number of different methods and technologies used to detect adulterants in food. The chosen method will depend on the type of food fraud that is being detected.

For example, a UV-visible light (UV-vis) spectrometer is considered a useful and simple instrument that detects adulterants in extra virgin olive oil. With olive oil

consumption increasing, this high-value product has become particularly susceptible to fraud.

One example of olive oil fraud is the addition of lower grade, refined olive oils to extra virgin olive oil. These lower-quality oils contain unsaturated hydrocarbons that absorb UV light in the 200 nm-300 nm spectral range. Therefore, a high absorption within this wavelength range points to a lower quality olive oil, meaning UV-vis spectroscopy can be used to differentiate between oils in a sample.

Extra virgin olive oil can also often contain significant levels of other edible oils that have a lower market price or are of a lower quality. Some examples of common adulterants include hazelnut oil, sunflower oil, soybean oil, rapeseed oil, or corn oil. UV-vis spectroscopy offers a simple method for checking whether an analysis result is above a specific limit, and therefore whether other oils have potentially been added to a sample of extra virgin olive oil.

In situations where there is uncertainty about the type of adulteration that may have taken place, IR spectroscopy is the preferred method for rapid, onsite analysis of samples in other commonly adulterated foods like honey and orange juice. As IR spectroscopy requires little sample preparation, it is also an easy-to-implement method that is useful in providing a rapid pass/fail analysis of adulteration. This, along with the fact that it does not require significant training to be operated, means IR spectroscopy can be used for testing at any point during the supply chain.

For example, herb and spice adulteration—such as replacing oregano with olive or myrtle leaves, the addition of dyes to chili powders, or adding peanut and almond material to ground cumin powder—is rapidly becoming more commonplace in the food industry and is a prime fit for IR spectroscopy. One issue with herb and spice samples, as with most food samples, is that they typically contain many sources of natural variation and are therefore difficult to analyze. Near-IR (NIR) spectroscopy can overcome this issue, enabling deeper penetration into samples in comparison to mid-IR or far-IR. NIR can therefore produce stronger spectra, making it easier to detect adulterants in these complex samples.

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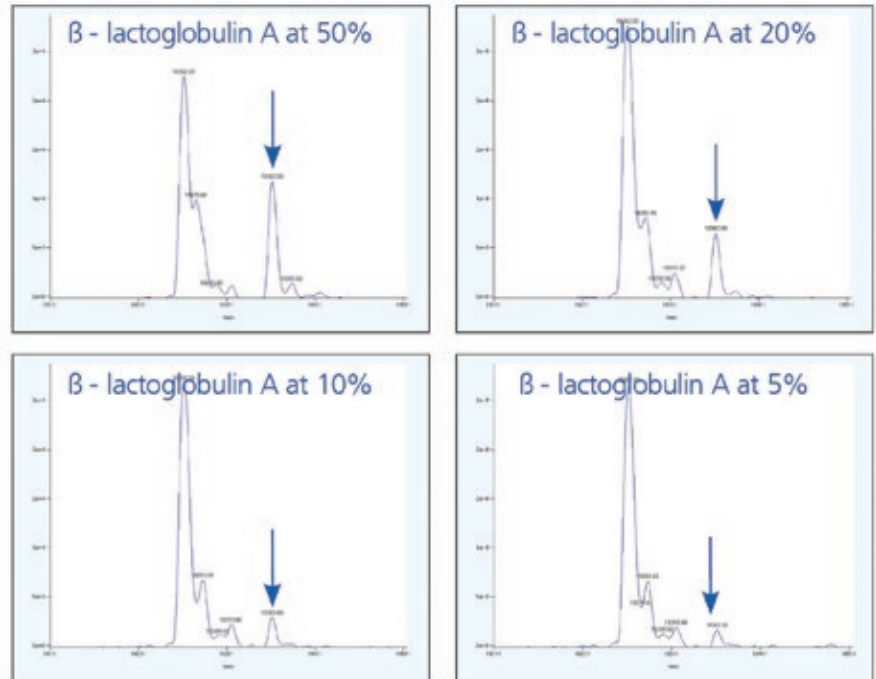
By combining this instrumentation with advanced analysis technology, it is possible to compare the spectra of a specific food sample with a database of known “pure” samples. These algorithms and chemometric techniques then enable

This led to the nitrogen-rich, but highly toxic compound melamine being added to milk products in order to raise their apparent protein content.

users to classify complex samples, determine authenticity, and estimate the level of a certain adulterant without the need to run a further test.

After the 2008 melamine scandal in China, detecting adulteration in milk has also become a critical application for IR analysis. Typically, milk with a higher protein content will in turn attract a higher price in the market. Unfortunately, the

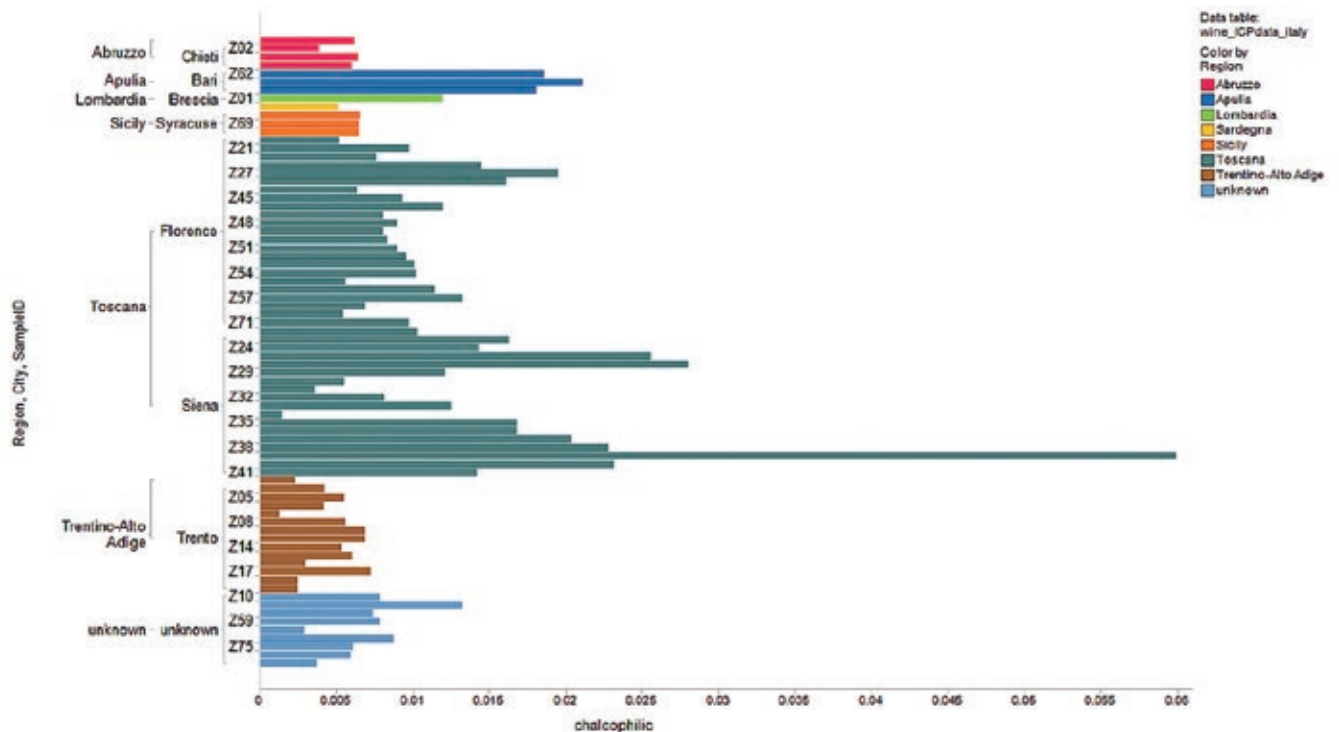
Figure 1. Adulteration levels down to 5% of cow's milk in buffalo's milk are detected in the deconvoluted spectrum of the averaged lactoglobulin elution region using  $\beta$ -lactoglobulin A as the marker protein.



typical methods for testing the protein content of a milk product are based around measuring nitrogen levels. This led to the nitrogen-rich, but highly toxic compound melamine being added to milk products in

order to raise their apparent protein content. IR analysis is crucial in determining the concentration of this adulterant in milk, as well as identifying any other adulterants such as sugars or urea.

Figure 2. Bar chart for samples ordered by region then city, with bars colored by region, showing levels for the custom chalcophilic category (sum of Zn, Sb, As, and Sn levels) are higher for the Toscana (Tuscany) wines (blue) than for the Trentino wines (brown).





### Next Level: LC-MS/MS and ICP-MS

In instances of food fraud where adulterants are at too low a concentration to be picked up by IR, or where stricter regulations demand more precise determination of adulterant levels, LC-MS/MS comes into play.

In the case of milk, for example, mass spectrometry offers an alternative method for the detection of adulterants. Aside from melamine and the addition of other small molecules, large molecules can also be added to milk for the purpose of fraud—for example, diluting more expensive milks such as buffalo, camel, goat, or sheep,

cooked, and processed meat products for the presence of pork.

LC-MS/MS is also crucial for the detection of synthetic azo and non-azo dyes down to 10-100 ppb concentrations. Although once used in the industry as food colorings, these dyes have now been widely banned due to their potentially genotoxic or carcinogenic properties. However, they are still being detected in the food supply chain—particularly in spices—making it crucial that sensitive methods are available for the detection of even minuscule amounts of these banned substances. First, a simple dye extraction

is therefore imperative that they are detected as quickly and reliably as possible. LC-MS/MS can simultaneously determine the concentrations of both pesticides and pigments in a single analytical run, providing users with a quick and easy method for monitoring these compounds in their products.

ICP-MS can also be used to combat fraud in wine by helping to determine the geographical origin of grapes—an important factor in driving product price and consumer expectations.

Using ICP-MS, it is possible to identify the unique and varying levels of trace elements present in the wine. After an elemental profile is created by ICP-MS, informatics solutions can then deliver a visualization of the data correlating the levels of trace elements in certain wines to that in different, geographically situated soils. (See Figure 2.)

### Future of Combating Food Fraud

Although food fraud is certainly not a new concept, the increasing cost of food ingredients is making it more common. This is combined with ever-stricter regulations and the fact that those committing food fraud are also becoming more creative and intelligent in finding new ways to adulterate food. It's therefore clear that the more in-depth information available on fraudulent activity, the more effectively fraud can be reduced and controlled.

Advanced yet intuitive testing innovations will continue to play a big role in helping to combat these challenges at all points of the food chain. Informatics will also continue to emerge as an ever-critical component in the fight against food fraud. With informatics, labs, scientists, organizations, and companies have easier and more intelligent ways to visualize their data. Data can be shared more easily and securely via the cloud, and actionable insights can be drawn more quickly and easily. The food industry and solution providers must therefore continue to work closely together to ensure optimal and advancing instrumentation and tools are being leveraged to help uphold the integrity of the food supply chain. ■

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ICP-MS can also be used to combat fraud in wine by helping to determine the geographical origin of grapes— an important factor in driving product price and consumer expectations.

with cow's milk. By using LC-MS/MS, it is possible to measure the addition of bovine milk to these pricier milks by detecting the presence of  $\beta$ -lactoglobulin A. (See Figure 1.) This species-specific marker protein is found only in cow's milk, enabling users to detect the presence of this cheaper alternative in other more expensive types of milk.

A similar method can be used to detect the presence of pork in certain foods, which is crucial for consumers whose culture or religion prohibits the consumption of this meat. Pork meat, like milk, contains certain peptides that can be used as biomarkers for detection in food samples. LC-MS/MS enables the detection of these biomarkers, offering a rapid, selective, and sensitive method for analyzing raw,

is performed using an organic solvent, with the filtrate then injected into the liquid chromatography column. Using certain methods, LC-MS/MS can achieve exceptional chromatographic repeatability and peak resolution in under four minutes.

Additionally, LC-MS/MS can be used to detect both adulterants and contaminants in wine. As with other food products such as olive oil, additives might be introduced into wine to improve its flavor or color. There is also a high chance pesticides or fungicides could end up in the final product if the grapevines have been sprayed with these compounds during growth. Both of these additives, whether intentional or unintentional, can cause significant harm to humans if ingested. It

# In The Lab

HYGIENE MONITORING



## Seeing Double?

Though vastly different, both hygiene monitoring and pathogen control programs both verify that cleaning and sanitation are effective as written and applied

BY VIRGINIA DEIBEL, PHD, AND LAURIE POST, PHD

**W**hen a manufacturing facility conducts microbial testing internally, the lab is expected to have hygiene and pathogen control programs in place and verified for effectiveness. These internal labs are to operate under their own quality systems, which may or may not be operated under the scope of an ISO 17025 platform.

Either way, the lab follows its own standard operating procedures and cross-contamination mitigation techniques with goals in keeping with the food safety systems employed by the facility that the lab is serving. A documented and carefully implemented laboratory environmental monitoring program (EMP) will provide the scientific evidence that sanitation ac-

tivities are being conducted and pathogens are being controlled within the lab.

Hygiene monitoring and pathogen monitoring programs fall under the environmental monitoring umbrella and contain the same general elements of a manufacturing facility EMP including:

- Site selection and site lists;
- Assigning zones to each site;
- Determination of test organisms and test assays;
- Specification setting;
- Site selection randomization;
- Designated sampling times;
- Result tracking and trending;
- Corrective/preventive actions; and
- Verification activities.

It may seem as if you are seeing double—“hygiene monitoring” and “patho-

gen control programs” are the same thing, right? In a word, no. The main difference relates to the organisms that are tested. In a hygiene monitoring program indicator organisms are tested, while in a pathogen monitoring program all pathogen assays that are routinely run in the lab are tested. Similarities between the programs are that they both verify that cleaning and sanitation are effective as written and applied.

### Hygiene Monitoring

**Assays and organisms tested.** A hygiene monitoring program will use assays that yield quantitative as opposed to qualitative results. Quantitative results will give a numerical value and are reported in colony forming units (CFU/swab, CFU/sponge or unit of time for air plates). The assays include aerobic plate count (synonyms: total plate count, total viable count), *Enterobacteriaceae*, *coliforms*, *E. coli*, *Enterococcus faecalis*, yeast, and mold.

**Sampling times and result interpretation.** There are three sampling times, each of which will have a different objective:



1) To assess cleaning/sanitation efficacy: Samples are taken after cleaning and before the application of a sanitizer, and then again after application of the sanitizer;

2) To assess potential soil accumulation points: Sites include scales, water baths, and under and within pieces of equipment; and

3) To assess the efficacy of Good Laboratory Procedures during lab operations: Sample times include after sampling powders, during and at end of operations.

**Organisms.** An aerobic plate count (APC) measures the number of bacteria that grow aerobically in media at the ideal growth temperatures of most bacteria. Results are obtained in 48 hours. An APC assay can assess the efficacy of cleaning and sanitization when sponges or swabs are taken immediately after the cleaning or sanitizing event. When the results are out-of-specification (OOS), management should view how cleaning/sanitation procedures are performed along with reviewing chemicals and application frequency. When areas such as door handles, carts, or incubator racks are swabbed during lab operations, the results can be used to provide an indication not only of their current microbial load, but also how often the sites are cleaned/sanitized and disassembled.

*Enterobacteriaceae*, *coliform*, *E. coli*, and *E. faecalis* test results are used for the same purposes as APC in ensuring hygienic conditions. They are particularly useful as indicators of environmental control (i.e., the removal of soil accumulation), whether the lab routinely runs tests for these organisms or not.

Yeast and molds are an indicator of air quality. The ventilation system in a lab may not be exclusive to the lab and monitoring can be used to assess air vent buildup that may impact the lab or the external environment. This is expressly indicated if the lab does not have HEPA filtration units. Mold is a common indication of water leaks and can be found in areas that have been exposed to water, especially when pooled.

There are a number of methods to monitor air quality. The use of an air sampler that draws air and impales it onto a petri dish is a valuable tool because it draws in large quantities of air. Alternatively, passive air monitoring (settling plates) is a common, inexpensive method to collect samples wherein media is exposed to operational air for a predetermined amount of time (commonly 15-45 minutes) and the plates are then incubated. Normal operations should be taking place during air monitoring.

### Pathogen Control Programs

**Assays and organisms tested.** A pathogen control program will use assays that yield qualitative as opposed to quantitative results. Qualitative results will yield a negative or positive and are reported per gram weight of the sample tested or per sponge/swab. The assays usually include an enrichment step that will repair injured cells and allow cells, if present, to multiply to a concentration that can be detected by the assay. Detection limits, the lowest concentration required for a positive result, varies according to the assay. Some assays are more sensitive than others. Cross-reactivity (false positives) may occur with some organisms that have genetic similarities to the target. Test kit manufacturers have information on detection limits and false positive rates available. With all assays, confirmation that the assay is suitable to the matrix (sample tested) is always an important component prior to testing.

(Continued on p. 40)

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(Continued from p. 39)

**Organisms.** Organisms tested within a pathogen control program are the same as those used for the samples tested in the lab. However, it is not necessary to run all testing platforms if the lab uses multiple methods when testing samples. Select one platform and assay sponges/swabs taken at various lab locations for all the pathogens that are tested in the lab. Select sites where the pathogens are sampled, incubated, handled, and discarded within the lab. Do not exclude technician lab coats, gloves, or common areas such as sinks, cart paths, and locations where hand contact may occur.

**Laboratory EMP Components**

**Compiling site list.** Each lab area where the samples are logged-in/staged, media prepared, dishes washed, assays conducted, plates read, and transfer points must have representation within the site list. Within each area, all equipment used, environmental areas (walls, floors, cabinets), and utensils are to be accounted for on the site list. The site list should be reviewed on a periodic basis to account for equipment added or removed, construction or site modifications, and any facility issues such as roof leaks. Plotting all sites on a lab diagram is a step to help determine that each area and piece of equipment has been represented.

**Assignment of zones.** Similar to the manufacturing plant, site zones are designated as Zones 1 through 4:

- Zone 1: Any surface where a sample has contact (e.g., pipette tip, sampling scoops, mixing vessel);
- Zone 2: Adjacent to sample contact (e.g., lab coat, gloves, stomacher, centrifuge, handles, laminar flow hoods and bio-safety cabinets, scale, control panels);
- Zone 3: Equipment and infrastructure where samples are exposed (e.g., cabinets, carts, hand wash sinks, floor/floor mat); and
- Zone 4: Hallways leading into or out of the lab, air ducts exterior to the lab, pathways to remove waste, offices.

**Sample selection and frequency.**

Sample selection from the site list should be randomized. The use of a random number generator is recommended so that all sites will have an equal chance

Table 1. Sampling frequency for zones and organisms

Area	Check of:	Number of Sites	Organism(s)	Frequency
Zones 1 and 2	Sanitation/good laboratory practices	5	<i>Enterobacteriaceae, Coliforms, E. faecium, E. coli</i>	Weekly or daily
	Sanitation/good laboratory practices		Aerobic Plate Count (APC)	
	Cross-contamination, Sanitation/good laboratory practices		<i>E. coli</i> 0157:H7	
	Sanitation/good laboratory practices Cross-contamination	5	<i>Salmonella</i>	
	Sanitation/good laboratory practices Cross-contamination		<i>Listeria spp.</i>	
	Air quality	Each lab room	Yeast and mold	
Zones 3 and 4	Sanitation/good laboratory practices	3	<i>Enterobacteriaceae, Coliforms, E. faecium, E. coli</i>	
	Sanitation/good laboratory practices Cross-contamination		<i>E. coli</i> 0157:H7	
	Sanitation/good laboratory practices Cross-contamination	3	<i>Salmonella</i>	
	Sanitation/good laboratory practices Cross-contamination		<i>Listeria spp.</i>	

Without species-level identifications, corrective/preventive actions are difficult to conduct.

of selection. The goal is for each sample site to be tested at a desired frequency. For example, if the lab has 200 sites on the site list and the lab would like each sample to be tested within a quarter and samples taken on a weekly basis, then approximately 13 samples are to be tested per week (See Table 1). This volume will increase if the same site is sampled immediately after cleaning, after sanitation, during lab operations, and at the end of the operational day.

Additionally, swabs/sponges should be taken whenever a pathogen is recovered from a sample or when proficiency check samples are run in the lab. Segregated

rooms (areas) where pathogen isolates are handled will require sponges/swabs to be taken whenever the room is in use—often on a daily basis, and especially after cleaning and sanitation.

**Setting specifications.** Zone 1 post-sanitation specifications should be set at <10 cfu/sponge for hygiene assays and negative for pathogens. Zone 2 and 3 specifications may be set initially and then change depending on the baseline data. Six to 12 months of baseline data will be needed to create specifications that are achievable and provide insight throughout high and low sample volumes, seasonal changes, and varying technician scheduling.

After baseline collection, lab management should reassess and revise specifications as needed. Table 2 provides examples of specifications for each zone.

**Data collection and review.** Each month, the site list and results are to be reviewed by laboratory management, ensuring that sampling is conducted as

Table 2: Specifications for microorganisms for the three zones

Zone	Organism	Specification (per sponge/swab/air plate)	
		After cleaning/sanitation	During lab operations
1	<i>Enterobacteriaceae, Coliforms, E. faecium, E. coli</i>	<10 CFU	<20 CFU
	Aerobic Plate Count	<10 CFU	<50 CFU
	<i>E. coli</i> 0157:H7	<10 CFU	Negative
	<i>Salmonella</i>	Negative	Negative
	<i>Listeria spp.</i>		
	Other pathogen assay		
	Yeast and mold air plate	<10 CFU/15 minutes	<15 CFU/15 minutes
2	<i>Enterobacteriaceae, Coliforms, E. faecium, E. coli</i>	<10 CFU	<50 CFU
	<i>E. coli</i> 0157:H7	Negative	Negative
	<i>Salmonella</i>	Negative	Negative
	<i>Listeria spp.</i>		
3 and 4	<i>Salmonella</i>	Negative	Negative
	<i>Listeria spp.</i>		

per the SOP, that OOS results have been addressed, and that corrective/preventive actions were effective by verification sampling. This review also allows identification of developing trends and assurance that the program is working as intended. All data should also be reviewed in a historical context (e.g., comparison of present data to the last 30 days, last several months, previous year's results).

If any pathogen result is positive, *Salmonella* serological testing or identifications to the species level is to be performed. The information can be compared to the positive strains used in the lab for quality control (QC) to determine if there was a cross-contamination. If the strain is not from the QC program, this may point

to a routine lab sample that was run in the near past that tested positive or to a harborage point within the laboratory that will need to be isolated and removed. Without species-level identifications, corrective/preventive actions are difficult to conduct.

Some of the examples of trends to note:

- Increasing counts over several weeks;
- Increasing OOS results;
- Multiple OOS results on similar sites, within a zone, or across several zones;
- Identifications that point to QC or sample cross-contamination; and
- Multiple identifications of the same organism that may point to a harborage site within the lab.



## Corrective/Preventive Actions

**Corrective actions.** When presumptive and/or OOS results are returned, corrective actions are conducted immediately to minimize/contain the risk. This usually involves intensive cleaning/sanitizing that may also require equipment disassembly if appropriate. It is important to note that prior to initiation of any corrective actions, a review of the laboratory area must be conducted noting hygienic state, activity and equipment in the area. Investigative swabbing must be conducted prior to any cleaning/sanitizing activity to preserve "evidence."

**Investigative process.** Investigative samples are taken with the objective of identifying the cause of the OOS result. Investigations are conducted after a corrective action and will lead to appropriate preventive actions. Samples are taken in a vectoring manner (in 360-degree radius, if possible, surrounding the site). Vector samples should include locations adjacent, under, and above the initial site. In addition to vector sampling, the investigative team should observe the sample site and lab operations nearby. The team is looking at the process, lab environment, equipment, and utensils and identifying circumstances that led to the results.

**Preventive actions.** As opposed to corrective actions, preventive actions are performed only after the cause of the OOS has been identified. Actions are preventive in nature, such as making repairs, sealing against water incursions, or increasing equipment disassembly.

An effective laboratory EMP verifies that good laboratory practices are in place and that pathogen cross-contamination is prevented within the food laboratory. Both a quantitative hygiene monitoring and a qualitative pathogen monitoring program are essential to providing the evidence that the food laboratory environment is in control. Having a documented system and trained staff in place is an essential component of effective and efficient laboratory operations. ■

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# Manufacturing & Distribution

PLANT DESIGN



## Contamination Hazards Hiding in Utilities

Identifying the risks and methods for filtering air, gases, water, and steam | BY ROBERT CONNOR ROJINA

**W**hen you drive, you take multiple precautions to prevent accidents. You put your cellphone away, use turn signals, observe stop signs, and stay a safe distance from the car ahead of you. No single measure guarantees a safe ride, but each one lowers your risk.

It's the same with safeguarding your process. Each contamination hazard that you can identify and address reduces your risk. This is why food processors are required to develop a Hazard Analysis and Critical Control Points (HACCP) plan under FDA's Food Safety and Modernization Act (FSMA).

### Why Attention Is Required

A leading contamination risk is the utilities: the compressed air or gases, water,

and steam used to perform processing steps. They can introduce dirt and bacteria from the outside world or pick up metal debris and oil from plant equipment. Deposited into food or onto food contact surfaces in a warm, moist environment, minor microbe concentrations can rapidly multiply into harmful colonies downstream.

For this reason, it is essential to address filtering air, gases, water, and steam in an HACCP plan. Generally, there are three areas in every process that require attention to utility filtration.

**1. Where contaminants could first be generated or introduced.** This is usually in utility rooms where water, steam, and compressed air or inert gases are generated or stored. Pre-filtration here with larger micron-size elements that are designed to

filter coarser particles can lessen wear and tear on downstream microfilters.

**2. Where the process or product has direct exposure.** These are points of use where utilities come into direct contact with the product or food contact surfaces after traveling through equipment. Filters rated for removing microorganisms at a high capture efficiency should be placed as close as possible to each point of use.

**3. Where there is a last chance to prevent irreversible damage.** This is at the end of a process, before product packaging. In some cases, such as water bottling, final membrane filtration is recommended. Whenever water, steam, or compressed air are used to blow-mold, clean bottles, or open bags, filter those utilities just before the application.

### Unique Risks of Each Utility

Each utility has unique properties and risks for contamination. Specific filters are designed for each challenge. Effective, cost-efficient filtration is all about placing the right elements and micron sizes in the right locations. The following are examples of applications, their associated risks, and best practices to consider.

### Air and Gas

**Applications.** Gases used in food processing include pure oxygen, carbon dioxide, nitrogen, and most commonly, compressed air. Air moves ingredients, texturizes food, dries sterilized equipment, and forms containers. In storage tanks, compressed air or nitrogen are often injected as protective blankets around product.

**Risks.** Gas tanks and air compressors can be breeding grounds for microorganisms. As they draw in ambient air, compressors concentrate any bacteria present in that air volume. As compressed air cools, condensation creates the moist environment microbes need to multiply and equipment lubricants provide the food. The end result can be contamination and a permanent biofilm deposited in



downstream piping. If you use inert gases such as nitrogen or carbon dioxide—even if supply tanks come from a vendor—changing tanks can expose open lines to airborne contaminants.

**Best practices.** Keeping air dry and oil-free helps keep it sterile. This can be achieved with a series of filters just after the compressor consisting of a cyclone separator to spin out bulk liquid, one or more 1- to 5-micron coalescing pre-filters to catch oil aerosols, and an adsorption air dryer to remove remaining vapors. At each

**If you use inert gases such as nitrogen or carbon dioxide—even if supply tanks come from a vendor—changing tanks can expose open lines to airborne contaminants.**

point of use on air or gas downstream, place an absolute rated 0.2-micron final filter on injection equipment.

### Water

**Applications.** Water is universal throughout food processing, both as an ingredient and as a power source. It is used to wash raw produce, rehydrate concentrations, cook ingredients, heat steam boilers, drive product recovery systems, and sterilize equipment and containers, among other applications.

**Risks.** Incoming water lines can carry harmful corrosion and debris. Sediment can build up on boiler equipment and interfere with efficient heat exchange or end up in the final product. If water is used as an ingredient, it must be dechlorinated with activated carbon, which can then be a food source for any remaining bacteria. Wash water is a cross-contamination risk that can carry microorganisms onto downstream surfaces.

**Best practices.** Pre-filter the water line coming into your process using nominal polypropylene depth filters of 10 microns. Higher levels of suspended solids may require a series of 50-, 20-, or

10-micron liquid pre-filters. Analyze water quality and adjust filtration for seasonal changes to help ensure product consistency. A 10-micron element provides an acceptable level of industrial water for non-food contact, steam-in-place (SIP), and clean-in-place (CIP) processes. Downstream in the process, install final filters on water lines dedicated to your washing, cooking, blending, or injection stations. Bacterial-retentive sterile filters of 0.2 microns are recommended. In many cases, microfilters of this grade can be used to produce pasteurized-equivalent water.

### Steam

**Applications.** Large volumes of steam are required in food processing as a heat source for cooking and as a cleaning agent. Steam is either culinary grade—fit for direct injection into food or to sterilize food contact surfaces—or utility steam, suitable for efficient indirect heating.

**Risks.** Steam temperatures resist microbial growth, but boiler deposits, debris, and rust are a common hazard. Lengthy steam lines are generally made of carbon or galvanized steel, which can corrode quickly under constant condensation and heat. These byproducts threaten both product and equipment. Stainless steel will not rust when exposed to water, but it will when exposed to rust shed by nearby carbon steel. Corrosion can also plug the spray balls on steam injectors and cross-contaminate stainless steel.

**Best practices.** On each steam line into your process, place an entrainment separator—a pre-filter that coalesces bulk moisture out of the system and drains it away. The relatively dry steam remaining transfers energy more efficiently and reduces the amount of boiler water entering your product. Each pressure reduction valve should also be protected with an entrainment separator. Place a final steam filter at each point of use. For direct steam injection or CIP/SIP use, culinary-grade steam is required by 3-A Sanitary Standards. Culinary grade is defined as steam filtered to remove 95 percent of particles 2 microns and larger.

### General Principles for All Utility Filtration

There are general principles that apply to all utility filtration—steam, water, and air

Donaldson filtration products for sterile air have the ability to filter bacteria, viruses, and particles down to 3 nm.

DONALDSON COMPANY



or gases—regardless of the process or application. Remember the following tips as you plan your system.

**Redundancy.** Similar to accident prevention on the road, filtration at multiple points in a process is far more effective than relying on one filter alone. Pre-filtration upstream can help minimize replacement costs and downtime by helping to protect more expensive microfilters on your process line.

**Placement.** As stated in the outset, place final filters as close as possible to point of use. If there are 1,000 feet of piping between a final filter placed in a utility room and the food contact point, that is 1,000 feet of line that could shed condensation, oil, debris, and microbes into the product.

**Filter media.** Traditional melt-blown filters are not always less expensive in the long run. Newer pleated cartridge filters have roughly 12 times the surface area and depth-loading capacity of a melt-blown filter. That added surface area supports a long filter life.

**Maintenance.** Monitor the pressure across each filter element and change it at a pre-determined pressure drop. Watch for sudden reductions in the pressure differential across the filter, which could indicate a filter is damaged. Pressure gauges upstream and downstream from filters are helpful in providing this visibility.

**Ratings.** Don't select filters based on micron size alone; double-check the filter's capture efficiency at the stated particle size and look for verified performance. The standard for filtration in food and beverage processing is a log

(Continued on p. 50)



# Opening the Doors for GMPs

Next generation doors and walls are meeting current Good Manufacturing Practice requirements while maintaining an efficient operation

BY JON SCHUMACHER

The combination of technological advancements, increased regulation, and efficiency initiatives has transformed many industries, but perhaps none more than food manufacturing and processing.

Good Manufacturing Practices (GMPs)—as written law—have officially been around since 1962. However, they are continually evolving as new equipment and processes are developed. Sometimes they are changed as the result of other regulations being implemented, which happened recently when the Food Safety Modernization Act (FSMA) was enacted earlier this decade.

Suddenly GMPs weren't just Part 111 in the Code of Federal Regulations (CFR). FSMA's Preventative Controls for Human Food in Title 21 CFR Part 117 mandates rules that are enforced by FDA. Subpart B spells out specific GMPs that all food operators must adhere to.

## Knowing Your cGMPs

For food operations, it's important to know all of the GMPs that FDA audits. Here are seven that are the most commonly audited, yet easiest to comply with.

1. It starts with **Part 117.10 Personnel**. Essentially, this one boils down to keep-

ing out anyone with illnesses and open wounds who might spread a disease. It offers rules of cleanliness—washing hands and wearing hairnets when appropriate—as well as education/training and supervision standards.

2. **Part 117.20 Plant and grounds** requires facilities to maintain the grounds to minimize potential sources of contamination, including proper drainage to reduce breeding areas for pests. Subsection B mandates that facilities must consider plant construction and design, including ways personnel can continue to maintain the facility regularly.

3. Hygiene for the facility and the equipment inside the facility are covered in **Part 117.35 Sanitary operations**. This means that pests must be controlled and that the cleaning compounds and sanitizing agents used inside the facility are stored properly.

4. In connection to sanitary operations, **Part 117.37 Sanitary facilities and controls** mandates that facilities have the equipment needed on hand to keep operations clean. This ranges from a basic water supply and plumbing to sewage and a rubbish and offal disposal.

5. **Part 117.40 Equipment and utensils** requires that all plant equipment used in

manufacturing, processing, and packaging must be designed in such a way that it can be adequately cleaned and maintained to protect against allergen cross-contact and contamination.

6. The manufacturing and processing portion of **Part 117.80 Processes and controls** mandates that clean equipment be used and that conditions are kept to minimize the growth of microorganisms.

7. According to **Part 117.93 Warehouse and distribution**, the storage and transportation of food must be under conditions that will protect against allergen cross-contact, food contamination, and food and container deterioration.

Once these regulations are understood, facility managers should apply them to their specific situation. Since cleanliness and temperature controls are essential in most food operations, it's important to explore the often-overlooked equipment that separates various critical environments: doors and walls.

## The Role of High-Speed Doors

High-speed doors and fabric curtain walls play a key role in maintaining clean operations and food product integrity. These high-performance doors feature a minimum opening rate of 32 inches per second, a minimum closing rate of 24 inches per second, and a means to automatically reclose the door. Designed to address food facility needs for environmental control, productivity, and safety (as well as cleanliness), they are used not only to prevent cross-contamination, but also to help improve air circulation rates and optimal operating efficiency.

FDA standards outline recommendations and requirements for manufacturers. The starting point is to look for doors compliant with cGMPs.

Key considerations for any door configuration are ease of cleaning and durability. Especially in food operation cases, doors must be able to stand up to repeated cleaning with chemical solvents and have a smooth, nonporous surface that is resistant to microbial and fungal growth. Doors should have tapered surfaces that essentially eliminate harborage of dust or other contaminants and possess no sharp angles to minimize harborage of microbes.

Additionally, they should be corrosion-resistant (which is often a problem with older door systems) and use stainless steel or other non-corrosive sideframes.

It is also advisable to avoid doors with exposed fasteners and coils, as they will take longer to clean and could harbor contaminants.

### New Generation of cGMP-Compliant Doors

Food manufacturing facilities have been using bi-parting doors made from stainless steel since the 1950s (and many facilities continue to use bi-parting doors). However, many facilities are moving toward upward-acting roll-up doors due to limited wall space in a plant. A rigid-panel center-opening door spanning a 6-foot-wide opening, for example, requires approximately 3 feet of wall space on each side when its panels open. A roll-up door, on the other hand, requires none, since its fabric “curtain” collects in a head assembly at the top of the door when it is opened.

A new generation of roll-up doors—featuring antimicrobial materials and other clean room upgrades—has come on the market in recent years. These new features, coupled with their tight sealing and ability to operate at high-cycle

speeds, are reasons they are catching on with food manufacturers. State-of-the-art high-speed door models can move at up to 100 inches per second, minimizing air intrusion while also decreasing the likelihood of forklift collisions. If they are bumped or impacted, however, their curtain automatically snaps back onto the door track.

Made from smooth 100 mil Duramax (which is highly resistant to acids and bases and has a low water absorption rate), industry-leading doors are highly resistant to mold and have superior wash-down qualities. They use a one-piece radial header (with easy draining during cleaning) and non-corrosive Lexan and ultra-high molecular weight side frames that stand off from the wall to minimize surface-to-surface contact, reducing pockets where bacteria can grow.

To ensure complete 360-degree clean capability, the side frames can be removed for cleaning, and the drive system and controls are completely sealed and wash-down rated, meeting both USDA and FDA standards as well as cGMP requirements.

### Wash-Down Walls

Fabric walls and industrial curtain partitions also play key roles in maintaining sanitary conditions in food manufacturing facilities, where they are increasingly being used for applications related to blending, mixing, powder ingredient, raw ingredient, or other production operations. While antimicrobial walls have always been important in segmenting environments there is a growing use of flexible, industrial fabric walls around processes where wash-down protocols apply. Not only are they quicker, easier, and less expensive to install than walls made of traditional materials, they can be moved or reconfigured if the facility’s needs or floor plan changes.

One of the most common uses for industrial fabric walls in the food industry is for the isolation of production lines so they can be cleaned while other lines nearby continue to run at peak efficiency. Not only do these flexible fabric walls allow plant engineers to enclose areas and contain overspray from cleaning, but they can also help reduce potential for cross-contamination during production processes.

Some wash-down fabric walls are constructed of durable, cleanable, antimicrobial vinyl specifically designed for use in operations where compliance with federal food regulations is paramount. To eliminate the potential for harborage concerns, fabric walls with manufactured panels with heat- or radio frequency-welded seams and air- and water-tight panel-to-panel connections should be employed.

Wash-down fabric walls are typically suspended from existing ceiling structures or roof decks. Stainless steel components and hardware allow the walls to hold up to wet and harsh conditions that occur when production equipment is cleaned as part of HACCP best practices protocol. Should the ability to open and close the wall be needed, heavy-duty stainless steel track and trolley systems are available to ensure easy operation and durability in the wash-down environment.

Flexibility and potential cost savings are among the main benefits of fabric walls in any application. Since they are not rigid, they can easily be custom designed to match a facility’s specific needs or workspace and can be moved or reconfigured if those needs change. When combined with antimicrobial wash-down features, this flexibility allows plant managers to achieve cleanliness protocols and production goals without the cost, permanence, or space requirements of rigid walls.

To ensure product integrity, food manufacturing facilities require the most sanitary operations and equipment possible. From high-speed, roll-up doors to antimicrobial wash-down fabric walls, new products are keeping food safe for consumers while meeting FDA and cGMP requirements. ■

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*AUTHOR’S NOTE: The information herein is provided as a general reference regarding the use of the applicable product(s) in specific applications. This information is provided without warranty. It is your responsibility to ensure that you are using all mentioned products properly in your specific application and in accordance with all laws and regulations.*



The new generation of cGMP-compliant doors are highly resistant to mold and have superior wash-down qualities.





## Automated Partners

Is robotics process automation an up-and-comer behind the scenes for food safety?

BY JIM ROMEO

**T**he robots are coming! Actually, they have already arrived for many applications in the food industry. While physical robotics are commonly used in food processing to perform tasks such as butchering, picking and placing fruit into containers, decorating cakes, and more, a new category of robotics—robotics process automation (RPA)—is likely to be more popular in the food industry in the near future.

RPA employs artificial intelligence (AI) to automate processes via a non-physical robot. RPA can fill out forms, validate invoices, copy and paste data, check and track data, and follow any other rules it is programmed for. It is an ideal fit for repetitive tasks that can be automated with software. The application, which may be implemented from a cloud application or on-premise, is gaining ground in many

back-office operations. While the food industry is a late adopter at best, RPA could become valuable technology.

The researcher Information Services Group (ISG) reports that RPA affords a 43-percent reduction in resources for order-to-cash processes: billing, credit, collections, and pricing. Savings ranged from 32 to 34 percent. ISG predicts that by the end of this year, 72 percent of all companies will use RPA to automate support functions and reduce costs, improve productivity, increase compliance, and shorten transaction times.

Mars, Inc., the global manufacturer of confectionery, pet food, and other food products, boasted about using RPA to consolidate back-office operations into one streamlined operation. A food producer in Europe used RPA to streamline its vendor procurement with AI to analyze vendor

documents, perform a vendor credit check, and recommend a vendor to select. The European firm also applied RPA to answer customer order inquiries via their email system: A virtual AI robot logged into their shipping portal, replied to the customer, and moved to the next customer inquiry, with no human involvement. The company claimed to eliminate 40 to 60 percent of the manual effort that otherwise would have been required.

### RPA for Food Safety?

While many back-office operations—such as human resources, finance, accounting, and routine processing—use RPA, the food industry is more likely to adopt functions, including as managing documentation and data surrounding product recall management and Food Safety Modernization Act (FSMA) compliance. Heather Larabee, executive vice president of GoSpot-Check and a former executive at Whole Foods Market, says that a single food safety-related event can create tremendous risk for brands, cause harm to customers, and generally erode long-term trust.

“The financial and relational impacts of events can be enormous,” she

says. “The proactive nature of FSMA requirements lends itself to robotic process automation to create a dynamic ‘safety net’ for companies. Used in tandem with Internet of Things (IoT) sensors that feed data to machine learning (ML)/AI tools, it also reduces cost and labor. We’re seeing brands invest with Testo to monitor when oil should be changed in fryers, automate temperature measurements of food, and understand things like how many times a bathroom door has been opened. This helps them optimize cleaning schedules and gain real-time, trusted insights into food safety and sanitation conditions.” Larrabee adds that AI and ML can detect and predict potential safety issues before they occur, as well as assist in reporting—automated reports can proactively signal busy leaders to risks in their locations.

“As we see increased costs to serve across restaurants and food services, high rates of attrition, and an increasingly complex global food system that amplifies foodborne illness risks in supply chains, AI and ML can provide an essential protection to safeguard consumers and brands alike,” Larrabee notes. “We’re also strong advocates for companies striking a balance between humans and machines. AI and ML are great at forecasting based on past performance, but as the technology evolves, we believe there is an essential role for humans to continue to play in the system. Ultimately, AI and ML can’t necessarily make decisions. We still need people in businesses to analyze the data and make critical calls. In the case of a food safety crisis, it’s paramount to understand what role the machine plays and what role people play in solving problems and keeping consumers safe.”

The sometimes-daunting activity level of products moving through complex distribution webs creates a challenge to not only ensure compliance but to act swiftly when a product recall occurs. “With countless regulations and compliance requirements, it can be difficult for businesses to keep track of many moving parts, especially within larger corporations that mass distribute product,” explains Richard French, chief revenue officer at Kryon. “RPA is an essential tool for businesses looking to improve compliance within the food and beverage industry. Once integrated into a company’s existing software,

management can use RPA to track, trace, and measure inventory through SKU numbers, barcodes, or any preferred system.”

French notes that bots can use this system to identify product coming in and going out, and every stop it takes along the way.

### Aside from the aforementioned aid in recall management and FSMA compliance, RPA enables food products to arrive on time and avoid spoilage.

“Recording this data will allow employees to analyze the database and determine if a product is non-compliant, whether due to perished ingredients or unsafe storage temperatures. Even further, RPA enables companies to set up alerts that will notify workers when inventory is non-compliant, preventing issues before they arise and reducing eaten costs and waste.”

#### When Will RPA Become an Influencer?

Oded Karev, vice president and head of advanced process automation for NICE, which develops software for automation, including RPA, says that fast-moving consumer goods industries, including food perishables, are slow adopters in comparison to other industries such as retail, telecom, utilities, and financial services. Those who are using RPA are applying it to processes such as order optimization and operations streamlining, similar to how the European food processor example is using it.

Indirectly, RPA improves the quality and safety of food in many ways. Aside from the aforementioned aid in recall management and FSMA compliance, RPA enables food products to arrive on time and avoid spoilage. Waqqas Mahmood, the director of advanced technology for the consulting firm Baker Tilly Virchow Krause, LLP, says that suppliers and transportation companies expect that if an invoice is sent, it must be promptly paid within the terms of service or the product

will arrive late. “If you have an automated processor to tackle that issue, it alleviates those delays,” he notes. “Plus, it takes care of your call center volume: What are they going to do if they don’t get paid? They’re going to pick up the phone and call you. Now you have a call center that’s taking a lot of these calls that could instead be mitigated by robotics.”

While automation is widely used in many industries, RPA is bound to play a more prominent role in food quality safety where IoT and the aggregation of big data are more important than ever. “I don’t think it’s going to be a disruptor because there are so many other advanced technologies that play with IoT, sensor data, and so forth,” says Mahmood. He adds that RPA and other ways to automate, like python code or application programming interface development, will be beneficial to automate production and monitoring. “It can really accelerate that process, consuming data really quickly into the system where you want it,” he adds. “Then you can create a real-time dashboard out of that process.”

Mahmood sees RPA assisting greatly in building a platform for analytics. “Data sources come from IoT structured data, unstructured data, databases, and actual physical robot throughput,” he says. “All that information gets fed to the engine. The way it gets ingested is where I think robotics play a role in really moving it faster to the right system. Once it’s in the engine, that’s where you build in data modeling techniques, AI, machine learning, natural language processing, and more.”

Larrabee of GoSpotCheck predicts adoption will continue to be incremental and calculated. As the use of RPA gains traction in other industries, more food companies will adopt it for their operations. She concludes, “Brands will also want to set benchmarks and continue to evaluate whether their RPA investments are working as intended, delivering efficiencies without compromising food safety. In doing so, it frees their teams to focus on high-value work: serving customers, driving sales, making decisions, solving problems, innovating, and making great food.” ■

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# Food Service & Retail

CLEANING



## Making the Right Choice

How product audits can play an integral role in selecting from numerous cleaning solutions | BY MICHAEL WILSON

**F**ood service professionals have myriad cleaning products to choose from. Cleaning solutions typically used for commercial food service kitchen facilities include grill cleaners, cooktop cleaners, all-purpose cleaners, window cleaners, oven cleaners, degreasers, sanitizers, scrubbing powders, bienzymatic cleaners, stainless steel cleaners/polishes, and more.

Cleaning containers are available in various sizes, anywhere from a few pints to 55-gallon containers. Some products have fragrances, such as lemon or berry, while others are fragrance-free. Solutions may be available as a foam, liquid, or powder. Some earned Green certification, while others contain what are considered more harsh ingredients.

Prices can vary based on the sizes of the containers and concentrations of the solutions. In addition, while they may contain similar ingredients, some work better in certain situations and on certain types of surfaces or are easier to work with.

This all means that food service professionals have an exhausting amount of things to consider when selecting cleaning solutions to properly clean and maintain kitchens.

What often happens is they purchase the same cleaning solutions repeatedly or select different products from different manufacturers—commonly known as trial-and-error purchasing.

### Issues and Concerns

Neither method—purchasing the same products over and over and trial-and-error purchasing—is effective. For instance, someone who selects the same products year after year may not be aware that newer products exist that may be more effective and/or less expensive. Chemical manufacturers typically do not introduce a new cleaning solution unless it is an improvement upon a comparable product of their own or from a competitor. It's simply too expensive and time consuming to manufacture a new cleaning solution that does not stand out in some way. Thus, newer cleaning solutions should always be considered.

Administrators with a trial-and-error purchasing program have the most to lose. It can be costly, especially if some cleaning solutions end up in the closet never to be used again. It can also be dangerous. Cleaning solutions, even Green certified solutions, are made of potent ingredients.

Over time, the containers in the closet may release vapors or start to leak. When this happens, it's possible the ingredients of different products will mix together, creating a major health risk.

Additionally, training is needed for selecting different types of cleaning solutions. This should never be overlooked. Many types of cleaning solutions have different dilution levels, so what works with one product may not work with another. For example, some products are applied to surfaces sparingly with a cloth, while others require more substantial concentrations and must be worked into surfaces using a brush. Therefore, for the safety of the crew as well as the health and cleanliness of the kitchen, training is

## Cleaning Solution Purchasing Tips

**Compare apples to apples.** Most cleaning solutions used in commercial kitchens must be mixed and diluted with water. While the cost of two cleaning solutions may be comparable, in reality, one may be far more costly over time than the other. For instance, of two products that cost the same, if Product A requires one part chemical to five parts water, and Product B requires two parts chemical to five parts water, then product A is less expensive.

**Ask the experts.** It is always advised to work with an astute distributor of cleaning solutions. Many market different brands of kitchen cleaning solutions. Therefore, it often can more objectively identify those products that might work best in a specific type of kitchen.

**Buy in bulk.** If you have a large facility, always ask the distributor if discounts are available when making large purchases of specific products. Usually there are, but even if there are none, in some cases the distributor can work with the manufacturer to provide a volume discount.—M.W.



needed for every different type of cleaning solution used.

Is there a better way to purchase cleaning products that saves time and money, improves cleaning effectiveness, and enhances safety? While it is not a cure-all, conducting a product audit may do the trick.

### Product Audits

The ideal way to understand a product audit is to see it in action. Imagine this scenario: A food service facility purchases four cleaners from four different manufacturers, all designed to clean griddles, stovetop grills, and cooktops. Let's call them products A, B, C, and D.

Working with its janitorial distributor, at least one administrator, and members of the cleaning crew, the facility evaluates the products as follows:

**Product A:** Second least expensive, ranked third in performance;

**Product B:** Most expensive, ranked first in performance;

**Product C:** Second expensive, ranked second in performance; and

**Product D:** Least expensive, ranked fourth (poorest) in performance.

According to this evaluation, it's determined:

- While Product D is the least expensive, it is also the least effective, so it will not be purchased again;
- Since Product A does not seem to have any unique attributes, it's eliminated;
- Product B is the costliest, but is also the most effective; and
- Product C is slightly less costly and almost as effective as Product B, the most costly.

The audit indicates that Product C should be the only product selected to perform this cleaning task. It is slightly less costly but still performs well.

Once a product is selected using a product audit, administrators should choose larger quantities and possibly take advantage of volume discounts or rebates from the manufacturer.

### The Role of Technology

Administrators need to view purchasing as a journey. To help them on that journey, software programs and online dashboards systems can compare cleaning and other products for cost and effectiveness as well as introduce other new products.

These systems also indicate if a product is, for instance, Green certified and by which certification organization. Different Green certification organizations may have different focuses. Some may place more emphasis on indoor air quality while others may put more focus on the sustainability aspects of a products.

However, these software/dashboard systems should be viewed only as an aid. Before making any final purchasing decisions, it's a good idea to consult with a janitorial distributor for their expertise so they can better explain the advancements of new cleaning solutions and technologies. ■

Wilson is the vice president of marketing for AFFLINK. Reach him at [wmwilson@AFFLINK.com](mailto:wmwilson@AFFLINK.com).

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## Increasing Safety... (Continued from p. 26)

### Accreditation and Certification Process

FDA authorized independent accreditation bodies to assess the program integrity for those certification bodies that have applied for and achieved accreditation under this program. The certification bodies currently accredited are listed on the [FDA website](#) as well as with the accreditation bodies (ANSI, ANAB, IAS, etc.).

Accreditation of certification bodies, such as NSF International, under the FDA Third-Party Accredited Certification Program requires that the certification body establish a system for managing the certification process integrity, demonstrate auditor and personnel competence, training and qualifications, and maintain records of certification activities.

The audit duration and cost are variable depending on the scope and complexity of the requested audit, and are determined by the requirements of the accredited certification body. Typically

the full process from application to certification decision requires three to four months to complete. The certification process is similar to third-party food safety certification programs in several ways, including:

- Application and contract review;
- Determination of scope and assignment of auditor;
- Document and records review;
- Resolution of any non-conformance from document review;
- Certification audit;
- Technical review for accuracy and quality of report;
- Non-conformance corrective action and closure; and
- Certification decision and report issued within 45 days of audit.

Following a positive certification decision, the certificate is valid for 12 months. In cases where the product is seasonal, the certificate is valid only for the audited season of production. Additional audits are

required for multiple seasons within the annual production cycle.

Broad adoption of this newly available and flexible solution will help to reduce audit fatigue on the part of the manufacturers and suppliers engaging in supplier verification activity to comply with FSMA. The scope of the audit can be broad to service the full range of production at a supplier site or limited to only a narrow scope of product or process. It recognizes the robust structures in place established through GFSI while also covering the gap for FDA-specific compliance verification.

Whether the audit is conducted at the supplier for eligibility for VQIP, as FDA import certification, or as an FSVP verification activity, the audit against FDA regulations provides a consistent standard of equivalent compliance, regardless of the origin of the food. ■

**Allen** is the associate managing director of Supply Chain Food Safety Operations at NSF International. Reach her at [callen@nsf.org](mailto:callen@nsf.org).

## Contamination Hazards ... (Continued from p. 43)

5 reduction, meaning the filter must remove 99.9998 percent of contaminants in its listed micron range. For example, Donaldson Co.'s 0.2-micron sterile liquid and air filters are validated to remove 99.999998 percent of particles at 0.2 micron (the higher log 7 reduction observed in the pharmaceutical industry).

**Certification.** Look for equipment and products with the 3-A symbol. It means an independent third party verified its sanitary design, including 316/316L gauge stainless steel, a fully drainable, easily cleanable design, and a specified surface finish.

After considering these basic principles, there are other factors to weigh with your filtration provider:

- Depth-loading capacity (retention);
- Number of sterilization cycles the element can safely tolerate;
- How often the element will need changing (filter life); and
- Flow rates, which drive energy costs.

All of these performance factors contribute to total cost of ownership.



The design and maintenance of filtration systems is critical. It's helpful to obtain a comprehensive evaluation of your system by a qualified process filtration consultant. Also, be sure to work with suppliers who are knowledgeable about filter operation and maintenance needs from end to end,

and whose equipment is validated to meet objective standards. ■

**Rojina** is an application engineer in the Donaldson's Process Filtration division of Donaldson Company, a global provider of filtration solutions for sterile air, gas, liquids, and steam used in the food and beverage, and other processing industries. Reach him at [Robert.Rojina@Donaldson.com](mailto:Robert.Rojina@Donaldson.com).

# NEW PRODUCTS



## CIP System for Hemp Industry

In partnership with Advanced Extraction Systems, Diversey's new cleaning process and CIP system is developed for application with the CO<sub>2</sub> extraction process in the hemp industry. Historically CO<sub>2</sub> extraction systems have been cleaned with ethanol. However, as a volatile cleaning agent, its use has been subject to the strictest regulation, which presents a significant safety issue regarding storage, says the company. The use of ethanol in the hemp processors' cleaning protocols has exercised a constricting grip on the industry. Many of these hemp manufacturers are looking to extend or add to their existing facilities. Under prior ethanol restrictions, this would have involved the necessity to construct an explosion proof standard, resulting in additional expenditure being added to actual construction costs. By reducing ethanol in the cleaning process, the new CIP system reduces the capital cost of expansion. The system is constructed as a skid that sits alongside the extraction unit and automates the cleaning. The CIP process produces a cleaning efficacy due to the change from ethanol—which works more as a sanitizing agent than as a cleaner—to an alkali process using a food grade cleaning agent. **Diversey, 803-746-2200, <https://diversey.com>.**

## Molecular Tests for STEC

Two new 3M assays for STEC enables food safety laboratories to test with or without *eae* gene results. The Molecular Detection Assay 2-STEC Gene Screen (*stx* and *eae*) rapidly detects the genes for Shiga toxin types 1 and 2, as well as *eae*, the intimin gene that allows the bacteria to attach to intestinal cells. The second assay, the Molecular Detection Assay 2-STEC Gene Screen (*stx*) detects only Shiga toxin genes, allowing labs to serve varying screening needs. Both test kits are applicable to samples enriched from foods and from food processing environments. Both have PTM certification from AOAC Research Institute. The company says they both demonstrate equivalent performance to the USDA FSIS method for raw ground beef, and to the FDA BAM reference method for fresh spinach. In addition, Molecular Detection Assay 2-STEC Gene Screen demonstrates equivalent performance to the USDA FSIS method for raw beef trim. **3M Food Safety, 888-364-3577, [www.3m.com](http://www.3m.com).**

## Leak Detection

The Contura S600, which features an oversized test chamber, is designed to test products sold for bulk retail and food service applications as well as large format Modified Atmosphere Packaging and flexible packages. It helps manufacturers extend shelf life, prevent recalls and returns, and reduce waste. The S600 model relies on a proprietary differential pressure method to



detect both gross and fine leaks and offers a quantifiable alternative to methodologies like water baths and gas-based testing. With the test chamber, food manufacturers can increase efficiencies by testing multiple products at the same time. The system is ideal for a variety of food applications including pet food, meat and poultry, baked goods, snack foods, confectionery/candy, cheese, grains and cereals, prepared food, and produce. **INFICON, [www.inficon.com](http://www.inficon.com).**

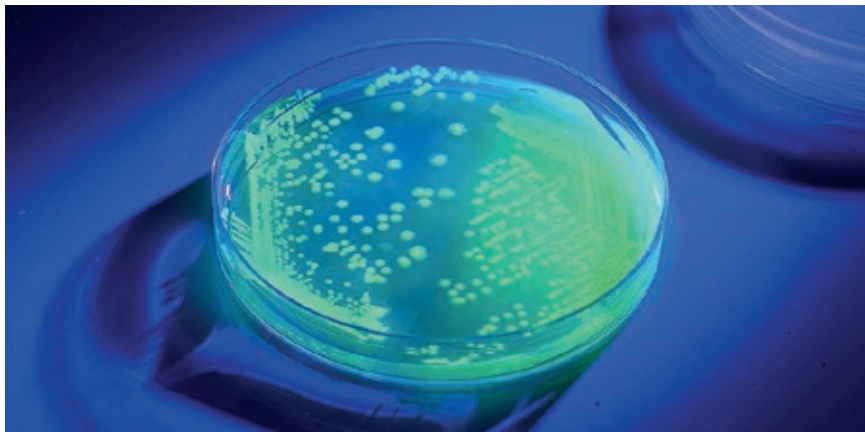


## Dual Footwear Sanitizing Unit

The HACCP SmartStep2 Walk-Through Dual Footwear Sanitizing Unit reduces cross-contamination from footwear before employees enter the production area or other critical control zones. This foot-operated unit requires no electricity and uses compressed air to deliver an atomized spray of Alpet D2 Surface Sanitizer or Alpet D2 Quat-Free Surface Sanitizer to the bottom of footwear soles. The unit's walk-through design provides greater throughput while maintaining a compact footprint (27 in. L x 33 in. W x 44 in. H). It features atomizing spray nozzles (four per boot) to provide ample coverage yet uses only 0.4 ounces of chemical (0.2 oz per boot), which minimizes chemical waste and improves moisture control. **Best Sanitizers, Inc., 888-225-3267, [sales@bestsanitizers.com](mailto:sales@bestsanitizers.com), [www.bestsanitizers.com](http://www.bestsanitizers.com).**



(Continued from p. 51)



### Listeria innocua Controls

Microbiologics launches *Listeria innocua* in its UV-BioTAG format, a product line of QC microorganisms expressing the Green Fluorescent Protein reporter from a stable chromosomal integration. Designed for QC testing in food microbiology laboratories, UV-BioTAG cultures visibly fluoresce under UV light, making them easily distinguishable from naturally occurring strains that may be isolated from food samples. UV-BioTAG is available in two test-ready formats. UV-BioTAG Vial kits contain six vials of one lyophilized microorganism pellet (six pellets per kit), which are rehydrated in a sterile fluid, such as saline, and then plated on growth medium. UV-BioTAG Swab kits contain six all-in-one devices including a lyophilized microorganism pellet, ampoule of rehydration fluid, and a swab, which allows for direct inoculation of growth medium. **Microbiologics Inc., 800-599-2847, info@microbiologics.com, www.microbiologics.com.**

### Corn Aflatoxin Strip Test

The AuroFlow AQ Afla strip test helps lab professionals, technicians, and farmers quickly conduct first-round screening for toxic compounds in corn. The strip test, used with PerkinElmer's QuickSTAR Horizon strip reader, delivers results for mycotoxins, including aflatoxins like B1, B2, G1, and G2 at detection levels of 2 to 300 ppb in six minutes. The AuroFlow AQ Afla strip test and QuickSTAR Horizon strip reader solution feature a single-step, water-based extraction method and lateral flow testing at room temperature—removing the need for incubators and centrifuges during analysis. The handheld reader is battery operated and ruggedized, allowing flexible in-field testing. Once results are viewed on the strip reader's touchscreen, the information is then stored for future access and archiving, creating accurate audit trails. The company says that the AuroFlow AQ Afla strip test can provide key grain market players with the ability to prevent mycotoxins from entering the food chain. **PerkinElmer, Inc., 800-762-4000, www.perkinelmer.com.**



### Next-Generation Monitoring

The EnSURE Touch Monitoring System collects, analyzes, and reports data from multiple quality tests such as ATP, microorganisms, and enzymes, providing necessary data for audit and risk management. It features a responsive 5-in. shatter-proof touchscreen that works while wearing gloves. The system is accompanied by the latest version of Hygiena's SureTrend Data Analysis Software, SureTrend Cloud. The updated software is available in cloud-based or desktop formats and enables users to monitor, track, and trend testing results across one or multiple facilities, schedule automatic reports, and configure one or hundreds of monitoring systems from a single SureTrend account. **Hygiena, 805-388-8007, customerservice@hygiena.com, www.hygiena.com.**

### Exterior Rodent Protection

Dual Autogate Connect system was created as an expansion of the company's PestConnect portfolio to allow active monitoring of exterior rodent activity all day, every day. The system consists of an electronic bait station designed to enhance the user's exterior rodent protection program. Its smart gate mechanism can differentiate between target and non-target species and opens when rodent activity is detected. When the sensor is triggered three times based on activity, the motorized door will open allowing the rodents access. This level of control prevents non-target animals and unauthorized personnel from accessing the station. **Rentokil Steritech, 888-255-4776, www.rentokilsteritech.com.**



### In Other News

**Trace Register** adds blockchain to its Full-Chain Traceability platform.

**Thermo Scientific's Sentinel Multiscan Metal Detector** now meets stringent standards set by Marks & Spencer.

**3M Food Safety's Coconut Protein Rapid Test**, a qualitative immunochromatographic lateral flow test, earns AOAC PTM Certificate number 061903.

**Registrar** adds U.S. FDA registration numbers to its FDA Compliance Monitor so users can verify their suppliers' registration status prior to import.

**Clear Labs** announces new *Listeria* testing and Environmental Mapping capabilities on its Clear Safety platform.

**LexaGene Holdings**, which develops genetic analyzers for pathogen detection and other molecular markers, files additional patents to protect the proprietary science and designs of the LX2 technology.

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## Events



### AUGUST

27-29

#### Preventive Controls for Human Foods Certification

University Park, Penn.

Visit <https://extension.psu.edu/preventive-controls-for-human-foods-certification>.

### SEPTEMBER

8-11

#### AOAC Annual Meeting & Expo

Denver, Colo.

Visit [www.aoac.org](http://www.aoac.org), email [AOAC@aoac.org](mailto:AOAC@aoac.org), or call 800-379-2622.

10

#### Arkansas Nutrition Conference

Rogers, Ark.

Visit [www.thepoultryfederation.com/events/3-nutrition-conference](http://www.thepoultryfederation.com/events/3-nutrition-conference).

23-25

#### Pack Expo

Las Vegas

Visit <https://www.packexpolasvegas.com/>.

### OCTOBER

7-8

#### 2nd International Nutrition and Food Technology Conference

Madrid, Spain

Visit <https://foodtechnology.pulsusconference.com> or email [foodtech@pulsusgathering.com](mailto:foodtech@pulsusgathering.com).

8-11

#### PROCESS EXPO

Chicago, Ill.

Visit [www.myprocessexpo.com](http://www.myprocessexpo.com) or call 703-663-1212.

15-16

#### Dairy Plant Food Safety Workshop

Minneapolis, Minn.

Visit <https://www.idfa.org/events/dpfs#Minneapolis>, email [registrar@idfa.org](mailto:registrar@idfa.org), or call 202-737-4332.

15-17

#### Food Safety and Sanitation for Food Manufacturers Short Course

University Park, Pa.

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

17-18

#### 2nd International Conference on Food Safety and Health

Abu Dhabi, UAE

Visit <https://foodsafety.nutritional-conference.com/>

26-29

#### Food & Nutrition Conference and Expo 2019

Philadelphia

Visit <https://eatrightfnce.org> or email [membership@eatright.org](mailto:membership@eatright.org).

30-31

#### China International Food Safety & Quality Conference

Beijing City, China

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

### NOVEMBER

6-8

#### Dairy Practices Council Annual Conference

Portland, Maine

Visit [www.dairypc.org/dpc-conferences](http://www.dairypc.org/dpc-conferences).

13-14

#### Sensory Evaluation

New Brunswick, N.J.

Visit <http://www.cpe.rutgers.edu/courses/current/lf0606ca.html> or call 848-932-9271.

15

#### Statistics for Food Scientists

New Brunswick, N.J.

Visit <http://www.cpe.rutgers.edu/courses/current/lf0607ca.html> or call 848-932-9271.

### JANUARY

28-30

#### IPPE

Atlanta, Ga.

Visit <http://ippexpo.com/>, email [info@ippexpo.org](mailto:info@ippexpo.org), or call 770-493-9401.

### FEBRUARY

25-28

#### GFSI Conference

Seattle, Wash.

Visit [www.theconsumergoodsforum.com/events/gfsi-conference](http://www.theconsumergoodsforum.com/events/gfsi-conference).

### MARCH

1-5

#### Pittcon

Chicago

Visit <https://pittcon.org/pittcon-2020> or email [expo@pittcon.org](mailto:expo@pittcon.org).

### MAY

4-7

#### Food Safety Summit

Rosemont, Ill.

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

### JULY

12-15

#### IFT

Chicago

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

#### Have an Upcoming Event to Promote?

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

# SCIENTIFIC FINDINGS

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



## **ARTICLE: [Brazilian Coffee Blends: Sensory Evaluation](#)**

The diversity of compounds and variations in the aroma and flavor of ground and roasted coffee makes the sensory evaluation by the “cupping test” a complex task. A total of 217 commercial coffee samples classified as different beverage types and with different roast degrees were evaluated by official cuppers in the “cupping test.” The responses for sensory attributes were used to verify the correlation to the near-infrared (NIR) spectra. Chemometric models based on partial least squares were built for the powder fragrance, drink aroma, acidity, bitterness, flavor, body, astringency, residual flavor, and overall quality. Linearity, residual prediction deviation, sensitivity, analytical sensitivity, limits of detection, and quantification were evaluated. All sensory attributes were predicted with adequate values according to the parameters of merit. The proposed method, when compared to the “cupping test,” is an alternative to determining coffee sensory attributes. The results showed that the use of NIR associated with chemometrics is efficient and recommended for predicting sensorial attributes of coffee by means of the direct analysis of roasted and ground samples, and without any additional preparation, making it a promising tool for the coffee industry. **Journal of Food Science, Volume 84, Issue 6, June 2019, Pages 1247-1255.**

## **ARTICLE: [Pulse Flour Characteristics from a Wheat Flour Miller’s Perspective](#)**

Pulses (grain legumes) are of interest to product formulators as they seek to exploit their fiber- and protein-rich reputation in developing nutritionally attractive new products, particularly in the bakery, gluten-free, snack, pasta, and noodle categories. The processing of pulses into consistent high-quality ingredients starts with a well-defined and controlled milling process. However, in contrast to the extensive body of knowledge on wheat flour milling, the peer-reviewed literature on pulse flour milling is not as well defined, except for the dehulling process. This review examines information on milling of leguminous commodities such as chickpea (kabuli and desi), lentil (green and red), pea, and bean (adzuki, black, cowpea, kidney, navy, pinto, and mung) from the perspective of a wheat miller to explore the extent to which pulse milling studies addressed the objectives of wheat flour milling. These objectives are to reduce particle size, separate components (to improve value and/or functionality), and affect mechanochemical transformations. **Comprehensive Reviews in Food Science and Food Safety, Volume 18, Issue 3, May 2019, Pages 775-797.**



## **ARTICLE: [The Influence of Berry Perforation on Grape Drying Kinetics and Total Phenolic Compounds](#)**

Drying is one of the traditional methods used for the conservation of fruits. In recent years, different methods have developed to obtain higher quality products. Chamber-drying methods with hot air at controlled temperature are reliable and easy to use. This article explains how the effect of piercing the structure of grape berries on their drying time was studied experimentally during convective drying within a temperature range of 30-50°C. Experimental moisture loss results were fitted to different mathematical models, evaluated for goodness of fit by comparing their respective  $R^2$ ,  $\chi^2$ , and root mean square error. **Journal of the Science of Food and Agriculture, Volume 99, Issue 9, July 2019, Pages 4260-4266.**



## **ARTICLE: [Lactic Acid Fermentation of Edible Mushrooms](#)**

Various raw materials are subjected to lactic acid fermentation (vegetable and animal origin), which yields food products with high nutritional and dietary value. In many regions of the world, the process of lactic acid fermentation is also traditionally used to preserve fruiting bodies of edible mushrooms. Mushrooms are appreciated for their organoleptic qualities as well as their bioactive substances that exhibit healing and health-promoting properties. This article reviews the literature related to the use of lactic acid fermentation in the process of mushroom preservation. Particular attention is paid to the aspects of the technological process and its impact on the quality and suitability of the final products. Moreover, research results concerning the influence of lactic acid fermentation on chemical and physical changes in fruiting bodies of edible fungi are also discussed. **Comprehensive Reviews in Food Science and Food Safety, Volume 18, Issue 3, May 2019, Pages 655-669.**



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